NEVADA STATE
BOARD OF PHARMACY

BOARD MEETING

April 15-16, 2026

HYATT PLACE
1790 E PLUMB LN
RENO, NV

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

Please do not remove the book from the meeting room.

JOE LOMBARDO
Governor

DR. KRISTOPHER SANCHEZ
Director

PERRY FAIGIN
NIKKI HAAG
MARCEL F. SCHAERER
Deputy Directors

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

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

Date Posted: March 26, 2026

AGENDA

◈ PUBLIC NOTICE ◈

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, April 15, 2026, at 9:00 am. The meeting will continue Thursday, April 16, 2026, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

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

Please Note:

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

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

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

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

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

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

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

◈ CONSENT AGENDA ◈

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

3. Approval of the March 4-5, 2026, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

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

   A. Aeroflow Inc – Arden, NC
   B. Anodyne Inc – Minnetonka, MN
   C. Comfort Medical LLC – Tigard, OR
   D. HR HealthCare Patient Services – Woodstock, GA
   E. Ivy Technology LLC – Louisville, KY
   F. Livongo Health LLC – Lewisville, TX
   G. Orthofix US LLC – Lewisville, TX
   H. Pediatric Orthotic & Prosthetic Services – Sacramento, CA
   I. Reliable Respiratory Inc – Norwood, MA
   J. Shield California Health Care Center Inc – Valencia, CA
   K. Shield Denver Health Care Center Inc – Aurora, CO
   L. Urological Supplies Inc – Fort Myers, FL
   M. Watkins-Conti Products Inc – Edmond, OK

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

Background Check Not Required by Law.

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

N. McKesson Medical Surgical – Uxbridge, MA

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

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

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

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

O. Langham Logistics Inc – Whitestown, IN
P. Langham Logistics Inc – Whiteland, IN
Q. On Target Laboratories Inc – West Lafayette, IN
R. Patterson Veterinary Supply Inc – Saint Paul, MN

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

S. AOSS Medical Supply LLC – Richardson, TX
T. Aryeh Pharma Corp – Skillman, NJ
U. Aurora Pharmaceutical Inc – Northfield, MN
V. Avadel CNS Pharmaceuticals LLC – Chesterfield, MO
W. Bayer Medical Care Inc – Indianola, PA
X. Bayer Medical Care Inc – Pittsburgh, PA
Y. Carl Zeiss Meditec USA Inc – Dublin, CA
Z. Genzyme Corporation – Cambridge, MA
AA. Safecor Health LLC – Rockford, IL
BB. Sanofi Vaccines US Inc – Swiftwater, PA
CC. Scioto Pharmaceuticals LLC – Columbus, OH
DD. Umedica Laboratories USA Inc – Parsippany, NJ
EE. Upsher-Smith Laboratories LLC – Maple Grove, MN

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

FF. Clinical Solutions Wholesale LLC – Franklin, TN

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

GG. EnableCV LLC – West Valley City, UT
HH. Sequel Med Tech LLC – Manchester, NH

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

II. Birdi Inc – Plymouth, MI
JJ. Klutch Cargo LLC – Chicago, IL

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

KK. Renown Pharmacy – Reno, NV

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

LL. Accumix Pharmacy – Elmhurst, IL
MM. Beaker Pharmacy – McKinney, TX
NN. Blue Door Pharmacies LLC – Rockville, MD
OO. Green Stone Rx – Miami, FL
PP. InfuCare Rx – Glendale, CA
QQ. InfuCare Rx – Kenner, LA
RR. InfuCare Rx – Aston, PA
SS. RxCompoundStore.Com – Miami, FL
TT. St. Luke Compounding Pharmacy – New Port Ritchey, FL
UU. Tailor Made Compounding – Nicholasville, KY
VV. University Compounding Pharmacy – San Diego, CA

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

WW. AnovoRx Group LLC – Chandler, AZ
XX. AnovoRx Group LLC – Memphis, TN
YY. ClearMedix Pharmacy LLC – Worthington, OH
ZZ. Customedico Pharmacy + Wellness – Scottsdale, AZ
AAA. Infinite Health Pharmacy Inc – West Palm Beach, FL
BBB. Medbridge Pharmacy – Granada Hills, CA
CCC. MRH Outpatient Pharmacy – Aberdeen, MS
DDD. Specialty Care Rx – Orange, CA
EEE. Spectrum Solutions Rx LLC – Draper, UT
FFF. Swyft Scripts – DFW – Hurst, TX

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

GGG. Desert Rose Surgery Center – Las Vegas, NV

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

HHH. Ivan Fernandez

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

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

III. Hyalo Technologies LLC – Somerset, NJ

◈ REGULAR AGENDA ◈

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

A.	Festus Ebonka	(19-012-CS-S)
B.	Festus Ebonka	(25-215-CS-S)
C.	Renown Pharmacy	(25-139-PH-N)
D.	Oliver Swafford	(25-139-RPH-N)
E.	Martin Farrell	(25-233-RPH-O)
F.	CVS Pharmacy #8792	(25-247-PH-N)
G.	Joshua Lee	(25-247-RPH-N)
H.	Raymond Graber	(23-340-CS-N)
I.	Raley's Pharmacy #123	(24-366-PH-N)
J.	Patrick Awa	(24-366-RPH-N)
K.	PharMerica	(24-370-PH-N)
L.	Camilla Kim	(24-370-RPH-N)
M.	Sean Arora	(24-509-CS-N)
N.	Cassie Gifford	(24-509-PR-A-N)
O.	Gabrielle McIntyre	(24-509-PR-B-N)
P.	Allison Jaggard	(24-509-PR-C-N)
Q.	Michael Stellmacher	(24-364-CS-S)
R.	Philip Rich	(25-021-CS-N)
S.	Laura Oki	(25-112-CS-A-N)
T.	Apria Healthcare LLC	(25-138-MP-N)
U.	CVS Pharmacy #9586	(25-350-PH-N)
V.	Mark Pardini	(25-350-RPH-N)
W.	Lyfe Pharmacy	(25-360-PH-S)

X. Nazokat Nigmatova (25-360-RPH-S)
Y. Tera Pharmacy (25-370-PH-S)
Z. Nazokat Nigmatova (25-370-RPH-A-S)
AA. Gezel Ashley Gonzalez (26-092-PTT-N)

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

A. Oxus America, Inc (25-470-O)

7. Applications for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6944) – Appearance (**FOR POSSIBLE ACTION)**

A. Dignified Medical Equipment LLC – Las Vegas, NV
B. Montgomery DME – Las Vegas, NV
C. Sora Health LLC – Las Vegas, NV
D. Supercare Health – Las Vegas, NV
E. Supercare Health – Sparks, NV

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

A. Carson Valley Health – Gardnerville, NV
B. Las Vegas Apothecary – Las Vegas, NV
C. LUX Infusion 13 – Henderson, NV
D. Saint Mary Pharmacy – Las Vegas, NV
E. Specialty Care Rx – Las Vegas, NV

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

A. Med Solutions Compounding Pharmacy – Winston Salem, NC

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

A. Elizbiz Limited Liabilty Company – Henderson, NV - Background Check completed in compliance with NRS 639.500

11. Application for Pharmacist Registration by Reciprocation NRS 639.134) – Appearance (**FOR POSSIBLE ACTION**)

A. Mark Mullins

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

A. Camila Gonzalez

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

A. Frances Anne Puesta
B. Jeffrey Gross
C. Kelly Turner

14. Discussion and possible action to amend, revise and/or approve proposed FY27 budget **(FOR POSSIBLE ACTION)**

◈ WORKSHOP ◈

Thursday, April 16, 2026 – 9:00 am

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

A. Amendment to Nevada Administrative Code (NAC) 639. The proposed amendments establishes record keeping requirements of controlled substances by a pharmacy and other matters properly relating thereto.

B. Amendment to Nevada Administrative Code (NAC) 453. The proposed amendments relate to controlled substances adding mitragynine, 7-hydroxymitragynine and mitragynine pseudoindoxyl to the controlled substances listed in Schedule I.

C. Amendment to Nevada Administrative Code (NAC) 639.708. Regulation authorizing the delivery of a commercially manufactured prescription drug product to a practitioner.

◈ PUBLIC HEARING ◈

Thursday, April 16, 2026 – 9:00 am

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

A. A REGULATION relating to the authority of a homeopathic physician who is not licensed as an allopathic or osteopathic physician in Nevada to possess, administer, prescribe and dispense controlled substances and dangerous drugs; and providing other matters properly relating thereto. (LCB File No. R106-25)

B. Amendment to Chapter 639 of the Nevada Administrative Code. The proposed amendments reduce the minimum age to register to become a pharmaceutical technician in training along with modify certain requirements to become a pharmaceutical technician in training. (LCB FILE NO. R010-26)

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

18. Executive Secretary Report:

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

19. Date and Location of Next Scheduled Board Meeting:

June 3-4, 2026 – Las Vegas, NV

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

21. Adjournment

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

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

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

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

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NEVADA STATE BOARD OF PHARMACY

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

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

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

BOARD MEETING MINUTES

March 4-5, 2026

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, March 4, 2026, at 9:00 am. The meeting will continue Thursday, March 5, 2026, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

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

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

Board Members Present:

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

Board Staff Present:

David Wuest	Yenh Long	Gregory Zunino	Brett Kandt
Laura Tucker	Skylar Young	Todd Weiss	Darlene Nases
Erin Miller	Dena McClish	Darla Zarley	Jessette Phaynarikone
John Castaldo	Ken Scheuber	Clayton Bailey	William Kuykendall
Michael Castaneda			

Call to Order and Roll Call – Establishment of Quorum

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

DRAFT

Public Comment on March 4, 2026, 9:02 AM

There was no public comment.

1. Approval of January 14-15, 2026, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

Board Action:

Motion: Krystal Freitas moved to approve the January 14-15, 2026, Board Meeting Minutes.

Second: Jade Jacobo

Action: Passed unanimously.

◈ CONSENT AGENDA ◈

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

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

A. CloudCath – San Francisco, CA
B. Geodis Logistics LLC – Plainfield, IN
C. Intouch Med Supply Co – King of Prussia, PA
D. Medline Industries – Perryville, MD
E. SleepSafe Drivers Inc – Lenexa, KS
F. Unicare Diagnostics LLC – Newbury Park, CA

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

Background Check Not Required by Law.

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

G. Cogent Biosciences Inc – Waltham, MA
H. MIMEDX Group Inc – Marietta, GA
I. McKesson Medical-Surgical Inc – Kansas City, MO
J. NuSmile Ltd – Houston, TX

DRAFT

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

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

K. Ethicon Endo-Surgery Inc – Cincinnati, OH
L. Stryker Spine LLC – Allendale, NJ
M. Stryker Sustainability Solutions Inc – Tempe, AZ
N. Viridian Therapeutics Inc – Waltham, MA

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

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

O. J & B Medical Supply Co. Inc – Wixom, MI
P. Optime Care Inc – Earth City, MO
Q. Teleflex LLC – Chelmsford, MA
R. Teleflex LLC – Olive Branch, MS

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

S. Abrasive Technology LLC – Lewis Center, OH
T. Aiping Pharmaceutical Inc – Hauppauge, NY
U. Arvato USA LLC – Memphis, TN
V. Ascent Pharmaceuticals Inc – Central Islip, NY
W. Blueprint Medicines Corporation – Cambridge, MA
X. B. Braun Medical Inc – Carrollton, TX
Y. Ceva Animal Health LLC – Lenexa, KS
Z. K2M Inc – Leesburg, VA
AA. LifeScience Logistics LLC – Memphis, TN
BB. Novartis Manufacturing LLC – Carlsbad, CA
CC. Philips Image Guided Therapy Corporation – San Diego, CA
DD. Renaissance Lakewood LLC – Lakewood, NJ
EE. Reliable Healthcare Logistics LLC – Boca Raton, FL
FF. Reliable Healthcare Logistics LLC – Dayton, NJ
GG. Reliable Healthcare Logistics LLC – Lockbourne, OH
HH. Reliable Healthcare Logistics LLC – Pompano Beach, FL
II. Reliable Healthcare Logistics LLC – Sugarland, TX
JJ. Trilliant Surgical LLC – Houston, TX
KK. Visus Therapeutics Inc – Beavercreek, OH

DRAFT

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

LL. Coupler LLC – West Chester, PA

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

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

MM. A2A Alliance Pharmaceuticals LLC – Franklin, KY
NN. FedEx Supply Chain Inc – Indianapolis, IN
OO. Schraders Medical Supply Inc – Montclair, CA

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

PP. Spring Mountain Sahara an extension of Spring Valley Hospital – Las Vegas, NV

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

QQ. Chartwell Pennsylvania LP – Oakdale, PA
RR. Hartley Medical Center Pharmacy – Long Beach, CA
SS. Lake Hills Pharmacy – Austin, TX
TT. Logos Pharmacy – Tampa, FL
UU. Pharmacorr Sterile LLC – Oklahoma City, OK
VV. PharmaLogic Los Angeles – Los Angeles, CA
WW. Source Pharmacy – West Palm Beach, FL

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

XX. Affordable Script – Valley Stream, NY
YY. Almac Clinical Services LLC – Durham, NC
ZZ. Brightside Specialty Pharmacy – Santa Ana. CA
AAA. City Drug – Evanston, WY
BBB. Formulate Rx Pharmacy – Winter Springs, FL
CCC. Gifthealth Pharmacy AZ – Mesa, AZ
DDD. Honeybee Health – Culver City, CA
EEE. InfuCare Rx of MD – Cumberland, MD
FFF. InfuCare Rx of NJ – Pine Brook, NJ
GGG. Innovarx Inc – Morganville, NJ
HHH. Magic City Pharmacy – Pelham, AL

DRAFT

III. Optime Care Inc – Earth City, MO
JJJ. Pharma Fusion LLC – Bullhead City, AZ
KKK. Santa Rosa Pharmacy – Santa Rosa Beach, FL

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

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

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

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

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Consent Agenda with the exception to Agenda Items 4PP and 4H.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Adam Porath moved to approve Consent Agenda Item 4PP .

Second: Jade Jacobo

Action: Motion passed (Freitas recused).

◈ REGULAR AGENDA ◈

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

D. Ivan Goldsmith (24-488-CS-S)

Crane Pomerantz, Esq., was present on behalf of Ivan Goldsmith.

DRAFT

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Ivan Goldsmith alleging that Respondent Goldsmith failed to timely renew his Certificate of Registration No. CS33713 prior to issuing controlled substance prescriptions and failed to review patient utilization reports in the PMP database prior to issuing controlled substance prescriptions.

The proposed stipulated penalties for Ivan Goldsmith, Certificate of Registration No. CS33713, are the following: Respondent's Certificate of Registration No. CS33713 is suspended for a period of two (2) years. The suspension is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent fined $5,000 for the violations; 2) Respondent assessed $1,000 in attorney's fees and costs, both to be due and payable by May 1, 2026; and 3) Respondent shall complete training from Board staff on use of the PMP database within sixty (60) days of the effective date of this Order and shall complete follow-up training six (6) months after the initial training.

Board discussion ensued.

Mr. Pomerantz stated that his client was in agreement with the amended Stipulation and Order.

Board Action:

Motion: Richard Tomasso moved to approve amended Stipulation and Order for Ivan Goldsmith as presented by Mr. Kandt.

Second: Jade Jacobo

Action: Passed unanimously.

Q. First Choice Pharmacy	(25-110-PH-S)
R. Nicole Sy	(25-110-RPH-A-S)
S. Kirk Beaulieu	(25-110-RPH-B-S)

Nicole Sy, Kirk Beaulieu, and John Courtney, Esq. (counsel), were present.

President Park disclosed that she was familiar with Nicole Sy, but she could participate in this matter fairly and without bias.

Laura Tucker, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against First Choice Pharmacy, alleging that the Respondent, as pharmacy/pharmacy owner, Respondent purchased prescription drugs from pharmacies not licensed for wholesale distribution in Nevada.

The proposed stipulated penalties for First Choice Pharmacy, Pharmacy License No. PH04395, are the following: 1) Respondent fined $5,000 for the violations; and 2)

DRAFT

Respondent assessed $1,000 in attorney's fees and costs, both to be due and payable within 30 days of the entry date of this order.

Laura Tucker, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Nicole Sy, alleging that, as managing pharmacist at the time of the events of January 2023 and October 2023, Respondent Sy purchased prescription drugs from pharmacies not licensed for wholesale distribution in Nevada.

The proposed stipulated penalties for Nicole Sy, Certificate of Registration No. 20646, are the following: 1) Respondent fined $5,000 for the violations; 2) Respondent assessed $1,000 in attorney's fees and costs, both to be due and payable by July 1, 2026; and 3) Respondent shall complete two (2) additional CE hours on ethics and two (2) CE hours on duties of a managing pharmacist, in addition to the CE hours she must otherwise complete to maintain licensure, and shall provide certificates demonstrating completion of additional CE hours by July 1, 2026.

Laura Tucker, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Kirk Beaulieu, alleging that, as managing pharmacist at the time of the events of December 2023 and April 2024, Respondent Beaulieu purchased prescription drugs from pharmacies not licensed for wholesale distribution in Nevada.

The proposed stipulated penalties for Kirk Beaulieu, Certificate of Registration No. 20184, are the following: 1) Respondent fined $5,000 for the violations; 2) Respondent assessed $1,000 in attorney's fees and costs, both to be due and payable within thirty (30) days of the Order; and 3) Respondent shall complete two (2) additional CE hours on ethics and two (2) CE hours on duties of a managing pharmacist, in addition to the CE hours she must otherwise complete to maintain licensure, and shall provide certificates demonstrating completion of additional CE hours by July 1, 2026.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Stipulations and Orders for First Choice Pharmacy, Nicole Sy, and Kirk Beaulieu, as presented by Ms. Tucker.

Second: Chanyis Taylor

Action: Passed unanimously.

T. Jill Allison Oliver (25-111-CS-S)

Jill Allison Oliver and Bridget Kelly, Esq., were present.

DRAFT

Laura Tucker, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Jill Allison Oliver alleging that Respondent Oliver allowed an employee to perform duties of a dispensing technician in training without the required registration.

The proposed stipulated penalties for Jill Allison Oliver, Certificate of Registration Nos. CS15479 and PD15479, are the following: Respondent's Certificate of Registration Nos. CS15479 and PD15479 are suspended for a period of one (1) year. The suspension is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent fined $2,000 for the violations; and 2) Respondent assessed $500 in attorney's fees and costs, both to be due and payable within 30 days of the order.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Stipulation and Order for Jill Allison Oliver as presented by Ms. Tucker.

Second: Adam Porath

Action: Passed unanimously.

B. Thomas Umbach (24-044-PD-B-S)

Janet Jenson, Esq., was present on behalf of Thomas Umbach.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Thomas Umbach alleging that Respondent Umbach committed numerous violations related to controlled substances.

The proposed stipulated penalties for Thomas Umbach, Certificate of Registration Nos. CS16064 and PD00512, are the following: Respondent's Certificate of Registration No. PD00512 is revoked, and Respondent cannot petition for reinstatement for a period of five (5) years from the effective date of the order. In the event Respondent applies for reinstatement of his certificate of registration, or applies for any other certificate, license or permit with the Board, he shall appear before the Board to answer questions and give testimony regarding his application. Respondent's Certificate of Registration No. CS16064 is suspended for a period of two (2) years. The suspension is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent fined $5,000 for the violations; and 2) Respondent assessed $1,000 in attorney's fees and costs, both to be due and payable by April 3, 2026.

Board discussion ensued.

Jade Jacobo was excused from the meeting at 10:06AM.

DRAFT

Board Action:

Motion: Chanyis Taylor moved to approve the Stipulation and Order for Thomas Umbach as presented by Mr. Kandt.

Second: Adam Porath

Action: Passed unanimously.

H. CVS Pharmacy #8822 (23-051-PH-S)
I. Ryan Clements (23-051-RPH-S)

Ryan Clements and Brian Convery, Esq. (Representative for CVS Pharmacy #8822), were present.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case against CVS Pharmacy #8822, alleging that, as pharmacy/pharmacy owners, CVS Pharmacy #8822 is responsible for the acts of its employees who made an error in a prescription that resulted in a negative patient outcome.

The proposed stipulated penalties for CVS Pharmacy #8822, Pharmacy License No. PH01145, are the following: 1) Respondent fined $1,000 for the violations; and 2) Respondent assessed $500 in attorney's fees and costs, both to be due and payable by April 30, 2026.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Ryan Clements alleging that Respondent Clements made an error in a prescription that resulted in a negative patient outcome.

The proposed stipulated penalties for Ryan Clements, Certificate of Registration No. 21841, are the following: 1) Respondent fined $1,000 for the violations; and 2) Respondent assessed $500 in attorney's fees and costs, both to be due and payable by April 30, 2026.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Stipulations and Orders for CVS Pharmacy #8822 and Ryan Clements as presented by Mr. Zunino.

Second: Chanyis Taylor

Action: Passed unanimously.

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Y. Grace Singson (25-370-RPH-B-S)

Craig Perry, Esq., was present on behalf of Grace Singson.

Laura Tucker, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Grace Singson, alleging that, as managing pharmacist at the time of the events, Respondent Singson filled prescriptions that were not valid from October 22, 2025, to November 4, 2025.

The proposed stipulated penalties for Grace Singson, Certificate of Registration No. 24727, are the following: 1) public reprimand; 2) Respondent fined $2,500 for the violations; 3) Respondent assessed $750 in attorney's fees and costs, both to be due and payable by September 4, 2026; and 4) Respondent shall participate in training with Board staff on laws related to controlled substances in Nevada within sixty (60) days of the effective date of this order.

Jade Jacobo returned to the meeting at 10:33AM.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Stipulation and Order for Grace Singson with the amendment that she cannot be a managing pharmacist for a period of one (1) year from the effective date of the Order.

Second: Chanyis Taylor

Action: Passed unanimously.

M. CVS Pharmacy #6717 (24-013-PH-S)
N. Analeah Presbitero (24-013-RPH-A-S)
O. Todd Spears (24-013-RPH-B-S)

Roger Morris, Esq. (Pro hac vice counsel for all Respondents), Todd Spears, Analeah Presbitero, and Jasmine Harshman (pharmaceutical technician) were present.

President Park disclosed that she was familiar with Analeah Presbitero, but she could participate in this matter fairly and without bias.

Jade Jacobo recused herself from this matter to her previous employment with CVS.

Laura Tucker, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Analeah Presbitero alleging that Respondent Presbitero made an error in a prescription while using virtual verification.

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The proposed stipulated penalties for Analeah Presbitero, Certificate of Registration No. 23353, are the following: 1) Respondent fined $500 for the violations; and 2) Respondent assessed $500 in attorney's fees and costs, both to be due and payable within thirty (30) days of the order.

Laura Tucker, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Todd Spears alleging that Respondent Presbitero made an error in a prescription while using virtual verification.

The proposed stipulated penalties for Todd Spears, Certificate of Registration No. 18123, are the following: 1) Respondent fined $1,000 for the violations; and 2) Respondent assessed $500 in attorney's fees and costs, both to be due and payable within thirty (30) days of the order.

Laura Tucker, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against CVS Pharmacy #6717, alleging that, as pharmacy/pharmacy owner, CVS Pharmacy #6717 is responsible for the acts of its employees who made an error in a prescription while using virtual verification.

The proposed stipulated penalties for CVS Pharmacy #6717, Pharmacy License No. PH01932, are the following: 1) Respondent fined $5,000 for the violations; 2) Respondent assessed $500 in attorney's fees and costs, both to be due and payable by April 30, 2026; 3) On of before April 30, 2026, CVS corporate management shall provide the Board's staff with copies of written policies, procedures, training manuals or other materials, if any, that specifically confirm or corroborate its contention that all CVS pharmacists in Nevada have the discretion to perform visual inspections by physical or manual manipulation of prescription drug products before dispensing them to patients. If no such policies, procedures, training manuals or other materials exist, CVS management shall provide a written statement to that effect; and 4) On of before April 30, 2026, CVS corporate management shall provide a written statement or summary of its plan, if any, to provide ongoing periodic reminders to or conduct training with its pharmacists concerning their discretion to perform visual inspections by physical or manual manipulation of prescription drug products before dispensing them to patients. If no such plan exists, Respondent CVS shall provide a written statement to that effect.

Board discussion ensued.

Board Action:

Motion: Richard Tomasso moved to approve the Stipulations and Orders for Analeah Presbitero and Todd Spears as presented by Ms. Tucker.

Second: Adam Porath

Action: Motion passed (Jacobo recused).

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Board Action:

Motion: Richard Tomasso moved to approve the Stipulation and Order for CVS Pharmacy #6717 as presented by Ms. Tucker.

Second: Adam Porath

Aye: Tomasso, Porath, Freitas, Taylor, Carr
Nay: President Park

Action: Motion passed (Jacobo recused).

C. Susan Nytes (24-213-CS-S)

Susan Nytes was present.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Susan Nytes alleging that Respondent Nytes failed to disclose prior Iowa Board of Nursing disciplinary action on her 2022 Nevada controlled substance application and failed to timely report to the Board the 2025 disciplinary action from the Nevada State Board of Nursing. She also issued at least 148 prescriptions between April 18, 2024, and June 11, 2024, without a valid Nevada DEA registration and without a registered practice location on file with the Board. Finally, she unlawfully accessed the Prescription Monitoring Program (PMP) database and subsequently disseminated the patient utilization report for a patient with whom she did not have a bona fide therapeutic relationship.

The proposed stipulated penalties for Susan Nytes, Certificate of Registration Nos. CS34530 and PR16791, are the following: Respondent's Certificate of Registration Nos. CS34530 and PR16791 are revoked. Respondent may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance or dangerous drug in Nevada until she has petitioned the Board for reinstatement. Respondent may not petition for reinstatement of her certificates of registration for a period of two (2) years from the effective date of this Order. If Respondent applies for reinstatement of her certificates of registration, or applies for any other certificate, license or permit with the Board, she shall appear before the Board to answer questions and give testimony regarding her application, her compliance with this Order, and the facts and circumstances underlying this matter. Respondent fined $5,000 for the violations; and Respondent assessed $1,500 in attorney's fees and costs, both to be due and payable by March 4, 2027.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Stipulation and Order for Susan Nytes

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as presented by Mr. Kandt.

Second: Chanyis Taylor

Action: Passed unanimously.

G. Festus Ebonka (25-215-CS-S)

Liborius Agwara, Esq., was present on behalf of Festus Ebonka.

Mr. Agwara requested that this matter be continued to a future Board meeting.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, informed the Board that Mr. Ebonka has not complied with the Order in Case No. 19-012-CS-S after his petition for judicial review was denied.

President Park stated that she would grant the requested continuance only once.

This matter will be continued to the next Board meeting on April 15, 2026, in Reno, NV.

E. Southwest DME (25-143-MP-S)

No one was present on behalf of Southwest DME.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against SouthwestDME alleging that Respondent failed to apply with the Board for a new license after the completion of the transaction which changed the controlling interest and not operate the business until the new owner was licensed by the Board. In addition, Respondent failed to notify the Board of the departure of its administrator within three business days and continued to operate as medical products provider for more than ten business days without an administrator being approved by the Board.

Mr. Kandt requested that the declarations of service by Board staff and the Memorandum of Attorney's Fees and Costs in the amount of $1,240.92 be entered into the record.

Mr. Kandt requested the Board to make Findings of Fact consistent with paragraphs 1-5 of the Accusation.

Board Action:

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

Second: Adam Porath

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Action: Passed unanimously.

Mr. Kandt requested the Board to make Conclusions of Law consistent with paragraphs 6-16 of the Accusation and to find the respondent guilty on Counts One through Four.

Board Action:

Motion: Krystal Freitas moved to make Conclusions of Law consistent with paragraphs 6-16 of the Accusation and to find the respondent guilty on Counts One through Four.

Second: Adam Porath

Action: Passed unanimously.

Mr. Kandt requested the Board find that Board staff properly noticed the Respondent of the charges and this hearing in conformance with Nevada law.

Board Action:

Motion: Krystal Freitas moved to find that Board staff properly noticed the Respondent of the charges and this hearing in conformance with Nevada law.

Second: Chanyis Taylor

Action: Passed unanimously.

President Park admitted the Declarations of service by Board staff and the Memorandum of Attorney's Costs and Fees into evidence.

Mr. Kandt requested the Board to revoke License No. MP03145. Respondent cannot petition for reinstatement for a period of two (2) years from the effective date of the order. In the event Respondent applies for reinstatement of his certificate of registration, or applies for any other certificate, license or permit with the Board, they shall appear before the Board to answer questions and give testimony regarding his application. Respondent fined $5,000 for the violations; Respondent assessed $1,240.92 in attorney's fees and costs as reasonable, necessary and actually incurred, both to be due and payable by September 4, 2026.

Board Action:

Motion: Krystal Freitas moved to revoke License No. MP03145. Respondent cannot petition for reinstatement for a period of two (2) years from the effective date of the order. Respondent fined $5,000 for the violations; Respondent assessed $1,240.92 in attorney's fees and costs as

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reasonable, necessary and actually incurred, both to be due and payable by September 4, 2026.

Second: Chanyis Taylor

Action: Passed unanimously.

A. Matthew Apel (24-044-PD-A-S)

This matter was continued.

F. Marika Kerr (25-146-CS-S)

This matter was continued.

J. PharMerica (24-370-PH-N)

This matter was continued.

K. Camilla Kim (24-370-RPH-N)

This matter was continued.

L. Amy Tseng (24-484-CS-S)

This matter was continued.

P. Michael Stellmacher (24-364-CS-S)

This matter was continued.

U. Lyfe Pharmacy (25-360-PH-S)

This matter was continued.

V. Nazokat Nigmatova (25-360-RPH-S)

This matter was continued.

W. Tera Pharmacy (25-370-PH-S)

This matter was continued.

X. Nazokat Nigmatova (25-370-RPH-A-S)

This matter was continued.

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

A. Carolina Molina (25-146-S)

This matter was continued.

B. Prime Plus Lakeview Pharmacy (25-110-V-O)

This matter was continued.

C. Oxus America, Inc (25-470-O)

This matter was continued.

7. Applications for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6944) – Appearance (**FOR POSSIBLE ACTION)**

A. ActivStyle, LLC – Las Vegas, NV

Darrell Rawlings (Chief Executive Officer) and Nicole Wysocki (Administrator) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Nevada Medical, Devices, Equipment and Gases license for ActivStyle, LLC.

Second: Chanyis Taylor

Action: Passed unanimously.

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

A. Arise Pharmacy – Las Vegas, NV

Modupe Irorobeje, Owner and Managing Pharmacist, was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

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Board Action:

Motion: Krystal Freitas moved to approve the Nevada pharmacy license for Arise Pharmacy, pending a favorable inspection.

Second: Chanyis Taylor

Action: Passed unanimously.

D. Lyfe Pharmacy – Las Vegas, NV

William Stilling, Esq. (Counsel), Ramy Massoud (Owner), and Mathew Eissa (Managing Pharmacist) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Richard Tomasso moved to approve the Nevada pharmacy license for Lyfe Pharmacy, pending a new application to Board staff and a favorable inspection.

Second: Krystal Freitas

Action: Passed unanimously.

G. Tera Pharmacy – Las Vegas, NV

William Stilling, Esq. (counsel), Mark Mahfouz (Owner), and Brett Bettinger (Managing Pharmacist) were present.

Krystal Freitas and Chanyis Taylor disclosed that they were familiar with Brett Bettinger, but they could participate in this matter fairly and without bias.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Richard Tomasso moved to approve the Nevada pharmacy license for Tera Pharmacy, pending a new application to Board staff and a favorable inspection.

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Second: Chanyis Taylor

Action: Passed unanimously.

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

A. Hisbay Ali

Hisbay Ali was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the controlled substance registration for Hisbay Ali, with the condition that the Nevada Board of Pharmacy mirrors the probation requirements from the Nevada Medical Board.

Second: Anna Carr

Action: Passed unanimously.

B. Michael Roach

Michael Roach was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the controlled substance registration for Schedule III only for Michael Roach.

Second: Chanyis Taylor

Action: Passed unanimously.

17. Executive Secretary Report

14. Discussion on Audit by Casey Neilon Pursuant to NRS 218G.400 for Fiscal Year Ending June 30, 2025 – **(FOR POSSIBLE ACTION)**

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

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the 2025 audit as presented by Mr. Wuest.

Second: President Park

Action: Passed unanimously.

18. General Counsel Report

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, and Brett Kandt, General Counsel for the Nevada Board of Pharmacy, presented.

Public comment at March 4, 2026, at 3:59 PM:

William “Bill” Lord, consultant for Stellar Rx and Chairman of the New Mexico Board of Pharmacy, made a public comment.

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

Board Members Present:

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

Board Members Absent:

Richard Tomasso

Board Staff Present:

David Wuest	Yenh Long	Gregory Zunino	Brett Kandt
Laura Tucker	Skylar Young	Todd Weiss	Darlene Nases
Erin Miller	Dena McClish	Darla Zarley	Jessette Phaynarikone
John Castaldo	Ken Scheuber	Clayton Bailey	William Kuykendall
Michael Castaneda			

Call to Order and Roll Call – Establishment of Quorum

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

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was established.

Public comment at March 5, 2026, at 9:01 AM:

There was no public comment.

◈ WORKSHOP ◈

Thursday, March 5, 2026 – 9:00 am

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

    A. Amendment to Nevada Administrative Code (NAC) 453. The proposed amendments relate to controlled substances adding N-pyrrolidino metonitazene and N-pyrrolidino protonitazene to the controlled substances listed in Schedule I.

Darla Zarley, Grant and Project Analyst for Nevada Board of Pharmacy, presented the proposed regulation workshop to the Board

President Park opened the floor for public comment.

There was no public comment.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the proposed regulation as presented by Board staff.

Second: Chanyis Taylor

Action: Passed unanimously.

◈ PUBLIC HEARING ◈

Thursday, March 5, 2026 – 9:00 am

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

    A. A REGULATION relating to controlled substances adding dipentylone and seven fentanyl related substances to the controlled substances listed in Schedule I; and providing other matters properly relating thereto. (LCB File No. R107-25)

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Darla Zarley, Grant and Project Analyst for Nevada Board of Pharmacy, presented the proposed regulation to the Board.

President Park opened the floor for public comment.

There was no public comment.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to adopt LCB File No. R107-25 as presented by Board staff.

Second: Krystal Freitas

Action: Passed unanimously.

7. Applications for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6944) – Appearance (**FOR POSSIBLE ACTION)**

   B. Dia-Foot – Las Vegas, NV

10. Applications for Nevada Wholesaler License (NRS 639.233) – Appearance – **(FOR POSSIBLLE ACTION)**

   B. Dia-Foot – Las Vegas, NV - Background Check Not Required by Law

Sara Simonson, Chief Operating Officer and MDEG administrator, was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Chanyis Taylor moved to approve the Nevada Medical, Devices, Equipment and Gases registration and the Nevada Wholesaler registration for Dia-Foot, pending a letter of authorization from the authorized representative.

Second: Adam Porath

Action: Passed unanimously.

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7. Applications for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6944) – Appearance (**FOR POSSIBLE ACTION)**

C. The Re-Habit Wellness Castle – Las Vegas, NV

Andrina Vasquez-Sanchez, Owner and Manager, was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Nevada Medical, Devices, Equipment and Gases registration for The Re-Habit Wellness Castle.

Second: Adam Porath

Action: Passed unanimously.

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

B. Capital Care Pharmacy – Las Vegas, NV

Mark Yu, Owner and Designated Representative, was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Nevada Pharmacy registration for Capital Care Pharmacy, pending submission of a new application by a qualified designated representative and a favorable inspection.

Second: Chanyis Taylor

Action: Passed unanimously.

C. Community Reach Pharmacy – Las Vegas, NV

Joseph Montemorano (Pharmacist in Charge) and Alexandre Bagdassarian (Owner) were present.

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The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Nevada Pharmacy registration for Community Reach Pharmacy, pending submission of a new designated representative application to the Board.

Second: Chanyis Taylor

Action: Passed unanimously.

E. Nevada Care Pharmacy – Las Vegas, NV

Richard Nguyen (Managing Pharmacist), Rocio Favela (Former Owner), and Guadalupe Sokol (Owner) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Nevada Pharmacy registration for Nevada Care Pharmacy.

Second: Krystal Freitas

Action: Passed unanimously.

F. QHR Pharmacy – Las Vegas, NV

Kevin Prieto (Owner) and Lucia Beltran (Designated Representative and Pharmacy Technician) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Chanyis Taylor moved to approve the Nevada Pharmacy registration for QHR Pharmacy.

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Second: Adam Porath

Action: Passed unanimously.

10. Applications for Nevada Wholesaler License (NRS 639.233) – Appearance – **(FOR POSSIBLLE ACTION)**

A. CAD-Ray Distribution, Inc – Las Vegas, NV - Background Check Not Required by Law

Jonathan Acker (Chief Operating Officer), Armen Vartanian (designated representative), and Rich LaFergola (President) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Nevada Wholesaler registration for CAD-Ray Distribution, Inc.

Second: Krystal Freitas

Action: Passed unanimously.

C. Stryker Orthopaedics – Las Vegas, NV - Background Check Not Required by Law
D. Stryker Orthopaedics – Reno, NV - Background Check Not Required by Law

Jennifer Santos (Senior Project Associate) and Shayne Schiedel (Regulatory Affairs Manager) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Nevada Wholesaler registrations for Stryker Orthopaedics in Las Vegas, NV, and Reno, NV, pending submission of an updated application that includes administration history.

Second: Chanyis Taylor

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Action: Passed unanimously.

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

C. Orlandis Wells

Orlandis Wells was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Chanyis Taylor moved to approve the controlled substance registration for Orlandis Wells to approve Schedules III-V only.

Second: Adam Porath

Action: Passed unanimously.

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

A. Crystal Lara

Crystal Lara was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the pharmaceutical technician registration for Crystal Lara.

Second: Adam Porath

Action: Passed unanimously.

11. Application for Pharmacist Registration by Reciprocation NRS 639.134) – Appearance (**FOR POSSIBLE ACTION**)

A. Paul Arp

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Paul Arp was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the pharmacist registration by reciprocation for Paul Arp.

Second: Chanyis Taylor

Action: Passed unanimously.

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

A. Orion Specialty Labs, LLC – Henderson, NV

John Hartwig (Consultant), Kimberly Moller (Owner), and Justin Curnutt (Pharmacist in Charge) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

President Park asked Ms. Moller if she would like to table her application.

This application was tabled.

◈ CONSENT AGENDA ◈

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

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve Item 4H of the Consent Agenda.

Second: Jade Jacobo

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Action: Passed unanimously.

18. Executive Secretary Report

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

20. Public Comment

President Park opened the floor for public comment.

Justin Curnutt, applicant and Pharmacist in Charge for Orion Specialty Labs, LLC.

President Park closed the floor for public comment.

19. Date and Location of Next Scheduled Board Meeting:

April 15-16, 2026 – Reno, NV

21. Adjournment

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4A

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Aeroflow Inc

MDEG Physical Address: 6 Commerce Way

City: Arden State: NC Zip: 27258

Mailing Address (if different from physical address): 3165 Sweeten Creek Rd

City: Asheville State: NC Zip: 28803

Telephone: 888-345-1780 Website: _____

Email: licensing@aeroflowinc.com

Name of MDEG Administrator (NAC 639.694): Jonathon Paquette

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

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

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

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

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

Name: _____ Credentials: _____ %: _____

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: North Carolina

Parent Company (if any): _____

Corporation/Organization Name: Aeroflow Inc

Mailing Address: 3165 Sweeten Creek Rd

City: Asheville State: NC Zip: 28803

Telephone: 888-345-1780 Email: licensing@aeroflowinc.com

Contact Person Name: Erin Rummel

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Cody Offenbacher

Print Name of Authorized Person Submitting Application

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

2/15/2025

Date

Board Use Only	Date Received: 4/29/25	Amount: $500.00

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 6/27/2025

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

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

PRODUCER Scott Insurance - Raleigh 2501 Blue Ridge Road Suite 250 Raleigh NC 27607	**CONTACT NAME:** Leslie Eyster **PHONE (A/C, No, Ext):** 919-341-0505 **FAX (A/C, No):** 434-455-8866 **E-MAIL ADDRESS:** leyster@scottins.com
INSURED AEROHEA-01 Aeroflow, Inc. 3165 Sweeten Creek Road Asheville NC 28803-2115	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Benchmark Insurance Company (A) — 41394 **INSURER B :** Trumbull Insurance Company (A+) — 27120 **INSURER C :** Great American Risk Solutions Surplus Lines Insura — 35351 **INSURER D :** Lloyd's of London (A+) **INSURER E :** Nutmeg Insurance Company (A+) — 39608 **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** 242659674 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X **COMMERCIAL GENERAL LIABILITY** [ ] CLAIMS-MADE [X] OCCUR X Incidentl Med PL X $500K Deductible GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			D1024G3706-18	7/1/2025	7/1/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG [ ]	$ 1,000,000 $ 100,000 $ 10,000 $ 1,000,000 $ 3,000,000 $ 3,000,000 $
B	**AUTOMOBILE LIABILITY** X ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY [ ]			22UENBR4BUF	7/1/2025	7/1/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) [ ]	$ 1,000,000 $ $ $ $
A	[ ] **UMBRELLA LIAB** X OCCUR X **EXCESS LIAB** [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $			UM10245538-10	7/1/2025	7/1/2026	EACH OCCURRENCE AGGREGATE [ ]	$ 10,000,000 $ 10,000,000 $
E	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** Y/N ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N **(Mandatory in NH)** If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		22WB AY9RYV	7/1/2025	7/1/2026	X PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
C D	Excess Liability: $10M xs $10M Cyber Liability			XSF208256-01 TRCP259DBA	7/1/2025 7/1/2025	7/1/2026 7/1/2026	Each Occu/Aggregate Aggregate/Retention	10M/10M 5M/150K

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

The excess liability policy UM10245538-10 does not apply to business auto. Hartford Casualty Insurance Company Commercial Umbrella #22XHUBT6HPT effective 7/1/25-7/1/26 applies to Business Auto policy #22UENBR4BUF only: $10,000,000 Umbrella Limit with $10,000 Self Insured Retention.
The excess liability policy XSF208256 does not apply to incidental medical professional liability. The excess liability policies UM10245538-10 and XSF208256 do not apply to cyber liability policy TRCP259DBA.

Reference: Aeroflow Inc, 6 Commerce Way, Arden, NC 28704.

CERTIFICATE HOLDER

Aeroflow Inc.
3165 Sweeten Creek Road
Asheville NC 28803

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

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NORTH CAROLINA
Department of the Secretary of State

CERTIFICATE OF EXISTENCE

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

AEROFLOW INC.

is a corporation duly incorporated under the laws of the State of North Carolina, having been incorporated on the 24th day of October, 2000, with its period of duration being Perpetual.

I FURTHER certify that, as of the date set forth hereunder, the said corporation's articles of incorporation are not suspended for failure to comply with the Revenue Act of the State of North Carolina; that the said corporation is not administratively dissolved for failure to comply with the provisions of the North Carolina Business Corporation Act; that its most recent annual report required by N.C.G.S. 55-16-22 has been delivered to the Secretary of State; and that the said corporation has not filed articles of dissolution as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 18th day of December, 2025.

Elaine F. Marshall

Secretary of State

Scan to verify online.

Certification# 125562689-1 Reference# 23579356- Page: 1 of 1
Verify this certificate online at https://www.sosnc.gov/verification

EXHIBIT A

NORTH CAROLINA
Department of The Secretary of State

To all whom these presents shall come, Greetings:

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify the following and hereto attached to be a true copy of

ARTICLES OF INCORPORATION

OF

HITE VENTURE CORPORATION

the original of which was filed in this office on the 24th day of October, 2000.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 24th day of October, 2000

Elaine F. Marshall

Secretary of State

Document Id: 202985024

20 298 5024

SOSID: 568124
Date Filed: 10/24/2000 4:20 PM
Elaine F. Marshall
North Carolina Secretary of State

Prepared by: William J. Trull, Jr.

ARTICLES OF INCORPORATION

of

HITE VENTURE CORPORATION

The undersigned natural person, being of the age of eighteen (18) years or more, does hereby make and acknowledge these Articles of Incorporation for the purpose of forming a business corporation under and by virtue of the laws of the State of North Carolina.

ARTICLE 1.00
Name, Office, Agent and Duration

(a) NAME: The name of the Corporation is:

HITE VENTURE CORPORATION

(b) REGISTERED AND PRINCIPAL OFFICE: The address of the initial registered office, and the principal office address, of the Corporation is: [redacted]

(c) REGISTERED AGENT: The name of the initial registered agent at such address is **DON J. HITE.**

(d) PERIOD OF DURATION: The period of duration of the Corporation shall be perpetual and unlimited.

ARTICLE 2.00
Purposes

The purposes for which the Corporation is organized are:

(a) To engage in the business of operating a discount tobacco business; and,

(b) To engage in any lawful act or activity for which corporations may be organized under the laws of the State of North Carolina.

ARTICLE 3.00
Shares, Minimum Consideration and Preemptive Rights

(a) AUTHORIZED: The aggregate number of shares which the Corporation shall have authority to issue is 100,000 shares of common stock, each having One Dollar ($1.00) par value.

(b) MINIMUM CONSIDERATION: The minimum amount of consideration to be received by the Corporation for its shares before it shall commence business is One Dollar ($1.00) in cash, property, or services of equivalent value.

(c) PREEMPTIVE RIGHTS: The shareholders of the Corporation shall have preemptive right to acquire additional shares of the Corporation, as provided in Section 55-6-30 of the North Carolina General Statutes.

ARTICLE 4.00
Directors

(a) INITIAL BOARD: The number of Directors constituting the initial Board of Directors shall be one (1).

(b) INCREASE AND DECREASE: The number of Directors may be increased or diminished from time to time by the Bylaws of this Corporation adopted by the stockholders, but shall never be less than one, and any such reduction of Directors shall not have the effect of shortening the term of an incumbent Director.

(c) NAME AND ADDRESS: DON J. HITE, whose address is [redacted] shall serve as the sole Director of the Corporation until the first annual meeting of shareholders, or until a successor shall have been duly elected and qualified.

ARTICLE 5.00
Incorporator

NAME AND ADDRESS: The name and address of the Incorporator of the Corporation is as follows:

Name	Address
DON J. HITE	[redacted]

IN WITNESS WHEREOF, the undersigned, being the Incorporator designated in Article 5.00 hereof, hereby executes these Articles of Incorporation and certifies to the truth of the facts herein stated, this 16 day of OCTOBER, 2000.

DON J. HITE, Incorporator

STATE OF NORTH CAROLINA
COUNTY OF BUNCOMBE

I, Phyllis S. Fitzgerald, a Notary Public of said County and State do hereby certify that DON J. HITE, a natural person of the age of eighteen (18) years or more, personally appeared before me this day and acknowledged the due execution of the foregoing Articles of Incorporation.

WITNESS my hand and Notarial Seal, this the 16 day of Oct, 2000.

Phyllis S. Fitzgerald
Notary Public

My Commission Expires: 09-15-2003

EXHIBIT B

BYLAWS
OF
HITE VENTURE CORPORATOPM

ARTICLE 1.00
Offices

1.01 PRINCIPAL OFFICE: The principal office of the Corporation shall be located at [redacted]

1.02 REGISTERED OFFICE: The registered office of the Corporation required by law to be maintained in the State of North Carolina may be, but need not be, identical with the principal office.

1.03 OTHER OFFICES: The Corporation may have offices at such other places, either within or without the State of North Carolina, as the Board of Directors may designate or as the affairs of the Corporation may require from time to time.

ARTICLE 2.00
Meeting of Shareholders

2.01 PLACE OF MEETINGS: All meetings of shareholders shall be held at the principal office of the corporation, or at such other place, either within or without the State of North Carolina, as shall be designated on the notice of the meeting or agreed upon by a majority of the shareholders entitled to vote thereat.

2.02 ANNUAL MEETINGS: The annual meetings of shareholders for the election of directors and the transaction of other business shall be held in October of each year on any day in that month as determined by the Board of Directors.

2.03 SUBSTITUTE ANNUAL MEETINGS: If the annual meeting shall not be held on the day designated by these Bylaws, a substitute annual meeting may be called in accordance with the provisions of Section 2.04. A meeting so called shall be designated and treated for all purposes as the annual meeting.

2.04 SPECIAL MEETINGS: Special meetings of the shareholders may be called at any time by the President, Secretary or Board of Directors of the Corporation, or by any shareholder pursuant to the written request of the holders of not less than one-tenth of all the shares entitled to vote at the meeting.

2.05 NOTICE OF MEETINGS: (a) Written or printed notice stating the time and place of the meeting shall be delivered not less than ten nor more than fifty days before the date of any shareholders' meeting, either personally or by mail, by or at the direction of the President, the Secretary, or other person calling the meeting to each shareholder of record entitled to vote at such meeting; provided that such notice must be given not less than twenty days before the day of any meeting at which a merger or consolidation is to be considered. If mailed, such notice shall be

deemed to be delivered when deposited in the United States mail, addressed to the shareholder at his address as it appears on the record of shareholders of the Corporation, with postage thereon prepaid.

(b) In the case of a special meeting, the notice of meeting shall specifically state the purpose or purposes for which the meeting is called; but, in the case of an annual or substitute annual meeting, the notice of meeting need not specifically state the business to be transacted thereat unless such a statement is required by the provisions of the North Carolina Business Corporation Act.

(c) When a meeting is adjourned for thirty days or more, notice of the adjourned meeting shall be given as in the case of an original meeting. When a meeting is adjourned for less than thirty days in any one adjournment, it is not necessary to give any notice of the adjourned meeting other than by announcement at the meeting at which the adjournment is taken.

2.06 VOTING LISTS: At least ten days before each meeting of shareholders the Secretary of the Corporation shall prepare an alphabetical list of the shareholders entitled to vote at such meeting or any adjournment thereof, with the address of and number of shares held by each, which list shall be kept on file at the registered office of the Corporation for a period of ten days prior to such meeting, and shall be subject to inspection by any shareholder at any time during the usual business hours. This list shall also be produced and kept open at the time and place of the meeting and shall be subject to inspection by any shareholder during the whole time of the meeting.

2.07 QUORUM: (a) A majority of the outstanding shares of the Corporation entitled to vote, represented in person or by proxy, shall constitute a Quorum at a meeting of shareholders, except that a substitute annual meeting of shareholders the number of shares then represented either in person or by proxy, even though less than a majority, shall constitute a Quorum for the purpose of such meeting.

(b) The shareholders present at a duly organized meeting may continue to transact business until adjournment, notwithstanding the withdrawal of enough shareholders to leave less than a Quorum.

(c) In the absence of a Quorum at the opening of any meeting of shareholders, such meeting may be adjourned from time to time by a vote of the majority of the shares voting on the motion to adjourn and at any adjourned meeting at which a Quorum is present, any business may be transacted which might have been transacted at the original meeting.

2.08 PROXIES: Shares may be voted either in person or by one or more agents authorized by a written proxy executed by the shareholder or by his duly authorized attorney in fact. A proxy is not valid after the expiration of eleven months from the date of its execution, unless the person executing it specifies therein the length of time for which it is to continue in force, or limits its use to a particular meeting, but no proxy shall be valid after ten years from the date of its execution.

2.09 VOTING OF SHARES: (a) Subject to the provisions of Section 3.04, each outstanding share entitled to vote shall be entitled to one vote on each matter submitted to a meeting of shareholders.

(b) Except in the election of directors as governed by the provisions of Section 3.03, the vote of a majority of the shares voted on any matter at a meeting of shareholders at which a Quorum is present shall be the act of the shareholders on that matter, unless the vote of a greater number is required by law or by the charter or Bylaws of this Corporation.

(c) Shares of its own stock owned by the Corporation, directly or indirectly, through a subsidiary Corporation or otherwise, shall not be voted and shall not be counted in determining the total number of shares entitled to vote, except that shares held in a fiduciary capacity may be voted and shall be counted to the extent provided by law.

2.10 INFORMAL ACTION BY SHAREHOLDERS: Any action which may be taken at a meeting of the shareholders may be taken without a meeting if a consent in writing, setting forth the action so taken, shall be signed by all of the persons who would be entitled to vote upon such action at a meeting, and filed with the secretary of the corporation to be kept as part of the corporate records.

ARTICLE 3.00
Board of Directors

3.01 GENERAL POWERS: The business and affairs of the Corporation shall be managed by its Board of Directors.

3.02 NUMBER, TERM AND QUALIFICATIONS: The number of directors constituting the Board of Directors shall be one (1). Each director shall hold office until his death, resignation, retirement, removal, disqualification, or his successor shall have been elected and qualified. Directors need not be residents of the State of North Carolina or shareholders of the Corporation.

3.03 ELECTION OF DIRECTORS: Except as provided in Section 3.06, the directors shall be elected at the annual meeting of shareholders, and those persons who receive the highest number of votes shall be deemed to have been elected. If any shareholder so demands, the election of directors shall be by ballot.

3.04 CUMULATIVE VOTING: Every shareholder entitled to vote at an election of directors shall have the right to vote the number of shares standing of record in his name for as many persons as there are directors to be elected and for whose election he has a right to vote, or to cumulate his votes by giving one candidate as many votes as the number of such directors multiplied by the number of his shares shall equal, or by distributing such vote on the same principle among any number of such candidates. This right of cumulative voting shall not be

Ownership (4/30/24):

67% Casey Hite, Individual 4034

30% The Casey L. Hite Dynasty Irrevocable Trust

3% JIH Irrevocable Trust

Aeroflow Health
3165 Sweeten Creek Road
Asheville, NC 28803-2115

Aeroflow Inc. Corporate Officers

Appointment of Officers Resolution Dated 01/01/2025.

Casey Hite, CEO; Sole Director (Board); Direct Owner 67%

[redacted]

Joshua Hill, Vice President

[redacted]

Dennis Patenotte, Treasurer

[redacted]

Ryan Bullock, Secretary

[redacted]

NORTH CAROLINA BOARD OF PHARMACY

DME PERMIT
(ORIGINAL)

This is to Certify

Aeroflow Inc
doing business as
Aeroflow Inc

Address **6 Commerce Way** City **Arden, NC**

Is Registered as a
DME

As Required by G.S. 90-85.21,
The Number of Said Permit Being:

Issued **03/06/2025** **03261**

North Carolina Board of Pharmacy

Executive Director

TO BE CONSIPCUOUSLY
DISPLAYED IN
MAIN LOBBY OF DME

THIS PERMIT IS NOT TRANSFERABLE IT MUST BE RENEWED BY JANUARY 1ST OF EACH YEAR

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Aeroflow Inc. dba Aeroflow Healthcare

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

Physical Address: 6 Commerce Way

City: Arden State: NC Zip: 28704-9712

Mailing Address (if different from physical address): 3165 Sweeten Creek Road

City: Asheville State: NC Zip: 28803-2115

Telephone: 888-345-1780 Website: www.aeroflowhealth.com

Licensing Company Email: info@aeroflowhealth.com

Section 2: Personal Information

First: Casey Middle: Leo Last: Hite

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

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

Mailing Address: [redacted]

City: [redacted] State: NC Zip: [redacted]

Telephone: 888-345-1780 x4504 Email: revalidation@aeroflowinc.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of South Carolina		1997 -2001	
Address	**City**	**State**	**Zip**
1027 Barnwell Street	Columbia	SC	29208
Diploma/Degree obtained, if any			
Bachelor of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Socastee High School		1994-1997	
Address	**City**	**State**	**Zip**
4900 Socastee Boulevard	Myrtle Beach	NC	29588
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2024 - present	[redacted]	[redacted]	NC	[redacted]
2017 - 2024			NC	
2017 - 2024			NC	
2017 - 2023			NC	
2011 - 2017			NC	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Aeroflow Inc. dba Aeroflow Healthcare			10/2004-Current	
Business Address		**City**	**State**	**Zip**
3165 Sweeten Creek Road		Asheville	NC	28803-2115
Phone	**Title**			
888-345-1780x4504	CEO			
Description of Duties				
Managing employee for Aeroflow Inc.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

01/27/2026

Date

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

Casey Hite

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/27/2026

Date

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

State of North Carolina, ss. County of Buncombe

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

Original Signature

01/27/2026

Date

Subscribed and Sworn to before me this 27th day of January, 2026

Notary Public Signature

Larissa L Pitts
Notary Public
Buncombe County
North Carolina
My Commission Expires 03/14/29

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Aeroflow Inc. dba Aeroflow Healthcare MDEG License # (if applicable) _____

Physical Address 6 Commerce Way

City Arden State NC Zip 28704-9712

Mailing Address (if different from physical address) 3165 Sweeten Creek Road

City Arden State NC Zip 28704-9213

Telephone 888-345-1780 Website www.aeroflowhealth.com

Licensing Company Email licensing@aeroflowinc.com

Section 2: Personal Information

First Jonathon Middle _____ Last Paquette

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

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

Mailing Address [redacted]

City [redacted] State NC Zip [redacted]

Telephone 888-345-1780 Email licensing@aeroflowinc.com

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

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) Honorably discharged May 2020.	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

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

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

School Name		From - To (MM/YY – MM/YY)	
Indiana State University		08/09-05/13	
Address	**City**	**State**	**Zip**
200 N 7th St	Terre Haute	IN	47809
Diploma/Degree obtained, if any			
Bachelor of Science, Criminology			
School Name		**From - To (MM/YY – MM/YY)**	
Cardinal Ritter High School		08/05-05/09	
Address	**City**	**State**	**Zip**
3360 W 30th St	Indianapolis	IN	46222
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/23-present	[redacted]	[redacted]	NC	[redacted]
12/20-12-22			UT	
04/20-12/20			UT	
04/19-04/20			NC	
07/17-04/19			NC	
06/16-06/17			CA	
01/16-06/16			CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Aeroflow Inc. dba Aeroflow Healthcare			12/24-present	
Business Address		**City**	**State**	**Zip**
3165 Sweeten Creek Road		Asheville	NC	28803
Phone	**Title**		**Number of Employed Hours**	
888-345-1780	CEO		Approx 2340	

Description of Duties
Director of Supply Chain: overseens and directs all distribution functions including reciving, picking, processing and shipping all Aeroflow DME products. Leads team of managers in fast paced production and order fulfillment.

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

Description of Duties

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

1/28/2026
Date

I, Jonathan Paquette, **certify that as the MDEG Administrator for**

Aeroflow Inc. dba Aeroflow Healthcare,

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

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

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

Jonathon Paquette

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/28/2026

Date

Board Use Only	Date Received: 2/18/26

4B

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Anodyne, INC.

MDEG Physical Address: 6024 Blue Circle Drive

City: Minnetonka State: MN Zip: 55343

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 952 546 5334 Website: www.anodynerehab.com

Email: BillM@anodynerehab.com

Name of MDEG Administrator (NAC 639.694): _____

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

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

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

MEDICARE# 0579650001 NPI- 1376507061

MN MEDICAID# 4033633900

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

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

   a) A practicing health professional; or

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

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: MINNESOTA

Parent Company (if any): N/A

Corporation/Organization Name: ANODYNE, INC.

Mailing Address: 6024 BLUE CIRCLE DRIVE

City: MINNETONKA State: MN Zip: 55343

Telephone: 952-546-5334 Email: INFO@ANODYNEREHAB.COM

Contact Person Name: BILL MARZOLF

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

William J. Marzolf, Jr., PRES./CEO

Print Name of Authorized Person Submitting Application

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

11/17/2025

Date

Board Use Only	Date Received: 12/1/25	Amount: $500-ck 21026

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 02/24/2026

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

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

PRODUCER AssuredPartners of Minnesota LLC 2685 Long Lake Road St. Paul MN 55113	CONTACT NAME: Michelle Sneen PHONE (A/C, No, Ext): (651) 644-7200 FAX (A/C, No): (651) 644-9137 E-MAIL ADDRESS: michelle.sneen@assuredpartners.com
INSURED Anodyne, Inc. & Marzolf Properties, LLC 6024 Blue Circle Drive Minnetonka MN 55343	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: Massachusetts Bay Insurance Co — 22306 INSURER B: Allmerica Financial Benefit In — 41840 INSURER C: Hanover Insurance Company — 22292 INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** 2026-2027 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR [X] Professional Liability Included GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			ZDX A528609 11	01/01/2026	01/01/2027	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 100,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ 2,000,000 $
B	AUTOMOBILE LIABILITY [X] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			AWX A528572 11	01/01/2026	01/01/2027	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) Uninsured/Underinsured	$ 1,000,000 $ $ $ $ 1,000,000
C	[X] UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $			UHX A528620 11	01/01/2026	01/01/2027	EACH OCCURRENCE AGGREGATE $	$ 2,000,000 $ 2,000,000 $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [ ] N/A If yes, describe under DESCRIPTION OF OPERATIONS below						[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $

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

CERTIFICATE HOLDER

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy #206
Reno NV 89521

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Michelle Sneen

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Office of the Minnesota Secretary of State
Certificate of Good Standing

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

Name:	Anodyne, Inc.
Date Filed:	07/10/1987
File Number:	5Q-151
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota
This certificate has been issued on:	01/30/2026

Steve Simon
Secretary of State
State of Minnesota

Kristy Langston

From: Bill Marzolf <Billm@anodynerehab.com>
Sent: Monday, February 23, 2026 7:35 AM
To: Kristy Langston
Subject: Anodyne DME Application

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Good Morning Kristy,

Safal has informed me that you require a list of our officers and directors to complete our registration as DME provider in Nevada.
I am please to inform you that I am 100% owner and sole shareholder of Anodyne, Inc., a Minnesota Subchapter S Corporation.
Additionally, I am the only corporate officer, serving as both the CEO and the President. We have no other Corporate Officers.

I hope that this is sufficient information for you to approve Anodyne as a registered DME in your state and give us the opportunity to
distribute the Felix, a peripheral nerve stimulation (PNS) device. for patients afflicted with Essential Tremor.

By the way, sadly, Safal is currently intending to return to his home country of Nepal in April so he is transitioning his workload over to me
during the interim. Please reach out to me if you have any questions, require additional documentation or if I can be of assistance to you in any way.

Thank you in advance for your help with this.

My best to you.

William J. Marzolf, Jr.
President/CEO
Anodyne, Inc.
6024 Blue Circle Drive
Minnetonka, MN 55343
M: [redacted]
O: 651-796-2555
Fax: 952-546-2657

Anodyne

PRIVILEGED AND CONFIDENTIAL COMMUNICATION - IMPORTANT-- HIPPA- This electronic transmission, and any files transmitted with it are confidential and/or legally privileged information of Anodyne Inc.. This information is intended solely for the use of the individual or entity to which they are addressed. Any disclosure, re transmission, reproduction, dissemination or other use of the contents of this

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG ANODYNE, INC. MDEG License # (if applicable) _____

Physical Address 6024 BLUE CIRCLE DR.

City MINNETONKA State MN Zip 55343

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First WILLIAM Middle J. Last MARZOLF, JR.

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

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

Mailing Address [redacted]

City [redacted] State MN Zip [redacted]

Telephone [redacted] Email BILLM@ANODYNEREHAB.COM

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
ST. THOMAS ACADEMY		09/68 - 05/72	
Address	City	State	Zip
949 MENDOTA HTS. RD.	MENDOTA HEIGHTS	MN	55120
Diploma/Degree obtained, if any			
HS-DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
ST. JOHN'S UNIVERSITY		09/75 - 05/78	
Address	City	State	Zip
2850 ABBEY PLACE	COLLEGEVILLE	MN	56321
Diploma/Degree obtained, if any			
BS-NAT. SCI BA PSYCH			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/14 – PRESENT	[redacted]	[redacted]	MN	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
ANODYNE, INC.			07/87 - PRESENT
Business Address	**City**	**State**	**Zip**
6024 BLUE CIRCLE DR.	MINNETONKA	MN	55343
Phone	**Title**	**Number of Employed Hours**	
952-546-5334	PRESIDENT/CEO	50 HRS/WK.	
Description of Duties			
ADMIN - ALL GEN DUTIES Accounting ETC			

Business Name			From - To (MM/YY – MM/YY)
KNEEWELL, LLC			11/19 - PRESENT
Business Address	**City**	**State**	**Zip**
6024 BLUE CIRCLE DR.	MINNETONKA	MN	55311
Phone	**Title**	**Number of Employed Hours**	
651-796-2555	PRESIDENT	15 HRS/WK	
Description of Duties			
SMALL CORP. ALL TASKS ADMIN. TO Marketing ETC			

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/17/2025
Date

I, William J. Marzolf, Jr, **certify that as the MDEG Administrator for** ANODYNE, INC.,

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

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

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

William J. Marzolf, Jr.
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/17/2025
Date

Board Use Only	Date Received: 12/1/25

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site ANODYNE, INC

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

Physical Address 6024 BLUE CIRCLE DR.

City MINNETONKA State MN Zip 55343

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 952-546-5334 Website ANODYNEREHAB.COM

Licensing Company Email INFO@ANODYNEREHAB.COM

Section 2: Personal Information

First William Middle J. Last Marzolf, Jr.

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

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

Mailing Address [redacted]

City [redacted] State MN Zip [redacted]

Telephone [redacted] Email BillM@AnodyneRehab.Com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
ST. THOMAS ACADEMY			09/68	TO 05/72
Address	City	State	Zip	
949 MENDOTA HEIGHTS ROAD	MENDOTA HEIGHTS	MN	55120	
Diploma/Degree obtained, if any				
H.S. DIPLOMA				

School Name			From - To (MM/YY – MM/YY)	
ST. JOHN'S UNIVERSITY			09/75 -	05/78
Address	City	State	Zip	
2850 ABBEY PLACE	Collegeville	MN	56321	
Diploma/Degree obtained, if any				
B.S NAT. SCI + BA PSYCHOLOGY				

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/14 - PRESENT	[redacted]	[redacted]	MN	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
ANODYNE, INC			07/05 - PRESENT
Business Address	**City**	**State**	**Zip**
6024 BLUE CIRCLE DR.	MINNETONKA	MN	55343
Phone	**Title**		
952-546-5334	PRESIDENT/CEO		
Description of Duties			
ADMIN, Accounting ETC.			

Business Name			From - To (MM/YY – MM/YY)
KNEEWELL, LLC			11/19 - PRESENT
Business Address	**City**	**State**	**Zip**
6024 BLUE CIRCLE DR	MINNETONKA	MN	55343
Phone	**Title**		
651-796-2555	PRESIDENT		
Description of Duties			
SMALL CORP. - ALL TASKS ADMIN TO Marketing ETC.			

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/17/2025
Date

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

William J. Marzolf, Jr
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/17/2025
Date

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

State of Minnesota, ss. County of Hennepin

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

Charleen Kollm
Original Signature

11/17/25
Date

Subscribed and Sworn to before me this 17 day of Nov 2025

Charleen Kollm
Notary Public Signature

CHARLEEN J KOLLM
Notary Public
Minnesota
My Commission Expires
Jan 31, 2026

(Seal)

William J. Marzolf, Jr.
Anodyne, Inc.
6024 Blue Circle Drive
Minnetonka, MN 55343

August 28, 2024

RE: Accreditation Award

Dear William J. Marzolf, Jr.,

The Healthcare Quality Association on Accreditation is pleased to inform you that Anodyne, Inc. meets the DME accreditation requirements under section 1834(a)(20) of the Social Security Act (SSA) and the federal regulations at 42 CFR 424.58. HQAA has based this finding on a review of your application and an onsite survey conducted August 20, 2024.

This three-year accreditation award applies to the following Anodyne, Inc. location through August 27, 2027:

6024 Blue Circle Drive
Minnetonka, MN 55343
NPI # 1376507061

Please maintain a copy of your current equipment list with this letter. We look forward to working with you as you serve your customers throughout your service area. If you have any questions, please contact us.

Sincerely,

Rhonda Pearce
Executive Director

Award of Accreditation

For DMEPOS Products & Services
Awarded to

Anodyne, Inc.
Minnetonka, MN
HQAA ID # 6KZ07U51F

On this day of

August 27, 2024

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

HQAA
HEALTHCARE QUALITY ASSOCIATION ON ACCREDITATION

Executive Director

HQAA ACCREDITED

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

Surety Bond
Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies
Medicare Program

Bond Number: 100076859

KNOW ALL PERSONS BY THESE PRESENTS, that subject to the terms, conditions and limitations of this bond, Anodyne, Inc., as Principal, Merchants Bonding Company (Mutual) P.O. Box 14498, Des Moines, IA 50306-3498, a corporation organized and existing under the laws of Iowa, as Surety, are held and firmly bound unto the Centers for Medicare & Medicaid Services ("CMS"), 7500 Security Boulevard, Baltimore, Maryland 21244, an agency of the United States Department of Health and Human Services ("CMS"), as Obligee, in the Penal Sum of Fifty Thonsand Dollars ($50,000.00) for payment of which Principal and Surety bind themselves, their heirs, executors, administrators and assigns, jointly and severally, by these presents.

WHEREAS, Principal is enrolled in or is seeking to be enrolled in the Medicare program as a supplier of durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS"); and

WHEREAS, pursuant to Section 4312(a) of the Balanced Budget Act of 1997 (Pub. L. 105-33) and 42 CFR § 424.57, the Principal is required to provide a surety bond as a condition of participation in the Medicare program, and this bond is provided in compliance with the supplier's obligations as set forth in those authorities.

NOW THEREFORE, the condition of this Bond is that if the Principal shall pay the Obligee any unpaid claims, civil money penalties and assessments (as such terms are defined by 42 CFR § 424.57(a)) then this Bond shall be null and void, otherwise to remain in full force and effect, subject, however, to the following:

1. Principal and Surety are liable under this Bond for only the amount of any unpaid claim, civil money penalty or assessment imposed by CMS or the Office of Inspector General, plus accrued interest, for which the Principal is responsible and for which, subject to Paragraph 7, the Obligee first demands payment from the Surety during the term of this Bond; provided, however, that any claim under this Bond must be related to overpayments or other events that occurred on or after March 3, 2009.
2. Surety agrees to pay a claim within 30 days of receiving written notice of the claim and sufficient evidence (as such term is defined by 42 CFR § 424.57(a)) to establish Surety's liability under this Bond.
3. CMS is the sole Obligee of this Bond, and no action may be brought on it by, or for the use or benefit of, any person or entity other than CMS or its contractors.
4. Regardless of the number of years this Bond is in effect, the number of premiums paid, or the number of claims made, the Surety's aggregate liability shall not be more than the penal sum of this Bond.
5. Subject to Paragraph 7, the Surety's liability under this Bond shall terminate and the Surety shall have no further liability upon the effective date of cancellation or expiration of this Bond by the Surety or Principal in accordance with Paragraph 6 of this Bond.

6. The Surety or Principal may cancel this Bond by providing written notice of such cancellation to the Obligee. Cancellation or expiration shall be effective 30 days after notice of cancellation or expiration is sent to the Obligee's contractor, the National Supplier Clearinghouse, provided such notice is actually received.
7. In the event this Bond is cancelled or expires, and the Principal fails to submit a new bond to the Obligee, the Surety remains liable for unpaid claims, civil money penalties or assessments that were imposed or assessed by CMS or the Office of Inspector General during the 2 years following the effective date of cancellation or expiration of this Bond.

[redacted]

Location covered by this bond:

Location: 6024 Blue Circle Drive
Minnetonka , MN 55343

Effective this 1st day of September, 20 23.

In witness whereof, the undersigned Principal and Surety have set their hands and seals on this 3rd day of April, 2023.

Principal

Anodyne, Inc.

Surety /Merchants Bonding Company (Mutual)

Surety TIN: 42-0410010 William Warner Jr., Attorney-in-Fact

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED 1933

LP 2494 (11/22)

MERCHANTS
BONDING COMPANY

POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa, d/b/a Merchants National Indemnity Company (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

William Warner Jr.

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the following By-Laws adopted by the Board of Directors of Merchants Bonding Company (Mutual) on April 23, 2011 and amended August 14, 2015 and adopted by the Board of Directors of Merchants National Bonding, Inc., on October 16, 2015.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and aut hority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner-Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 3rd day of April , 2023 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY INCORPORATED (MUTUAL) -o- 1933

MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.
d/b/a MERCHANTS NATIONAL INDEMNITY COMPANY

By Larry Taylor
President

STATE OF IOWA
COUNTY OF DALLAS ss.
On this 3rd day of April , 2023 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC.; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL IOWA
Kim Lee
Commission Number 702737
My Commission Expires
April 14, 2024

Kim Lee
Notary Public

(Expiration of notary's commission
does not invalidate this instrument)

I, William Warner, Jr., Secretary of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 3rd day of April , 2023 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY INCORPORATED (MUTUAL) -o- 1933

William Warner Jr.
Secretary

POA 0018 (10/22) For bond verification contact verify@merchantsbonding.com

State of Minnesota

SECRETARY OF STATE

Certificate of Good Standing

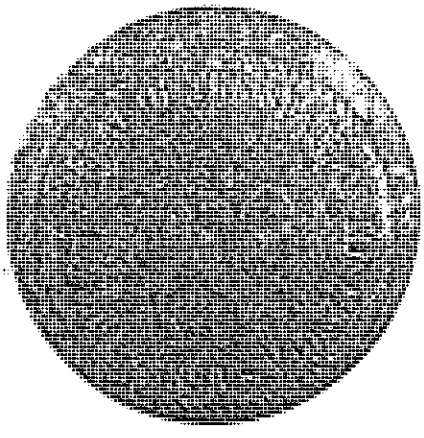
I, Joan Anderson Growe, Secretary of State of Minnesota, do certify that: The corporation listed below is a corporation formed under the laws of Minnesota; that the corporation was formed by the filing of Articles of Incorporation with the Office of the Secretary of State on the date listed below; that the corporation is governed by the chapter of Minnesota Statutes listed below; and that this corporation is authorized to do business as a corporation at the time this certificate is issued.

Name: ANODYNE, INC.

Date Formed: 07/10/1987

Chapter Governed By: 302A

This certificate has been issued on 06/04/96.



Joan Anderson Growe

Secretary of State.

Business Record Details »

Minnesota Business Name
Anodyne, Inc.

Business Type
Business Corporation (Domestic)

MN Statute
302A

File Number
5Q-151

Home Jurisdiction
Minnesota

Filing Date
07/10/1987

Status
Active / In Good Standing

Renewal Due Date
12/31/2025

Registered Office Address
6024 Blue Circ Drv
Mtka, MN 55343
USA

Number of Shares
1,000,000

Registered Agent(s)
William J Marzolf, Jr

Chief Executive Officer
William J Marzolf, Jr
6024 BLUE CIRCLE DR
MINNETONKA, MN 55343-9104
USA

Principal Executive Office Address
6024 BLUE CIRCLE DR
MINNETONKA, MN 55343-9104
USA

Filing History

Filing History

Select the item(s) you would like to order: Order Selected Copies

	Filing Date	Filing	Effective Date
☐	07/10/1987	Original Filing - Business Corporation (Domestic)	
	07/10/1987	Business Corporation (Domestic) Business Name (Business Name: ANODYNE, INC.)	

	Filing Date	Filing	Effective Date
☐	06/04/1990	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	12/20/1993	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	06/04/1996	Business Corporation (Domestic) Business Name (Business Name: Anodyne, Inc.)	
☐	01/06/1998	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	01/08/2007	Administrative Dissolution - Business Corporation (Domestic)	
☐	06/13/2007	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	06/13/2007	Annual Reinstatement - Business Corporation (Domestic)	
☐	01/07/2009	Administrative Dissolution - Business Corporation (Domestic)	
☐	10/13/2009	Annual Reinstatement - Business Corporation (Domestic)	
☐	2/25/2013	Administrative Dissolution - Business Corporation (Domestic)	
☐	4/3/2013	Annual Reinstatement - Business Corporation (Domestic)	
☐	2/20/2020	Administrative Dissolution - Business Corporation (Domestic)	
☐	3/18/2020	Annual Reinstatement - Business Corporation (Domestic)	

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Vulnerability Disclosure

Anodyne
SUPPLIES FOR HEALTHCARE

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

November 17, 2025

To whom this may concern:

Anodyne is making application to distribute Durable Medical Equipment (DME) within the boundaries of Nevada. In fulfillment of the requirement to provide notification of home state licensure I submit that there are no specific licensure requirements to distribute DME in Minnesota The requirements in Minnesota include being a state In-Network provider (MN Provider ID# 402263900) and the submission of a DMEPOS Surety Bond which is evidenced by virtue of our standing as a Medicare accredited provider for DME (enclosed). I am including a copy of fulfillment of these requirements in the accompanying packet.

For your reference Anodyne is interested in distributing a revolutionary device for control and management of Essential Tremors (ET). The Felix NeuroAI™ Just received the PDAC reference and offers tremendous hope for many that currently suffer from ET.

Should you have any questions or require additional information do not hesitate to reach out to me.

Thank you very much.

William J. Marzolf Jr.
President

WJM/
Encl.

4C

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located? ☐ Nevada ■ Out-of-State

***Is the business also a wholesaler? (NRS 639.016)** ☐ Yes ☐ No

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

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

Section 1: General Information

Facility Name: Comfort Medical, LLC

MDEG Physical Address: 9600 SW Oak Street, Suite 320

City: Tigard State: OR Zip: 97223-6596

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-700-4246 Website: www.comfortmedical.com

Email: credentialing@comfortmedical.com

Name of MDEG Administrator (NAC 639.694): _____

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies*	☐ Respiratory Equipment**
☐ Practitioners*	☐ Life-sustaining equipment**
☐ Hospitals/Clinics*	☐ Parenteral and Enteral Equipment**
☐ Clinics*	☐ Assistive Equipment
☐ Wholesalers*	☐ Diabetic Supplies
☐ Other business entities (specify)*:	☐ Orthotics and Prosthetics
	■ Others: Urology, Ostomy and Bowel Management Supplies
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
*If MDEG products will ALSO be sold to the Entities with an (*) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Marissa Phillips
	Telephone: 503-468-9826

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

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare # 4312130004
OR Medicaid : pending
WA Medicaid : pending

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

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): Coloplast Corp

Corporation/Organization Name: Comfort Medical, LLC

Mailing Address: 9600 SW Oak Street, Suite 320

City: Tigard State: OR Zip: 97223-6596

Telephone: 800-700-4246 Email: credentialing@comfortmedical.com

Contact Person Name: Timothy R. Jones

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Timothy R. Jones

Print Name of Authorized Person Submitting Application

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

01/27/2026

Date

Board Use Only	Date Received: 2/5/26	Amount: 500.00 / VF#7611

XL Insurance

Certificate of Insurance

This is to certify that XL Insurance Company SE has issued to the Insured named below a Public and Products Liability policy, brief details of which are set out below.
This certificate is only for information and does not confer any rights upon the holder.
The rights and liabilities of the parties will only be governed by the original policy including any amendments that may be agreed upon from time to time.

Certificate Holder:	Comfort Medical , LLC 9600 SW Oak Street, Suite 320, Tigard, OR 97223
Policyholder:	Coloplast A/S
Insured:	Coloplast A/S including subsidiary Comfort Medical , LLC 9600 SW Oak Street, Suite 320, Tigard, OR 97223
Type of Insurance:	General and Product Liability incl. PI
Limit of Indemnity:	USD 1,000,000 any one occurrence and USD 3,000,000 in the annual aggregate
Policy Number:	DK00000300LI25A
Period of Insurance:	1st October 2025 to 30th September 2026
Geographical Scope:	Worldwide

Nothing herein contained shall in any way be held or construed to alter or waive or vary any of the terms, conditions or provisions of the policy.
For full particulars of the insurance please refer to the policy document.

Copenhagen, Monday, 08 September 2025

Signed

Anne Jerris
For and on behalf of XL Insurance Company SE

XL Insurance Company SE, Sweden Filial
Kungsgatan 5, 2nd floor, 111 43 Stockholm, Sweden

Telephone: +46 8 440 89 80 Fax: +46 8 10 03 04 axaXL.com

XL Insurance Company SE |
Registrerat kontor Kungsgatan 5, Stockholm Registreringsnummer 516402-5123
XL Insurance Company SE
A European public limited liability company registered in Ireland
Registered in Ireland No. 641686 | Regulated by the Central Bank of Ireland

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/18/2025

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

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

PRODUCER MARSH USA LLC 333 South 7th Street, Suite 1400 Minneapolis, MN 55402-2400	CONTACT NAME: Marsh | US Operations PHONE (A/C, No, Ext): 866-966-4664 | FAX (A/C, No): 212-948-5382 E-MAIL ADDRESS: Minneapolis.CertRequest@marsh.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
INSURED Comfort Medical, LLC, 9600 SW Oak Street, Suite 320 Tigard, OR 97223	INSURER A : XL Insurance America, Inc.	24554
	INSURER B : N/A	N/A
	INSURER C : N/A	N/A
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** CHI-010911381-04 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			US00011271LI25A	10/01/2025	10/01/2026	EACH OCCURRENCE	$ 5,000,000
	X CLAIMS-MADE ☐ OCCUR			SIR: See ACORD 101			DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 5,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 5,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	☐ ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	DED | RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE | OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

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

CERTIFICATE HOLDER

Comfort Medical, LLC,
9600 SW Oak Street,
Suite 320,
Tigard, OR 97223

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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AGENCY CUSTOMER ID: CN102734708
LOC #: Minneapolis

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC	Comfort Medical, LLC, 9600 SW Oak Street, Suite 320 Tigard, OR 97223
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

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

Self Insured Retention
78,850 SIR for all other implants and all other claims than products (Applicable to all coverages shown above)
1,575,000 SIR for all implant products with 3,935,000 SIR aggregate
Separate SIR aggregate for penile implants of 7,870,000 SIR aggregate
5,900 non-ranking deductible applies per claim in the event of SIR agg exhaustion

- Defense Costs Included Within the SIR
- Deductible erodes the limit of liability
- Defense costs included in the deductible

Employee Benefits Deductible $ 1,000 per claim and $1,000,000 agg limit

ADDITIONAL NAMED INSUREDS
Affordable Medical, LLC - CM retro date 5/4/21
Atos Medical Inc. - CM retro date 04/01/22
Coloplast Corp. - CM 10/1/94
Coloplast Manufacturing US, LLC - CM 10/1/94
Comfort Medical, LLC - CM retro date 10/1/10
Griffin Laboratories - CM retro date 04/01/22
Hope Medical Supply, Inc. - CM retro date 3/1/21
Kerecis LLC - CM retro date 8/30/2023
Nine Continents Medical Inc - CM retro date 11/2/20
Rocky Mountain Medical LLC - CM retro date 1/4/21
ZI-Med Supply - CM retro date 6/30/2023

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State of Florida
Department of State

I certify from the records of this office that COMFORT MEDICAL, LLC is a limited liability company organized under the laws of the State of Florida, filed on November 19, 2010, effective July 9, 2001.

The document number of this limited liability company is L10000120798.

I further certify that said limited liability company has paid all fees due this office through December 31, 2025, that its most recent annual report was filed on January 13, 2025, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-second day of January, 2026

Type text here

Secretary of State

Tracking Number: 2379535969CU

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

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

Comfort Medical

List of all Officers and Directors

Officer:
Timothy R. Jones

Managers:
Morten Hansen
Shelley Mueller

This license is renewed, but not received yet, please see next page for renewal.

OREGON BOARD OF PHARMACY

MED DEVICE/EQUIP/GASES-C REGISTRATION

LICENSE NUMBER: NPC-0005488

This license is valid from:
05/15/2025-01/31/2026

ISSUED TO:

COMFORT MEDICAL LLC
9600 SW OAK ST STE 320
PORTLAND OR 97223

Executive Director
Issuing Authority: **ORS 475 & 689**

DO NOT COPY - Request certified copies in writing

MUST BE POSTED IN A CONSPICUOUS PLACE - **NOT TRANSFERABLE**

Comfort Medical

OREGON BOARD OF PHARMACY

Signed in as: COMFORTOR

Menu

- Apply for New License
- Certified Copies & Document Requests
- Update License Info & Upload Documents
- Pay Invoice

Licensing Home Page

The list below displays all of your licenses and applications. To update and maintain your registration, see the menu on the left.

If there is a change of name; ownership; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, or designated representatives, the Board must be notified within 15 days.

Change of Officers, licensing contacts, facility contacts or Designated Representative Notification can be completed online through the self-service process, by updating the information in the "Corporate Personnel" tab. This can be done within the renewal process or by selecting "Update License Info & Upload Documents" in the menu on the left.

A new application is required for any change of name or owner/location. All other notifications can be sent to **pharmacy.licensing@bop.oregon.gov**.

Name

Name: COMFORT MEDICAL LLC
Email: credentialing@comfortmedical.com

Address: 9600 SW OAK ST STE 320
Portland, OR 97223

My Licenses

Med Device/Equip/Gases-C # NPC-0005488 — View Documents

Issue Date: 5/15/2025 | Expiration Date: 1/31/2027 | License Status: Active

City of Tigard
City of Tigard c/o Business License
13125 SW Hall Blvd, Tigard, OR 97223
503-718-2628

BUSINESS LICENSE CERTIFICATE

This License is issued in accordance with Tigard Municipal Code 5.04.

Business Name:	COMFORT MEDICAL LLC DBA: COMFORT MEDICAL LLC	**Business Type(s):**	454110 Electronic Shopping and Mail-Order Houses
Business Location:	9600 SW OAK ST 320 TIGARD, OR 97223	**Mailing Address:**	9600 SW OAK ST 320 TIGARD, OR 97223
Owner:	COMFORT MEDICAL LLC		
License Number:	BIZ-001518-2025	**License Type:**	Business License
Issued Date:	12/31/2025	**Classification:**	Year-Round Business
Expiration Date:	12/31/2026	**Fees Paid:**	$160.00

TMC 7.24.120 has imposed reasonable restrictions on "door to door" solicitation and canvassing.
TMC 7.52.080 restricts the selling of goods or services in any city park.
A Business License does not imply city approval or endorsement to operate the business or the location of the business.

TO BE POSTED IN A CONSPICUOUS PLACE

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Comfort Medical LLC MDEG License # (if applicable) _____

Physical Address 9600 SW Oak Street, Suite 320

City Tigard State OR Zip 97223

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 503-468-9826 Website www.comfortmedical.com

Licensing Company Email credentialing@comfortmedical.com

Section 2: Personal Information

First Marissa Middle Lynn Last Phillips

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

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

Mailing Address [redacted]

City [redacted] State OR Zip [redacted]

Telephone [redacted] Email marissa.phillips@comfortmedical.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Portland Community College		2011	
Address	City	State	Zip
162 SE Water Ave	Portland	OR	97214
Diploma/Degree obtained, if any			
CNA/CNA II Acute Care			

School Name		From - To (MM/YY – MM/YY)	
Portland State University		1997-1997	
Address	City	State	Zip
1825 SW Broadway	Portland	OR	97201
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Western Oregon State College (Now Western Oregon University)		1986-1987	
Address	City	State	Zip
345 Monmouth Ave N	Monmouth	OR	97361
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Northern Arizona University		1983-1986	
Address	City	State	Zip
S San Francisco Street	Flagstaff	AZ	86001
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Coconino High School		1982-1983	
Address	City	State	Zip
2801 N Izabel Street	Flagstaff	AZ	86004
Diploma/Degree obtained, if any			
HS Diploma			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1/2024-present	[redacted]	[redacted]	OR	[redacted]
From - To (MM/YY – MM/YY)			State	
12/2019-1/2024			OR	
From - To (MM/YY – MM/YY)			State	
2012-2019			OR	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Comfort Medical			6/2025-Present	
Business Address		**City**	**State**	**Zip**
9600 SW Oak Street Suite 320		Tigard	OR	97223
Phone	**Title**		**Number of Employed Hours**	
503-468-9826	Ostomy Referral Coordinator / Office Manager		1500	
Description of Duties				
Assist patients in getting their needed Ostomy Suppllies, taking orders, preparing prescriptions for HCP signatures, reviewing progress notes for compliance. Coordinate office compliance with our corporate Compliance Team.				

Business Name			From - To (MM/YY – MM/YY)	
ComForCare Home Care Portland (business closed)			2/2012 - 6/2024	
Business Address		**City**	**State**	**Zip**
6700 SW 105th Ave		Beaverton	OR	97006
Phone	**Title**		**Number of Employed Hours**	
NA	Owner		80,000+	
Description of Duties				
Own and operate licensed In Home Care agency, employed over 500 staff, incl multiple nurses, served over 400 individuals cumulatively. Care ranged from homemaker to complex care w/ quads/vents/ostomies/catheters,etc				

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

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

I, Marissa Phillips, **certify that as the MDEG Administrator for**

Comfort Medical,

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

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

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

Marissa Phillips
Print Name (First, Last)

Marissa Phillips
Original Signature (electronic, copies or stamps not accepted)

2/19/2026
Date

Board Use Only	Date Received: 2/26/26

4D

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Donaco Medical Supply, LLC dba HR HealthCare Patient Services

MDEG Physical Address: 117 Towne Lake Parkway, Suite 200

City: Woodstock State: GA Zip: 30188-4831

Mailing Address (if different from physical address): 2295 Towne Lake Parkway, Suite 116 Box 237

City: Woodstock State: GA Zip: 30189-5562

Telephone: 877-424-2562 Website: https://www.hrhealthcare.com/patientservices/

Email: contractscredential@hrhealthcare.com

Name of MDEG Administrator (NAC 639.694): Dallas Donald, VP of Patient Services

Entities the MDEG will Serve	Type of MDEG products that will be sold (check all applicable)
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	■ Others: Urological, Ostomy, Wound Care, & Incontinence
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Dallas Donald
	Telephone: 404-312-8659

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

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare 6713050001 - FL Medicaid 121737600 - GA Medicaid 003129546A - KS Medicaid 30005393740001
KY Medicaid 7100970970 - MI Medicaid 1649531344 - NE Medicaid 10026557000 - OH Medicaid 0107751
PA Medicaid 104591765-0001

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

Name: Not Applicable _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

   a) A practicing health professional; or

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

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

Section 5: Publicly Traded Corporation

State of Incorporation: Not Applicable

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration: Not Applicable	SEC Registration Number: Not Applicable	Stock Exchange Symbol: Not Applicable

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Georgia

Parent Company (if any): _____

Corporation/Organization Name: Donaco Medical Supply, LLC dba HR HealthCare Patient Services

Mailing Address: 2295 Towne Lake Parkway, Suite 116 Box 237

City: Woodstock State: GA Zip: 30189-5562

Telephone: 877-424-2562 Email: ddonald@hrhealthcare.com

Contact Person Name: Dallas Donald

Section 7: Partnership

Partnership Name: Not Applicable

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: Not Applicable

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Dallas C. Donald, VP of Patient Services

Print Name of Authorized Person Submitting Application

Dallas C Donald

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

1-15-26

Date

Board Use Only	Date Received: 1/27/26	Amount: CK- 500 - 6640

HRPHARM-01 GVOGT

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 12/19/2025

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

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

PRODUCER Johnson, Kendall & Johnson, Inc. 109 Pheasant Run Newtown, PA 18940	CONTACT NAME: PHONE (A/C, No, Ext): (215) 968-4741 FAX (A/C, No): (215) 968-0973 E-MAIL ADDRESS: info@jkj.com
INSURED HR Pharmaceuticals Inc. DBA HR HealthCare and HR HealthCare Patient Services 2600 Eastern Blvd Ste 201 York, PA 17402-2916	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Great Northern Insurance Company — 20303 INSURER B : Federal Insurance Company — 20281 INSURER C : Chubb Indemnity Insurance Company — 12777 INSURER D : — INSURER E : — INSURER F : —

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY PRO-JECT X LOC OTHER:			36085564	1/1/2026	1/1/2027	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 3,000,000 $ 0
B	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY / SCHEDULED AUTOS HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY			73642555	1/1/2026	1/1/2027	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $ 0			56722584	1/1/2026	1/1/2027	EACH OCCURRENCE AGGREGATE Aggregate	$ 5,000,000 $ $ 5,000,000
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		71840954	1/1/2026	1/1/2027	X PER STATUTE / OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ 500,000 $ 500,000 $ 500,000
B	Products Liability			36090550	1/1/2026	1/1/2027	Each Occurrence/Agg	5,000,000
B	Errors & Omissions			36090550	1/1/2026	1/1/2027	Each Occurrence/Agg	3,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Insurance applies to the below entities:
Alma Respiratory Services, LLC DBA HR HealthCare Patient Services, - 4790 Wharf Pkwy, Bldg. F-208 Office C, Orange Beach, AL: 36561-9614
Apple West Home Medical Supply DBA HR HealthCare Patient Services, - 1122 Davis Street, San Leandro, CA 94577-2500
Donaco Medical Supply, LLC DBA HR HealthCare Patient Services, - 227 W 4th Street, Ste 318, Charlotte, NC 28202-1545
Donaco Medical Supply, LLC DBA HR HealthCare Patient Services, - 117 Towne Lake Parkway, Suite 200, Woodstock, GA 30188-4831
Donaco Medical Supply, LLC DBA HR HealthCare Patient Services, - 89 Old Trolley Rd, Ste 211, Summerville, SC 29485-4951

CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

ACORD 25 (2016/03)

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Donaco Medical Supply, LLC dba HR HealthCare Patient Services

Ownership Information

Hendrix Acquisition, LLC EIN: 93-4423701 2600 Eastern Blvd, Suite 201 York, PA 17402-2916 Phone: 717-252-1110 ext 133 County: York Email: dsempeles@hrhealthcare.com	100% Direct Ownership	Effective 11/30/2023
HR Pharmaceuticals, LLC EIN: 27-1584005 2600 Eastern Blvd, Suite 201 York, PA 17402-2916 Phone: 717-252-1110 ext 133 County: York Email: dsempeles@hrhealthcare.com	100% Indirect Ownership	Effective 05/31/2024 Change from Inc to LLC Effective 01/29/2026
HR LowerCo Holdings LLC EIN: 41-3707105 2600 Eastern Blvd, Suite 201 York, PA 17402-2916 Phone: 717-252-1110 ext 133 County: York Email: dsempeles@hrhealthcare.com	100% Indirect Ownership	Effective 01/29/2026
HR Parent Holdings LLC EIN: 41-3668588 2600 Eastern Blvd, Suite 201 York, PA 17402-2916 Phone: 717-252-1110 ext 133 County: York Email: dsempeles@hrhealthcare.com	100% Indirect Ownership	Effective 01/29/2026
Wiesman Capital & Co., LLC EIN: 81-4290490 2600 Eastern Blvd, Suite 201 York, PA 17402-2916 Phone: 717-252-1110 ext 133 County: York Email: dsempeles@hrhealthcare.com	95.1% Indirect Ownership	Effective 01/29/2026
Colby P. Wiesman 	70% Indirect Ownership	Effective 07/01/2024
Christopher P. Wiesman 	20% Indirect Ownership	Effective 07/01/2024
Jon P. Wiesman 	10% Indirect Ownership	Effective 07/01/2024

Control Number : 12043603

STATE OF GEORGIA

Secretary of State

Corporations Division
313 West Tower
2 Martin Luther King, Jr. Dr.
Atlanta, Georgia 30334-1530

CERTIFICATE OF EXISTENCE

I, **Brad Raffensperger**, the Secretary of State of the State of Georgia, do hereby certify under the seal of my office that

DONACO MEDICAL SUPPLY, LLC
a Domestic Limited Liability Company

was formed in the jurisdiction stated below or was authorized to transact business in Georgia on the below date. Said entity is in compliance with the applicable filing and annual registration provisions of Title 14 of the Official Code of Georgia Annotated and has not filed articles of dissolution, certificate of cancellation or any other similar document with the office of the Secretary of State.

This certificate relates only to the legal existence of the above-named entity as of the date issued. It does not certify whether or not a notice of intent to dissolve, an application for withdrawal, a statement of commencement of winding up or any other similar document has been filed or is pending with the Secretary of State.

This certificate is issued pursuant to Title 14 of the Official Code of Georgia Annotated and is prima-facie evidence that said entity is in existence or is authorized to transact business in this state.

Docket Number	: 30206515
Date Inc/Auth/Filed	: 05/22/2012
Jurisdiction	: Georgia
Print Date	: 11/11/2025
Form Number	: 211

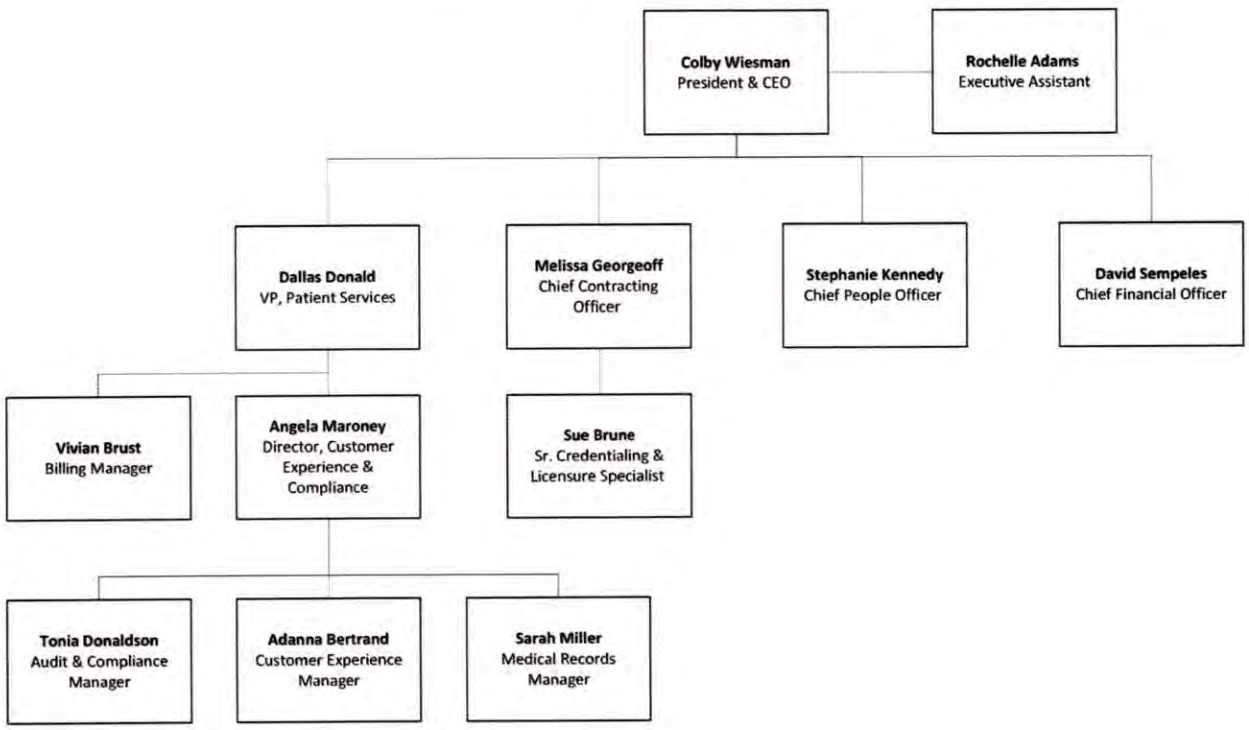
Brad Raffensperger

Brad Raffensperger
Secretary of State

HR HealthCare
Patient Services

Applicable Entities:
Donaco Medical Supply, LLC (DBA HR Healthcare Patient Services) Tax ID: 45-5351062
Alma Respiratory Service, LLC (DBA HR Healthcare Patient Services) Tax ID: 59-3494530
Apple West Home Medical Supply (DBA HR Healthcare Patient Services) Tax ID: 20-5413826

HR Healthcare Patient Services Organizational Structure



STATE OF GEORGIA
Georgia Board of Pharmacy
Durable Medical Equipment Supplier
LICENSE NO. PHDME000902 Status: Active

Donaco Medical Supply LLC
HR HealthCare Patient Services
117 Towne Lake Pkwy
Ste 200
Woodstock GA 30188

Expires: 06/30/2027
Issued: 03/14/2024

Real-time license verification is available at gadch.mylicense.com/verification

Above is your wall certificate license to practice as a **Durable Medical Equipment Supplier** in the State of Georgia. A pocket-sized license card is below.

Please make note of the expiration date on your license. It is your responsibility to renew your license before it expires.
Please notify the Board if you have a change of address.

STATE OF GEORGIA
Georgia Board of Pharmacy
Durable Medical Equipment Supplier
LICENSE NO. PHDME000902 Status: Active
Donaco Medical Supply LLC
117 Towne Lake Pkwy
Ste 200
Woodstock GA 30188

Expires: 06/30/2027
Issued: 03/14/2024
Real-time license verification is available at gadch.mylicense.com/verification

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Donaco Medical Supply, LLC dba HR HealthCare Patient Services

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

Physical Address: 117 Towne Lake Parkway, Suite 200

City: Woodstock State: GA Zip: 30189-5548

Mailing Address (if different from physical address): 2295 Towne Lake Parkway, Suite 116 Box 237

City: Woodstock State: GA Zip: 30189-5562

Telephone: 877-424-2562 Website: https://www.hrhealthcare.com/patientservices/

Licensing Company Email: contractscredential@hrhealthcare.com

Section 2: Personal Information

First: Colby Middle: P Last: Wiesman

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

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

Mailing Address: [redacted]

City: [redacted] State: PA Zip: [redacted]

Telephone: [redacted] Email: cwiesman@hrhealthcare.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
Nova Southeastern University			08/09 - 06/10	
Address		City	State	Zip
3300 S. University Drive		Ft. Lauderdale	FL	33328
Diploma/Degree obtained, if any				
N/A				
School Name			From - To (MM/YY – MM/YY)	
Eastern York High School			08/05 - 06/09	
Address		City	State	Zip
720 Cool Creek Road		Wrightsville	PA	17368
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/20 - Present	[redacted]	[redacted]	PA	[redacted]
10/19 - 01/20			PA	
04/13 - 10/19			PA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
HR Pharmaceuticals, Inc. DBA HR HealthCare			08/10 - Present
Business Address	**City**	**State**	**Zip**
2600 Eastern Blvd., Suite 201	York	PA	17402
Phone	**Title**		
717-252-1110	President & CEO		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Wiesman Capital			01/2017 - Present
Business Address	**City**	**State**	**Zip**
2600 Eastern Blvd., Suite 201	York	PA	17402
Phone	**Title**		
717-252-1110	Co-Owner		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Wiesman Farms			01/15 - Present
Business Address	**City**	**State**	**Zip**
2600 Eastern Blvd., Suite 201	York	PA	17402
Phone	**Title**		
717-252-1110	Co-Owner		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Wiesman Holdings			01/15 - Present
Business Address	**City**	**State**	**Zip**
2600 Eastern Blvd., Suite 201	York	PA	17402
Phone	**Title**		
717-252-1110	Co-Owner		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Wiesman Investments			01/12 - 12/21
Business Address	**City**	**State**	**Zip**
2600 Eastern Blvd., Suite 201	York	PA	17402
Phone	**Title**		
717-252-1110	Co-Owner		
Description of Duties			

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2024	Ongoing	DE	Wilmington	New Castle

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
24-1248-RGA-SRF	US District Court, District of Delaware

Reason/Charge
Patent Infringement

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Convatec, Inc. v. HR Pharmaceuticals, Inc.	Lawsuit

Name of Business/Industry/Entity
HR Pharmaceuticals, Inc.

Provide explanation below:

Convatec, Inc. alleged that HR Pharmaceuticals, Inc. infringed on certain patents acquired by Convatic with respect to a catheter design and manufacturing process. HR Pharmaceuticals, Inc. vehemently disputes the allegations made by Convatec and is vigorously defending itself in the litigation.

Original Signature (electronic, copies or stamps not accepted)

01 | 08 | 2026
Date

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

Colby Wiesman
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/08/2026
Date

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

State of Pennsylvania, ss. County of York

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

Original Signature

01/08/2026
Date

Subscribed and Sworn to before me this 8th day of January 2026.

Rochelle Lynn Adams
Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Rochelle Lynn Adams, Notary Public
York County
My commission expires June 23, 2027
Commission number 1435830
Member, Pennsylvania Association of Notaries

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Donaco Medical Supply, LLC dba HR HealthCare Patient Services

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

Physical Address: 117 Towne Lake Parkway Ste 200

City: Woodstock State: GA Zip: 30188-4831

Mailing Address (if different from physical address): 2295 Towne Lake Parkway, Suite 116 Box 237

City: Woodstock State: GA Zip: 30189-5562

Telephone: 877-424-2562 Website: https://www.hrhealthcare.com/patientservices/

Licensing Company Email: contractscredential@hrhealthcare.com

Section 2: Personal Information

First: Jon Middle: P Last: Wiesman

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

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

Mailing Address: [redacted]

City: [redacted] State: PA Zip: [redacted]

Telephone: [redacted] Email: jwiesman@hrhealthcare.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)
Adrian High School			09/75 - 05/79
Address	**City**	**State**	**Zip**
785 Riverside Ave	Adrian	MI	49221
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/21 - present	[redacted]	[redacted]	MD	[redacted]
01/90 - 06/21			PA	

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

Business Name			From - To (MM/YY – MM/YY)
HR Pharmaceuticals, Inc. DBA HR HealthCare			01/09 - 12/19
Business Address	**City**	**State**	**Zip**
2600 Eastern Blvd., Suite 201	York	PA	17402
Phone	**Title**		
717-252-1110	Founder and Owner/CEO		
Description of Duties			
Management of daily operations			

Business Name			From - To (MM/YY – MM/YY)
Wiesman Capital			01/2017 - Present
Business Address	**City**	**State**	**Zip**
2600 Eastern Blvd., Suite 201	York	PA	17402
Phone	**Title**		
717-252-1110	Co-Owner		
Description of Duties			
Management of operations			

Business Name			From - To (MM/YY – MM/YY)
Wiesman Farms			01/15 - Present
Business Address	**City**	**State**	**Zip**
2600 Eastern Blvd., Suite 201	York	PA	17402
Phone	**Title**		
717-252-1110	Co-Owner		
Description of Duties			
Management of operations			

Business Name			From - To (MM/YY – MM/YY)
Wiesman Holdings			01/15 - Present
Business Address	**City**	**State**	**Zip**
2600 Eastern Blvd., Suite 201	York	PA	17402
Phone	**Title**		
717-252-1110	Co-Owner		
Description of Duties			
Management of operations			

Business Name			From - To (MM/YY – MM/YY)
Wiesman Investments			01/12 - 12/21
Business Address	**City**	**State**	**Zip**
2600 Eastern Blvd., Suite 201	York	PA	17402
Phone	**Title**		
717-252-1110	Co-Owner		
Description of Duties			
Management of operations			

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

This is in response to Question # 4,5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2024	Ongoing	DE	Wilmington	New Castle

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
24-1248-RGA-SRF	US District Court, District of Delaware

Reason/Charge
Patent Infringement

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Convatec, Inc. v. HR Pharmaceuticals, Inc.	Lawsuit

Name of Business/Industry/Entity
HR Pharmaceuticals, Inc.

Provide explanation below:

Convatec, Inc. alleged that HR Pharmaceuticals, Inc. infringed on certain patents acquired by Convatec with respect to a catheter design and manufacturing process. HR Pharmaceuticals, Inc. vehemently disputes the allegations made by Convatec and is vigorously defending itself in the litigation.

Original Signature (electronic, copies or stamps not accepted)

1-9-2026
Date

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

Jon P. Wiesman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-9-2026

Date

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

State of Pennsylvania, ss. County of York

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

Original Signature

1-9-2026

Date

Subscribed and Sworn to before me this 9th day of January 2026.

Rochelle Lynn Adams

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Rochelle Lynn Adams, Notary Public
York County
My commission expires June 23, 2027
Commission number 1435830
Member, Pennsylvania Association of Notaries

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Donaco Medical Supply, LLC dba HR HealthCare Patient Services

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

Physical Address: 117 Towne Lake Parkway Ste 200

City: Woodstock State: GA Zip: 30188-4831

Mailing Address (if different from physical address): 2295 Towne Lake Parkway, Suite 116 Box 237

City: Woodstock State: GA Zip: 30189-5562

Telephone: 877-424-2562 Website: https://www.hrhealthcare.com/patient-services/

Licensing Company Email: contractscredential@hrhealthcare.com

Section 2: Personal Information

First: Christopher Middle: P Last: Wiesman

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

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

Mailing Address: [redacted]

City: [redacted] State: PA Zip: [redacted]

Telephone: [redacted] Email: chris.wiesman@hrhealthcare.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Nova Southeastern University		08/2010 - 05/2013	
Address	**City**	**State**	**Zip**
3301 College Ave	Davie	FL	33314
Diploma/Degree obtained, if any			
juris Doctor			

School Name		From - To (MM/YY – MM/YY)	
Northwood University		08/2005 - 05/2009	
Address	**City**	**State**	**Zip**
400 Whiting Drive	Midland	MI	48640
Diploma/Degree obtained, if any			
BBA, Marketing & Management			

School Name		From - To (MM/YY – MM/YY)	
Harrisburg Area Community College		06/2008 - 08/2008	
Address	**City**	**State**	**Zip**
1 HACC Drive	Harrisburg	PA	17110
Diploma/Degree obtained, if any			
None - Took a summer course			

School Name		From - To (MM/YY – MM/YY)	
Eastern York High School		08/2001 - 05/2005	
Address	**City**	**State**	**Zip**
720 Cool Creek Road	Wrightsville	PA	17368
Diploma/Degree obtained, if any			
High School Diploma			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2023 - Current	[redacted]	[redacted]	PA	[redacted]
10/2018 - 06/2023			PA	
05/2018 - 10/2018			PA	
04/2017 - 05/2018			TX	
04/2016 - 04/2017			TX	
01/2016 - -04/2016			TX	
01/2012 - 01/2016			FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
HR Pharmaceuticals, Inc. dba HR HealthCare			05/2018 - Current
Business Address	**City**	**State**	**Zip**
2600 Eastern Blvd. Suite 201	York	PA	17402
Phone	**Title**		
717-252-1110	Chief Commercial Officer		

Description of Duties

Lead commercial efforts (sales, marketing)

Business Name			From - To (MM/YY – MM/YY)
Quintairos, Prietro, Wood & Boyer, PA			07/2017 - 05/2018
Business Address	**City**	**State**	**Zip**
1700 Pacific Ave	Dallas	TX	75201
Phone	**Title**		
214-754-8755	Attorney		

Description of Duties

Associate attorney handling corporate defense matters in TX and NM.

Business Name			From - To (MM/YY – MM/YY)
Hawkins Parnell & Young, LLP			04/2016 - 07/2017
Business Address	**City**	**State**	**Zip**
6301 Gaston Ave, Suite 1434	Dallas	TX	75214
Phone	**Title**		
214-780-5100	Attorney		

Description of Duties

Associate attorney handling corporate defense matters

Business Name			From - To (MM/YY – MM/YY)
Zarco Einhorn Salkowski, P.A.			06/2013 - 12/2015
Business Address	**City**	**State**	**Zip**
2 Biscayne Blvd., 34th Floor	Miami	FL	33131
Phone	**Title**		
305-703-5058	Attorney		

Description of Duties

Associate attorney handling corporate, franchise, and food/beverage matters.

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2024	Ongoing	DE	Wilmington	New Castle
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
24-1248-RGA-SRF		US District Court, District of Delaware		
Reason/Charge				
Patent Infringement				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Convatec, Inc.v.HR Pharmaceuticals, Inc.			Lawsuit	
Name of Business/Industry/Entity				
HR Pharmaceuticals, Inc.				

Provide explanation below:

Convatec, Inc. alleged that HR Pharmaceuticals, Inc. infringed on certain patents acquired by Convatec with respect to a catheter design and manufacturing process. HR Pharmaceuticals, Inc. vehemently disputes the allegations made by Convatec, Inc. and is vigorously defending itself in the litigation.

Original Signature (electronic, copies or stamps not accepted)

1/8/26
Date

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

Christopher P. Wiesman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/8/26

Date

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

State of Pennsylvania, ss. County of York

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

Original Signature

1/8/26

Date

Subscribed and Sworn to before me this 8th day of January 2026.

Rochelle Lynn Adams

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Rochelle Lynn Adams, Notary Public
York County
My commission expires June 23, 2027
Commission number 1435830
Member, Pennsylvania Association of Notaries

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Donaco Medical Supply, LLC dba HR HealthCare Patient — MDEG License # (if applicable): Pending

Physical Address: 117 Towne Lake Parkway, Suite 200

City: Woodstock — State: GA — Zip: 30188-4831

Mailing Address (if different from physical address): 2295 Towne Lake Parkway, Suite 116 Box 237

City: Woodstock — State: GA — Zip: 30189-5562

Telephone: 877-424-2562 — Website: https://www.hrhealthcare.com/patientservices/

Licensing Company Email: contractscredentialing@hrhealthcare.com

Section 2: Personal Information

First: Dallas — Middle: C. — Last: Donald

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

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

Mailing Address: [redacted]

City: [redacted] — State: GA — Zip: [redacted]

Telephone: [redacted] — Email: ddonald@hrhealthcare.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Georgia State University		08/1999 - 12/2002	
Address	**City**	**State**	**Zip**
110 Courtland Street	Atlanta	GA	30303
Diploma/Degree obtained, if any			
BBA major in accounting, minor in hospitality			
School Name		**From - To (MM/YY – MM/YY)**	
Kennesaw State University		08/1998 - 05/1999	
Address	**City**	**State**	**Zip**
1000 Chastain Road	Kennesaw	GA	30144
Diploma/Degree obtained, if any			
None - transferred to Georgia State			
School Name		**From - To (MM/YY – MM/YY)**	
Lassiter High School		08/1994 - 05/1998	
Address	**City**	**State**	**Zip**
2601 Shallowford Rd	Marietta	GA	30066
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2015 - present	[redacted]	[redacted]	GA	[redacted]
05/2003 - 10/2015			GA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Donaco Medical Supply, LLC dba HR HealthCare Patient Services			12/2023 - present	
Business Address	**City**		**State**	**Zip**
2230 Towne Lake Parkway Bldg 200 Ste 100	Woodstock		GA	30189
Phone	**Title**		**Number of Employed Hours**	
404-312-8659	VP of Patient Services		3,360	

Description of Duties

In addition to managing day to day operations, performing back up to our order processing, document management, billing, contracting, credentialing.

Business Name			From - To (MM/YY – MM/YY)	
Donaco Medical Supply, LLC			05/2012 - 11/2023	
Business Address	**City**		**State**	**Zip**
2230 Towne Lake Parkway Bldg 200 Ste 100	Woodstock		GA	30189
Phone	**Title**		**Number of Employed Hours**	
404-312-8659	Owner/General Manager		24,960	

Description of Duties

Accounting, tax filing, payroll, Human Resource, and In addition to managing day to day operations, performing back up to our order processing, document management, billing, contracting, credentialing.

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

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

I, Dallas C. Donald, **certify that as the MDEG Administrator for**

Donaco Medical Supply, LLC dba HR HealthCare Patient Services,

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

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

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

Dallas C. Donald

Print Name (First, Last)

Dallas C Donald

Original Signature (electronic, copies or stamps not accepted)

1-14-26

Date

Board Use Only	Date Received:

4E

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Ivy Technology, LLC

MDEG Physical Address: 11201 Electron Drive

City: Louisville State: KY Zip: 40299

Mailing Address (if different from physical address): Same as physical address above.

City: State: Zip:

Telephone: (502) 240-1000 Website: www.ivytech.com

Email: Jeffrey.mccubbins@ivytech.com

Name of MDEG Administrator (NAC 639.694): Jeffrey W. McCubbins

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

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 6:00 AM - 7:00 PM	■ Tue: 6:00 AM - 7:00 PM	■ Wed: 6:00 AM - 7:00 PM	■ Thurs: 6:00 AM - 7:00 PM	■ Fri: 6:00 AM - 7:00 PM
☐ Sat: Closed	☐ Sun: Closed	☐ Holidays: Closed		

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

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

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

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

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Ivy Technology Holdings, LLC

Corporation/Organization Name: Ivy Technology, LLC

Mailing Address: 11201 Electron Drive

City: Louisville State: KY Zip: 40299

Telephone: (502) 240-1000 Email: Jeffrey.mccubbins@ivytech.com

Contact Person Name: Jeffrey McCubbins

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Jeffrey W. McCubbins

Print Name of Authorized Person Submitting Application

Jeffrey W. McCubbins

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

6/20/2025

Date

Board Use Only	Date Received: 7/14/25	Amount: $500-ck 2605

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 06/06/2025

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

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

PRODUCER Aon Risk Services, Inc of Florida 701 Brickell Avenue Suite 3200 Miami FL 33131 USA	**CONTACT NAME:** **PHONE (A/C. No. Ext):** (866) 283-7122 **FAX (A/C. No.):** (800) 363-0105 **E-MAIL ADDRESS:**
INSURED Ivy Technology Master Holdings LLC 11201 Electron Drive Louisville KY 40299 USA	**INSURER(S) AFFORDING COVERAGE** / **NAIC #** **INSURER A:** Endurance American Specialty Ins Co. 41718 **INSURER B:** American Casualty Co. of Reading PA 20427 **INSURER C:** The Continental Insurance Company 35289 **INSURER D:** Valley Forge Insurance CO 20508 **INSURER E:** **INSURER F:**

COVERAGES **CERTIFICATE NUMBER:** 570113091739 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			6076246573	06/03/2025	06/03/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $1,000,000 $15,000 $1,000,000 $2,000,000 $2,000,000
D	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			6076246587	06/03/2025	06/03/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$1,000,000
	UMBRELLA LIAB OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION						EACH OCCURRENCE AGGREGATE	
C B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N Y N/A If yes, describe under DESCRIPTION OF OPERATIONS below			6076246590 (AOS) 6076246606 (CA)	06/03/2025 06/03/2025	06/03/2026 06/03/2026	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	$1,000,000 $1,000,000 $1,000,000
A	Cyber Liability			PRO30008034103 Claims-Made SIR applies per policy terms & conditions	06/16/2024	06/16/2025	Limit SIR	$5,000,000 $150,000

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

Cyber Liability policy includes Tech E&O. RE: Ivy Technology AMS Global Services. Evidence of Insurance.

CERTIFICATE HOLDER

Ivy Technology Master Holdings LLC
11201 Electron Dr.
Louisville KY 40299 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Inc of Florida

Holder Identifier :

Certificate No : 570113091739

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Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "IVY TECHNOLOGY, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTEENTH DAY OF APRIL, A.D. 2025.

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

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

7108838 8300

SR# 20251540609

Authentication: 203426359

Date: 04-13-25

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

Attachment A

LLC Officer Information

Ivy Technology, LLC

Ivy Technology, LLC is wholly-owned by its parent company, Ivy Technology Holdings, LLC.

John Orleans
Senior Vice President, General Counsel

James Rodriguez
Senior Vice President

In the name and by the Authority of the

Commonwealth of Kentucky

Kentucky Board of Durable Medical Equipment Suppliers

Ivy Technology, LLC

11201 Electron Drive Louisville KY 40299

has fulfilled the provisions of the Kentucky Revised Statutes and is hereby licensed as a

Home Medical Equipment and Services Provider

and is hereby authorized to practice as a Home Medical Equipment and Services Provider within the Commonwealth of Kentucky.

Given under our hands and the Seal of the Department of Professional Licensing

/s Carolyn Basford

Chair

License Number: 300480
Issue Date: February 24, 2026
Expire Date: September 30, 2027

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Ivy Technology, LLC — MDEG License # (if applicable): Pending

Physical Address: 11201 Electron Drive

City: Louisville — State: KY — Zip: 40299

Mailing Address (if different from physical address): Same as physical address above.

City: — State: — Zip:

Telephone: (502) 240-1000 — Website: www.ivytech.com

Licensing Company Email: Jeffrey.mccubbins@ivytech.com

Section 2: Personal Information

First: Jeffrey — Middle: Wayne — Last: McCubbins

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

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

Mailing Address: 11201 Electron Drive

City: Louisville — State: KY — Zip: 40299

Telephone: [redacted] — Email: Jeffrey.mccubbins@ivytech.com

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

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

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

N/A

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

School Name		From - To (MM/YY – MM/YY)	
Indiana Weslyan University		2001 - 2002	
Address	**City**	**State**	**Zip**
4201 S. Washington Street	Marion	IN	46953
Diploma/Degree obtained, if any			
N/A - 19 hours towards BS in Business Management			
School Name		**From - To (MM/YY – MM/YY)**	
National Radio Institute		1995 - 1996	
Address	**City**	**State**	**Zip**
1401 Constitution Avenue, NW	Washington	DC	20230
Diploma/Degree obtained, if any			
Microcomputer Technology			
School Name		**From - To (MM/YY – MM/YY)**	
Doss High School		1985 - 1989	
Address	**City**	**State**	**Zip**
7601 St. Andrews Church Road	Louisville	KY	40214
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2004 - Current	[redacted]	[redacted]	KY	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Ivy Technology, LLC			12/96 - Current	
Business Address		**City**	**State**	**Zip**
11201 Electron Drive		Louisville	KY	40299
Phone	**Title**		**Number of Employed Hours**	
(502) 240-1000	Sr. Global Quality Manager		56,000+ hours	
Description of Duties				
Business Management, Operations Management, Lean Manufacturing, Engineering Management, Quality and Regulatory. FDA Correspondent. Environmental, Health, and Safety. Security. Facilities.				

N/A

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

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

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

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

Continue on next page if additional space is needed.

N/A

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

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

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

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

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

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

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

N/A

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

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

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

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

I, Jeffrey McCubbins, **certify that as the MDEG Administrator for**

Ivy Technology, LLC,

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

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

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

Jeffrey McCubbins
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/20/2025
Date

Board Use Only	Date Received: 7/14/25

COMMONWEALTH OF KENTUCKY

KENTUCKY BOARD OF PHARMACY

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

LICENSE/PERMIT: Third Party Logistics

EFFECTIVE DATE: 10/08/2020

NUMBER: TPL00353

EXPIRATION DATE: 06/30/2026

Facility Contact Person: Jeffrey McCubbins

Issued to:

Ivy Technology Llc

11201 Electron Drive
Louisville, KY 40299

License/Permit must be posted in public view.

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

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

4F

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG ■ Ownership Change* ■ Name Change* ■ Location Change*	* If making a change, provide current license number: M P01619	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Livongo Health, LLC

MDEG Physical Address: 1945 Lakeponte Drive, Suite 125

City: Lewisville State: TX Zip: 75057

Mailing Address (if different from physical address): 155 East 44th Street, Suite 1700

City: NewYork State: NY Zip: 10017

Telephone: 800-945-4355 Website: teladochealth.com

Email: complianceconcerns@teladochealth.com

Name of MDEG Administrator (NAC 639.694): Daniell Ortiz-Felix

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

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

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Michigan 1336439090
Maryland: 1623362 00

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

Name: NA _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Teladoc Health, Inc

Corporation/Organization Name: Livongo Health, LLC

Mailing Address: 155 East 44th Street, Suite 1700

City: New York State: NY Zip: 10017

Telephone: 800-945-4355 Email: complianceconcerns@teladochealth.com

Contact Person Name: Deanna McFadden

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Deanna McFadden

Print Name of Authorized Person Submitting Application

Deanna McFadden

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

12/1/2025

Date

Board Use Only	Date Received: 12/7/25	Amount: $500 ck 25679

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY): 02/11/2026

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

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

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. Chicago IL Office 200 East Randolph Chicago IL 60601 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Livongo Health, Inc. 1945 Lakepointe Drive Lewisville TX 75057-6424 USA	INSURER A: Hartford Fire Insurance Co.	19682
	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570117975346 **REVISION NUMBER:**

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

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			83UUNBR6AZJ	10/01/2025	10/01/2026	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
							MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$2,000,000
	OTHER:							
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	
	ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N/A						E.L. EACH ACCIDENT	
	(Mandatory in NH)						E.L. DISEASE-EA EMPLOYEE	
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-POLICY LIMIT	

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

Evidence of Insurance.

CERTIFICATE HOLDER

Livongo Health, Inc.
1945 Lakepointe Drive
Lewisville TX 75057-6424 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc.

Holder Identifier :

Certificate No : 570117975346

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Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "LIVONGO HEALTH, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINTH DAY OF FEBRUARY, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "LIVONGO HEALTH, LLC" WAS FORMED ON THE SIXTEENTH DAY OF OCTOBER, A.D. 2008.

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

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

4612649 8300

SR# 20260493348

Authentication: 203039344

Date: 02-09-26

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

Livongo Ownership Information - 5% or more

Name	Title	Tax ID/SSN	Business Address	Phone Number	Email Address	%	Effective Date	End/Change Date	County
Teladoc Health, Inc.	Corporate Entity	04-3705970	155 East 44th Street, Suite 1700 New York, New York 10017	(203) 635-2002		100% (Direct)	10/30/2020		New York

Officers	Title	SSN	Home Address	Phone	Date of Birth	Appointment Date	County	Driver's License	End Date
Jonathan Dorfman	President	[redacted]	[redacted]	[redacted]	[redacted]	1/20/2022	[redacted]	[redacted]	N/A

TEXAS Health and Human Services | Texas Department of State Health Services

License Details

"License" means a license, certificate, registration, permit, or other form of authorization, including a renewal of the authorization, that: a person must obtain to practice or engage in a particular business, occupation, or profession; or a facility must obtain before a particular business, occupation, or profession is practiced or engaged in within the facility. A "License Rank" is the level of license; a "License Modifier" provides additional information on the scope of the license.

A license may have one or two statuses. The first status is normally "Current" which means the license is in good standing. If the first status is "Expired" or "Null and Void", or if either status shows "Inactive", the licensee may not practice in the profession and/or operate as a licensed business.

For more information regarding this license, including any disciplinary information displayed below, please contact the appropriate board or program office. A list of DSHS licensing board and programs may be found at: http://www.dshs.state.tx.us/Licensee-Registrant-Permittee.aspx or click the link at the bottom of this page.

Press "Previous Record" to display the previous license.

Press "Next Record" to display the next license.

Press "Search Results" to return to the Search Results list.

Press "New Search Criteria" to do another search of this type.

Press "New Search" to start a new search.

License Number: 1003518 *Current Date: 10/28/2025 10:52 AM*

Name:	TELADOC HEALTH INC
License Type:	Dev Manufacturer
License Status:	Current
Expiry Date:	09/18/2026
Effective Rank Date:	09/27/2024
Modifier(s):	Class 2 In-Vitro Diagnostic Over-the-Counter Sterile-Packaged Re-Packager / Re-Labeler

Addresses

Physical Loc	Address	TELADOC HEALTH INC 1945 LAKEPOINTE DR LEWISVILLE , TX DENTON 75057 US
Mailing Address	Address	TELADOC HEALTH INC LEWISVILLE , TX DENTON 75057 US

Food & Drug Owner

Licensee's Role:	Food & Drug License	
Related Party Role:	Food & Drug Owner	
Related Party Name	**License**	**Address**
TELADOC HEALTH INC	Owner # Status: Current Expiration Date:	LEWISVILLE , TX DENTON 75057 US

Previous Record Next Record Search Results New Search Criteria New Search Print

DSHS Certifications, Licenses and Permits | Disclaimer

Last Updated Mar 27, 2013

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Livongo Health, LLC. MDEG License # (if applicable): MP01619

Physical Address: 1945 Lakepointe Drive, Suite 125

City: Lewisville State: TX Zip: 75057

Mailing Address (if different from physical address): 155 East 44th Street, Suite 1700

City: New York State: NY Zip: 10017

Telephone: 800-945-4355 Website: www.teladochealth.com

Licensing Company Email: complianceconcerns@teladochealth.com

Section 2: Personal Information

First: Daniell Middle: Merlos Last: Ortiz-Felix

Alias(es, nicknames, name changes, etc.): Daniell M. Ortiz, Daniell M. Metzker

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

Mailing Address: [redacted]

City: [redacted] State: TX Zip: [redacted]

Telephone: [redacted] Email: [redacted]

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Foothill COllege		08/1994 - 06/1997	
Address	City	State	Zip
12345 El Monte Rd	Los Altos Hills	CA	94022
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Mountain View High School		08/1990 - 06/1994	
Address	City	State	Zip
3535 Truman Ave	Mountain View	CA	94040
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/25 - Present	[redacted]	[redacted]	TX	[redacted]
From - To (MM/YY – MM/YY)			State	
06/10-09/25			CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
Teladoc Health, Inc			10/20 - Present
Business Address	**City**	**State**	**Zip**
1945 Lakepointe Dr	Lewisville	TX	75057
Phone	**Title**	**Number of Employed Hours**	
	Director, Regulatory Compliance	40/wk	
Description of Duties			
Ensure medical device and QMS compliance to FDA, ISO 13485:2016, MDSAP and other regulations/requirements.			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/25/25
Date

I, Daniell Ortiz-Felix **, certify that as the MDEG Administrator for**

Livongo Health, LLC ,

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

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

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

Daniell Ortiz-Felix
Print Name (First, Last)

Dane Felix
Original Signature (electronic, copies or stamps not accepted)

11/25/2025
Date

Board Use Only	Date Received: 12/17/25

4G

4

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located? ☐ Nevada ☒ Out-of-State

***Is the business also a wholesaler? (NRS 639.016)** ☒ Yes ☐ No

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

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

Section 1: General Information

Facility Name: Orthofix US LLC

MDEG Physical Address: 3451 Plano Parkway

City: Lewisville State: TX Zip: 75056-9453

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (214) 937-2000 Website: www.orthofix.com

Email: BGTPayerDevelopment@Orthofix.com

Name of MDEG Administrator (NAC 639.694): Steve Teeney

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

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8am - 5pm	■ Tue: 8am - 5pm	■ Wed: 8am - 5pm	■ Thurs: 8am - 5pm	■ Fri: 8am - 5pm
■ Sat: By Appt.	■ Sun: By Appt.	■ Holidays: By Appt.		

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare # 1057810001
Medicaid #'s - See attached Listing

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

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

   a) A practicing health professional; or

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

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

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): Orthofix Medical Inc.

Corporation Name: Orthofix US LLC

Mailing Address: 3451 Plano Parkway

City: Lewisville State: TX Zip: 7055-9453

Telephone: (214) 937-2000 Email: BGTPayerDevelopment@Orthofix.com

Contact Person Name: Jenn Chow (JennChow@Orthofix.com)

Date of SEC Registration: May 1992	SEC Registration Number: 0000884624	Stock Exchange Symbol: OFIX

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Anne Smith

Print Name of Authorized Person Submitting Application

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

1/31/2026

Date

Board Use Only	Date Received: 2/12/26	Amount: $300.00

ORTHOFIX®
Spine | Orthopedics | Sports Medicine

STATE	MEDICAID #	ENROLLMENT DATE
ALABAMA	150682	7/1/2013
ALASKA	1653791	3/27/2024
ARIZONA	335522-1	3/6/1996
ARKANSAS	129026716	3/1/1996
CALIFORNIA	1235136060	12/11/2017
COLORADO	51659000	1/12/2009
CONNECTICUT	008036531	11/11/2011
DELAWARE	698316	8/21/1995
HAWAII	008255	3/21/2024
GEORGIA	003109435A	5/01/2011
IDAHO	1235136060	3/12/2010
ILLINOIS	752608036001	8/21/1995
INDIANA	100022690A	6/05/1990
IOWA	0907857	9/01/1986
KANSAS	30003957830002	6/02/2015
KENTUCKY	90263088	10/17/1995
LOUISIANA	1925985	1/01/1992
MAINE	1235136060	2/01/2013
MARYLAND	419480200	1/25/2010
MASSACHUSETTS	110131402A	3/01/2018
MICHIGAN	3312173	10/20/2014
MINNESOTA	363226100	3/17/1996
MISSISSIPPI	000440446	3/19/1997
MISSOURI	1235136060	1/28/2016
MONTANA	560560	6/01/1997
NEBRASKA	100262549-00	10/17/2012
NEVADA	1235136060	12/24/2012
NEW HAMPSHIRE	3096972	5/01/1996
NEW JERSEY	7100604	8/21/1996
NEW MEXICO	000J5256	1/01/1996
NEW YORK	01669745	9/29/1996
NORTH CAROLINA	1235136060	7/11/2024
NORTH DAKOTA	58185	10/01/2013
OHIO	0693914	4/28/1987
OKLAHOMA	100814970C	8/01/2005
OREGON	500687335	6/12/2015
PENNSYLVANIA	001639432	1/18/2016
RHODE ISLAND	7810001	9/17/2014
SOUTH CAROLINA	DE1114	10/01/2011
SOUTH DAKOTA	9162560	8/08/2017
TENNESSEE	4581838	5/01/1995
TEXAS	0103533-01	10/23/2008
UTAH	1235136060	10/15/2012
VERMONT	1009681	4/23/2014
VIRGINIA	1235136060	8/01/2014
WASHINGTON	9043993	4/28/1995
WASHINGTON DC	066807500	11/23/2016
WEST VIRGINIA	0147662000	1/01/1999
WISCONSIN	81542900	10/20/1995
WYOMING	128225500	4/28/2007

February 3, 2026

Nevada State Board of Pharmacy

Re: **MDEG Application**

Please accept this letter as a written explanation of historical adverse actions involving Orthofix US LLC ("Orthofix") and an overview of its Compliance program and on-going commitment to fostering a culture of ethical behavior.

Historical Events

In December 2012, Orthofix pled guilty in a Massachusetts federal district court to obstructing a federal audit. As a result, Orthofix entered into a settlement agreement with the Department of Justice ("the DOJ Settlement").

The DOJ Settlement and plea arose out of a 2009 industry-wide investigation led by the U.S. Attorney's Office for the District of Massachusetts ("USAO") into the marketing and sale of bone growth stimulators. Orthofix fully cooperated with the investigation and, in 2012, Orthofix and the USAO reached a joint resolution. Orthofix admitted that during a June 2008 Medicare audit, it failed to disclose that some sales representatives in its Spinal Regeneration business unit improperly completed Medicare forms (i.e., in most instances the sales representatives were completing portions of the form that are required to be completed by a physician or a member of the physician's staff). As part of the resolution, Orthofix pled guilty to one felony count of obstruction of a federal audit. Orthofix was fined, received a five-year probation, entered into a civil settlement with the USAO and entered into a 5-year corporate integrity agreement ("CIA") with the HHS Office of Inspector General ("HHS-OIG"). The CIA imposed certain reporting and compliance obligations on Orthofix, its directors, officers and employees through June 2017. Orthofix completed its probationary period without incident and satisfied all obligations under its CIA, allowing it to timely expire in accordance with its terms in 2017. At all times, Orthofix was permitted to continue its participation in all federal and state health care programs.

Commitment to Compliance

As with many hospitals, pharmaceutical makers and medical device manufacturers, the last several years have proved to be a transformative time for Orthofix. Orthofix has adopted and implemented many controls and practices that have become standard in the healthcare industry to detect and prevent fraud and abuse. Additionally, Orthofix specifically adopted measures to address the conduct that led to the DOJ Settlement. Among other things, Orthofix focused on hiring individuals at all levels of its business, including senior leadership, who embrace a culture of ethical behavior and conduct that complies with applicable healthcare laws. Individuals who did not exemplify these values were exited from the company, including several mid and senior level employees. Orthofix implemented a system of claims audits and monitoring aimed at identifying errors, analyzing root causes, and strengthening controls. Orthofix trains its employees and distributors on health care compliance and the principles outlined in the AdvaMed Code (an industry code of conduct written, adopted and implemented by a society of medical device manufacturers). Orthofix has implemented

and maintained a compliance program that aligns with traditional guidance issued by the Department of Justice and HHS-OIG, which includes policies and procedures on appropriate interactions with healthcare professionals, a dedicated helpline to receive concerns and questions from employees and patients, and routine testing and monitoring of activities involving health care professionals and claims submissions. Orthofix created a stand-alone Compliance Department, led by a Chief Ethics and Compliance Officer who reports directly to the Chief Executive Officer as well as the Compliance Committee of the Board of Directors. Today, the role of Compliance is deeply embedded at all levels of the company.

Conclusion

In recognition of Orthofix's commitment to corporate responsibility and its extensive corrective measures before and after the DOJ Settlement, HHS-OIG, which oversees the Medicare and Medicaid programs – continues to permit Orthofix to participate in Medicare and other federal and state health care programs. Countless private insurers likewise continue to include Orthofix as a participating provider given Orthofix's stringent compliance controls and the benefit its products provide to their patients. Orthofix also maintains active Board of Pharmacy or equivalent licenses in every state in which licenses are required – including several that have examined the DOJ Settlement in detail and specifically determined that continued licensure is appropriate. Likewise, Orthofix has active state permits in every state where such permits are required. Finally, it has a long-standing history of being an accredited provider of durable medical equipment ("DME") by the Accreditation Commission for Health Care.

I provide this overview of Orthofix's 2012 conviction and resulting CIA to help you understand the factual context of these historical events. I share how the company implemented safeguards to mitigate past mistakes and prevent and detect wrongdoing in the future to illustrate that Orthofix continues to do its part to promote a culture of integrity and compliance - not just to instill confidence in Orthofix and its products, but to ensure physicians, patients and their loved ones can place their trust in the medical device industry as a whole. I respectfully ask that Orthofix be permitted to participate and provide covered services to your members. Should it be helpful to provide additional explanation, I would be glad to do so.

Respectfully submitted,

Jill Mason
Vice President, Legal – Bone Growth Therapies

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

CHRISTINA K. MCGARVEY, SENIOR COUNSEL
ADMINISTRATIVE & CIVIL REMEDIES BRANCH
OFFICE OF COUNSEL TO THE INSPECTOR GENERAL
330 INDEPENDENCE AVENUE, SW
COHEN BUILDING - ROOM 5527
WASHINGTON, DC 20201
TELEPHONE: (202) 205-3139
FACSIMILE: (202) 205-0604
EMAIL: CHRISTINA.MCGARVEY@OIG.HHS.GOV

October 17, 2017

Ms. Jill Mason
Chief Ethics and Compliance Officer
Orthofix
3451 Plano Parkway
Lewisville, TX 75056

Re: Completion of Corporate Integrity Agreement Requirements

Dear Ms. Mason:

Based on our review of the information provided in Orthofix's fifth Annual Report, it appears that Orthofix was in compliance with the terms of the Corporate Integrity Agreement (CIA) between the Office of Inspector General (OIG) of the Department of Health and Human Services and Orthofix during the fifth annual reporting period.

The five-year term of Orthofix's CIA has now concluded. During the term of the CIA, Orthofix submitted reports on the status of its compliance activities for each of the five reporting periods.

This acknowledgement that Orthofix has satisfied its CIA requirements is not a determination by the OIG that Orthofix has implemented an effective compliance program. It is Orthofix's responsibility to develop and implement a compliance program that is effective for ensuring compliance with all applicable Federal health care program requirements. The OIG makes no representations in this letter as to Orthofix's practices or conduct that may be the subject of ongoing investigations, if any. Also, our comments do not reflect our assessment of any legal claims that may be made against Orthofix in connection with any ongoing or future investigation.

We recommend that Orthofix continue to incorporate into its operations the compliance program elements that were implemented by Orthofix during the term of its CIA. We also suggest that Orthofix regularly consult the OIG's website in the future for information regarding the OIG's compliance guidance for device manufacturers.

At the next update, Orthofix will be removed from the current listing of Corporate Integrity Agreements posted on the OIG's website.

If you have any questions regarding this letter, please contact me at [redacted]

Sincerely,

Christina K. McGarvey
Senior Counsel

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

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Application For Certificate Of Authority for Orthofix US LLC (file number 10676006), a DELAWARE, USA, Foreign Limited Liability Company (LLC), was filed in this office on October 09, 1995.

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

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on January 22, 2026.

Jane Nelson
Secretary of State

ORTHMED-01 HPOOJARY

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 9/25/2025

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

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

PRODUCER	CONTACT NAME: Brenda Page	
Alliant Insurance Services, Inc. 701 B St 6th Fl San Diego, CA 92101	PHONE (A/C, No, Ext): (910) 530-0040	FAX (A/C, No):
	E-MAIL ADDRESS: brenda.page@alliant.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Federal Insurance Company	20281
INSURED	INSURER B : Great Northern Insurance Company	20303
Orthofix Medical, Inc 3451 Plano Parkway Lewisville, TX 75056	INSURER C : Beazley Excess and Surplus Insurance Inc (BESI)	17520
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$	1,000,000
	CLAIMS-MADE X OCCUR			36061594	9/30/2025	9/30/2026	DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	Excluded
	OTHER:						EBL AGGREGATE	$	1,000,000
B	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$	1,000,000
	X ANY AUTO			73617485	9/30/2025	9/30/2026	BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
A	X UMBRELLA LIAB X OCCUR						EACH OCCURRENCE	$	20,000,000
	EXCESS LIAB CLAIMS-MADE			78193311	9/30/2025	9/30/2026	AGGREGATE	$	
	DED RETENTION $						UMB Aggregate	$	20,000,000
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						X PER STATUTE OTH-ER		
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N / A			71832773	9/30/2025	9/30/2026	E.L. EACH ACCIDENT	$	1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
C	Products Liability			D35C67250301	9/30/2025	9/30/2026	Ea. Occ/Aggregate		10,000,000

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

*INSURED: Orthofix US LLC; Spinal Kinetics LLC. Orthofix Medical Inc.

Beazley Excess and Surplus Insurance, Inc. Policy #D35C67250301 is endorsed to include Healthcare Professional Services which only applies to the operations of the Medical Sales Representatives. Medical Sales Representatives are included as Additional Insureds as respects Products Liability as required by written/executed contract and as permitted by law, subject to the policy provisions.

Beazley Excess and Surplus Insurance, Inc. Policy #D35C67250301 (Products Liability):
SEE ATTACHED ACORD 101

CERTIFICATE HOLDER

Orthofix Medical, Inc.
3451 Plano Parkway
Lewisville, TX 75056

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

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AGENCY CUSTOMER ID: ORTHMED-01 HPOOJARY

LOC #: 1

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
Alliant Insurance Services, Inc.		Orthofix Medical, Inc 3451 Plano Parkway Lewisville, TX 75056
POLICY NUMBER		
SEE PAGE 1		
CARRIER	NAIC CODE	EFFECTIVE DATE: SEE PAGE 1
SEE PAGE 1	SEE P 1	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

Description of Operations/Locations/Vehicles:
$500,000 Deductible Each Claim/Occurrence without aggregate
$2,000,000 Deductible - Term Aggregate
Claims Made Coverage
Retro Date: 3/11/86
Provides Difference in Conditions (DIC) and Difference in Limits/Excess (DIL) over UK Foreign Master Products Liability Policy No. 2503749. UK Foreign Master Products Liability Policy No. 2503749 provides Difference in Conditions (DIC) and Difference in Limits (DIL) over foreign local admitted products liability policies in the Newline products liability OUS program.

POLICY ENDORSEMENT FORMS
Primary Products:
*EOM021 022024 ed. Amend Healthcare Professional Services Coverage - Medical Sales Reps Only
*EOM022 022024 ed. Amend Errors And Omissions Liability - Scheduled Products Only
General Liability:
*80-02-2056 Extended General Liability (Including Human Clinical Trials) For Life Sciences
-pages 8 to 15 Additional Insured provisions including where required by contract under "Who Is an Insured"
-pages 35 to 37 Primary Non-Contributory coverage provision where required by contract
-page 37 Waiver of Subrogation provision where required by contract

The Umbrella Policy is excess over the General Liability, Auto Liability & Worker's Compensation Policies.

Workers Compensation Policy (SEASPINE)
Policy Period: October 1, 2024 to October 1, 2025
Federal Insurance Company
Policy Number 71746981
Limits: $1,000,000 Ea. Accident/$1,000,000 Disease Policy Limit/$1,000,000 Disease Each Employee

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ORTHOFIX
Spine | Orthopedics | Sports Medicine

Orthofix US LLC Owner and Managing Employees

Name & Title	% of Ownership	DOB	SSN/TIN	Address
Massimo Calafiore, CEO	0%	[redacted]		
Jason Richard Shallenberger, President	0%	[redacted]		
Julie Beth Andrews, CFO	0%	[redacted]		
Anne Martha Smith, Payer Contracting Dir.	0%	[redacted]		
Steven Mitchell Teeney, VP, Sales Admin.	0%	[redacted]		
Orthofix Medical Inc., Owner	**100%**	**N/A**	**98-1340767**	**3451 Plano Parkway, Lewisville, TX 75056-9453**

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

ORTHOFIX US LLC
3451 PLANO PKWY
LEWISVILLE TX 75056

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

ORTHOFIX US LLC
3451 PLANO PKWY
LEWISVILLE, TX 75056

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

DEVICE MANUFACTURER

License # 1000373
Expires: March 28, 2026

NON-TRANSFERABLE

Commissioner

513944

TEXAS Health and Human Services | Texas Department of State Health Services

License Details

"License" means a license, certificate, registration, permit, or other form of authorization, including a renewal of the authorization, that: a person must obtain to practice or engage in a particular business, occupation, or profession; or a facility must obtain before a particular business, occupation, or profession is practiced or engaged in within the facility. A "License Rank" is the level of license; a "License Modifier" provides additional information on the scope of the license.

A license may have one or two statuses. The first status is normally "Current" which means the license is in good standing. If the first status is "Expired" or "Null and Void", or if either status shows "Inactive", the licensee may not practice in the profession and/or operate as a licensed business.

For more information regarding this license, including any disciplinary information displayed below, please contact the appropriate board or program office. A list of DSHS licensing board and programs may be found at: http://www.dshs.state.tx.us/Licensee-Registrant-Permittee.aspx or click the link at the bottom of this page.

Press "Previous Record" to display the previous license.

Press "Next Record" to display the next license.

Press "Search Results" to return to the Search Results list.

Press "New Search Criteria" to do another search of this type.

Press "New Search" to start a new search.

License Number: 1000373 ***Current Date: 03/25/2026 01:56 PM***

Name:	ORTHOFIX US LLC
License Type:	Dev Manufacturer
License Status:	Current
Expiry Date:	03/28/2028
Effective Rank Date:	05/03/2010
Modifier(s):	Manufacturer Class 1 Class 2 Class 3 Prescription Sterile-Packaged Implantable Software Driven

Addresses

Physical Loc	Address	**ORTHOFIX US LLC** **3451 PLANO PKWY** **LEWISVILLE , TX** **DENTON** **75056** **US**
Mailing Address	Address	**ORTHOFIX US LLC** **LEWISVILLE , TX** **DENTON** **75056** **US**

Food & Drug Owner

Licensee's Role:	Food & Drug License
Related Party Role:	Food & Drug Owner

Related Party Name	License	Address
ORTHOFIX US LLC	**Owner #A031913** Status: Current Expiration Date:	**LEWISVILLE , TX** **DENTON** **75056** **US**

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Orthofix US LLC MDEG License # (if applicable): _____

Physical Address: 3451 Plano Parkway

City: Lewisville State: TX Zip: 75056-9453

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: www.orthofix.com

Licensing Company Email: BGTPayerDevelopment@Orthofix.com

Section 2: Personal Information

First: STEVEN Middle: _____ Last: TEENEY

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

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

Mailing Address: [redacted]

City: [redacted] State: TX Zip: [redacted]

Telephone: [redacted] Email: STEVETEENEY@ORTHOFIX.COM

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
BROOKFIELD EAST HIGH SCHOOL		09/76 - 05/78	
Address	**City**	**State**	**Zip**
3305 N. LILLY ROAD	BROOKFIELD	WI	53005
Diploma/Degree obtained, if any			
H.S. DIPLOMA			

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

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/13 - 02/26	[redacted]	[redacted]	TX	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
ORTHOFIX			04/01 – 01/26	
Business Address	**City**		**State**	**Zip**
3451 PLANO PKWY.	LEWISVILLE		TX	75056
Phone	**Title**		**Number of Employed Hours**	
214-937-2284	VP, OPERATIONS		31,000	
Description of Duties				
MANAGE 150 EMPLOYEES OVERSEEING REVENUE CYCLE FOR BONE GROWTH THERAPIES				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

1-28-2026
Date

I, STEVEN TEGNEY, **certify that as the MDEG Administrator for**

ORTHOFIX US LLC,

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

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

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

STEVEN TEGNEY

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-28-2026

Date

Board Use Only	Date Received: 2/12/2026

4H

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Pediatric Orthotic & Prosthetic Services - West, LLC

MDEG Physical Address: 2425 Stockton Blvd

City: Sacramento State: CA Zip: 95817-2215

Mailing Address (if different from physical address): PO Box 947109

City: Atlanta State: GA Zip: 30394-7109

Telephone: 813-518-7832 Website: www.shrinerschildrens.org

Email: sroyster@shrinenet.org

Name of MDEG Administrator (NAC 639.694): Michael Wadekamper

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

Check the Days the Business will be Opened and provide the Hours of Operation				
☒ Mon: 8:00am - 5:00pm	☒ Tue: 8:00am-5:00pm	☒ Wed: 8:00am-5:00pm	☒ Thurs: 8:00am to 5:00pm	☒ Fri: 8:00am to 5:00pm
☐ Sat: Closed	☐ Sun: Closed	☐ Holidays: Closed		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Medicare: 7364250003

Medicaid: 1811213549

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.012S, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693!6933)

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

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

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): N/A

Corporation Name: N/A

Mailing Address: N/A

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

Telephone: N/A Email: N/A

Contact Person Name: N/A

Date of SEC Registration: N/A	SEC Registration Number: N/A	Stock Exchange Symbol: N/A

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any): N/A

Corporation/Organization Name: N/A

Mailing Address: N/A

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

Telephone: N/A Email: N/A

Contact Person Name: N/A

Section 7: Partnership

Partnership Name: N/A

Mailing Address: N/A

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

Telephone: N/A Email: N/A

Contact Person Name: N/A

Section 8: Sole Owner

Owner's Name: Shriners Chidlren's

Business Name: Shriners Children's

Business Address: 2900 N Rocky Point Dr

City: Tampa State: FL Zip: 33607-1460

Telephone: 813-281-0300 Email: sroyster@shrinenet.org

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

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

Shirley Royster

Print Name of Authorized Person Submitting Application

Shirley Royster

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

2/5/26

Date

Board Use Only	Date Received: 2/12/26	Amount: $500.00

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 12/08/2025

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

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

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. Chicago IL Office 200 East Randolph Chicago IL 60601 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	American Zurich Ins Co	40142
INSURER B:	Zurich American Ins Co	16535
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Shriners Hospitals for Children
2900 Rocky Point Drive
Tampa FL 33607-1460 USA

COVERAGES **CERTIFICATE NUMBER:** 570116992067 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY			GL0649520717	12/01/2025	12/01/2026	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$250,000
							MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$3,000,000
	X POLICY [ ] PRO-JECT [ ] LOC						PRODUCTS - COMP/OP AGG	$1,000,000
	OTHER:							
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	
	ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB [ ] OCCUR						EACH OCCURRENCE	
	EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	
	DED [ ] RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			WC667208132	12/01/2025	12/01/2026	X PER STATUTE [ ] OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y	N/A					E.L. EACH ACCIDENT	$1,000,000
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
RE: Pediatric Orthotic and Prosthetic Services - West, LLC: 2425 Stockton Blvd., Sacramento, CA 95817.

CERTIFICATE HOLDER

NP WEST
PO Box 100142
Columbia, SC 29202

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc.

Holder Identifier : West LLC

Certificate No : 570116992067

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Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	PEDIATRIC ORTHOTIC AND PROSTHETIC SERVICES - WEST, LLC
Entity No.:	201008510402
Registration Date:	03/25/2010
Entity Type:	Limited Liability Company - CA
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of February 02, 2026.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 417066022

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

Shriners Children's
Pediatric Orthotic & Prosthetic Services

February 24, 2026

Shriners Hospitals for Children (Shriners Children's) is 100% owned and operated by Shriners International. There are no individuals with ownership of the company.

Pediatric Orthotic & Prosthetic Services is an LLC under Shriners Children's.

Shirley Royster

Shirley Royster
Corporate Billing and Contracting Manager
Pediatric Orthotic & Prosthetic Services
813-367-2876
sroyster@shrinenet.org

Parker, Michele

To: klangston@pharmacy.nv.gov
Subject: Shriners Children's: List of all Officers and Directors

Board of Directors

- **Chairman:** Brad T. Koehn
- **President:** Leslie D. Stewart, M.D.
- **1st Vice President:** Lawrence J. "Larry" Leib
- **2nd Vice President:** Mark Hartz
- **Treasurer:** Scott Schuster
- **Secretary:** Matthew Sturlaugson
- **Assistant Secretary:** Martin L. "Marty" Bartlett
- **Members:** Jim Cain, Timothy D. "Tim" Forbis, Ron DeVoll, Davi Vrsalovich, Rick Holloway, and Richard G. Burke

Executive Leadership Team

- **Chief Medical Officer:** Frances A. Farley, M.D.
- **Executive Vice President, Chief Operating Officer:** John McCat
- **Chief Information Officer:** John McFarland
- **Vice President, Human Resources:** Kathy A. Dean
- **Chief Marketing and Communications Officer:** Mel Bower
- **Vice President, Hospital Operations:** Phillip Grady, DHA, FACH
- **Chief Quality Officer, Shriners Children's Medical Group:** Henry
- **Chief Medical Informatics Officer:** Richard Paula, M.D.
- **Chief Compliance Officer:** Nathan Stephens, J.D.
- **Vice President, Legal:** Laurie A. Spieler, J.D.

Michele Parker
Provider Enrollment Specialist
Pediatric Orthotic and Prosthetic Services
813-697-1176

Shriners Children's

City of SACRAMENTO
Finance Department

BUSINESS OPERATIONS TAX CERTIFICATE

Business Name	**PEDIATRIC ORTHOTIC AND PROSTHETIC SERVICES LLC**
Business Address	**2425 STOCKTON BLVD 236**
Owner	**SHRINERS HOSPITALS FOR CHILDREN**
Type of Business	**Medical Supplies**
Tax Classification	**Gross Receipts**
Expires	**03/31/2026**
Mailing Address	**JOANNE KANAS, POPS DIRECTOR** **PEDIATRIC ORTHOTIC AND PROSTHETIC SERVIC** **2900 N ROCKY POINT DR** **TAMPA, FL 33607-1460**

1004003

CITY OF SACRAMENTO
DEPARTMENT OF FINANCE
MARK OF AUTHENTICATION

1004003

TOTAL PAID:
$1,599.02

THIS STUB MAY BE FOLDED/DETACHED BEFORE POSTING

MUST BE POSTED IN CONSPICUOUS PLACE

This certificate is not to be construed as a business license or imply that the City of Sacramento has investigated, or approves or recommends, the holder of this certificate. Any representation to the contrary is fraudulent. This certificate must be renewed within 30 days of expiration.
Starting January 1, 2021, Assembly Bill 1607 requires the prevention of gender-based discrimination of business establishments. A full notice is available in English or other languages by going to: https://www.dca.ca.gov/publications/

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Pediatric Orthotic & Prosthetic Services - West, LLC MDEG License # (if applicable) _____

Physical Address 2425 Stockton Blvd

City Sacramento State CA Zip 95817

Mailing Address (if different from physical address) PO Box 947109

City Atlanta State GA Zip 30394-7109

Telephone 813-367-2876 Website www.shrinerschildrens.org

Licensing Company Email _____

Section 2: Personal Information

First Michael Middle John Last Wadekamper

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

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

Mailing Address [redacted]

City Sacramento State CA Zip [redacted]

Telephone [redacted] Email mwadekamper@shrinenet.org

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of Connecticut / Newington Certificate program (now at the University of Hartford)		2010-2011	
Address	**City**	**State**	**Zip**
181 East Cedar Street	Newington	CT	06111
Diploma/Degree obtained, if any			
Post Graduate Certificate in Prosthetics			

School Name		From - To (MM/YY – MM/YY)	
University Of Connecticut/ Newington Certificate program(now at the University of Hartford)		2003-2004	
Address	**City**	**State**	**Zip**
181 East Cedar Street	Newington	CT	06111
Diploma/Degree obtained, if any			
Post Graduate Certificate in Orthotics			

School Name		From - To (MM/YY – MM/YY)	
University of California, Davis		1997-2002	
Address	**City**	**State**	**Zip**
1 Shields Ave	Davis	CA	95616
Diploma/Degree obtained, if any			
B.S., Managerial Economics			

School Name		From - To (MM/YY – MM/YY)	
Amador High		1993-1997	
Address	**City**	**State**	**Zip**
1155 Santa Rita Road	Pleasanton	CA	94566
Diploma/Degree obtained, if any			
High School diploma			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
7/2014-Present	[redacted]	Sacramento	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,S00 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Pediatric Orthotic & Prosthetic Services			10/2018-Present
Business Address	**City**	**State**	**Zip**
2425 Stockton Blvd	Sacramento	CA	95817
Phone	**Title**	**Number of Employed Hours**	
916-453-2170	Clinic Manager	over 1500	

Description of Duties

Manages the clinic which provides custom-designed orthotic and prosthetic devices to children.

Business Name			From - To (MM/YY – MM/YY)
Pediatric Orthotic & Prosthetic Services			1/2016-10/2018
Business Address	**City**	**State**	**Zip**
2425 Stockton Blvd	Sacramento	CA	95817
Phone	**Title**	**Number of Employed Hours**	
916-453-2170	Certified Prosthetist and Orthotist		

Description of Duties

Treated patients for custom designed prosthetics and orthotics.

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/3/26
Date

I, Michael Wadekamper, **certify that as the MDEG Administrator for**

Pediatric Orthotics & Prosthetic Services - West, LLC,

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

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

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

Michael Wadekamper

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/3/26

Date

Board Use Only	Date Received: 2/12/26

41

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Reliable Respiratory Inc

MDEG Physical Address: 1502 Boston Providence TRKE, Suite 12

City: Norwood State: MA Zip: 02062-4643

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 781-551-3335 Website: https://reliablerespiratory.com/

Email: Contracting@reliablerespiratory.com

Name of MDEG Administrator (NAC 639.694): Michael Falkson

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

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

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare: 4106400001, Medicaid: 110031830B

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

Name: none Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: MA

Parent Company (if any): _____

Corporation/Organization Name: Reliable Respiratory Inc

Mailing Address: 1502 Boston Providence TRKE, Suite 12

City: Norwood State: MA Zip: 02062-4643

Telephone: 781-551-3335 Email: Contracting@reliablerespiratory.com

Contact Person Name: Yuliya Stoycheva

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Yuliya Stoycheva

Print Name of Authorized Person Submitting Application

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

01/07/2026

Date

Board Use Only	Date Received: 1/23/26	Amount: Check # 1649

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 06/26/2025

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

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

PRODUCER	CONTACT NAME: Colin Quirk	
Brown & Brown Insurance Services, Inc. 980 Washington Street Suite 325 Dedham MA 02026	PHONE (A/C, No, Ext): (617) 778-5000	FAX (A/C, No):
	E-MAIL ADDRESS: Colin.Quirk@bbrown.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A: Benchmark Insurance Company	
	INSURER B: United States Fire Insurance Company	21113
	INSURER C: Crum & Forster Indemnity Company	31348
	INSURER D: The North River Insurance Company	
	INSURER E:	
	INSURER F:	

INSURED	
Reliable Respiratory, Inc. 1502 Providence Highway Suite 10 & 12 Norwood MA 02062-4643	

COVERAGES **CERTIFICATE NUMBER:** 25-26 Norwood Suite 12 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			D1024 G6913-3	07/01/2025	07/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 1,000,000 $ 20,000 $ 1,000,000 $ 3,000,000 $ 3,000,000
B	AUTOMOBILE LIABILITY [X] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY			133-764732-9	07/01/2025	07/01/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
A	[X] UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $			UM1024 6914-3	07/01/2025	07/01/2026	EACH OCCURRENCE AGGREGATE	$ 5,000,000 $ 5,000,000
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [ ] (Mandatory In NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		408-750228-9	07/01/2025	07/01/2026	[X] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ 1,000,000 $ 1,000,000 $ 1,000,000

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

CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

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The Commonwealth of Massachusetts

Secretary of the Commonwealth

State House, Boston, Massachusetts 02133

William Francis Galvin
Secretary of the
Commonwealth

Date: July 25, 2025

To Whom It May Concern :

I hereby certify that according to the records of this office,

RELIABLE RESPIRATORY, INC.

is a domestic corporation organized on **June 01, 2007** , under the General Laws of the Commonwealth of Massachusetts. I further certify that there are no proceedings presently pending under the Massachusetts General Laws Chapter 156D section 14.21 for said corporation's dissolution; that articles of dissolution have not been filed by said corporation; that, said corporation has filed all annual reports, and paid all fees with respect to such reports, and so far as appears of record said corporation has legal existence and is in good standing with this office.

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

William Francis Galvin

Secretary of the Commonwealth

Certificate Number: 25070478850

Verify this Certificate at: http://corp.sec.state.ma.us/CorpWeb/Certificates/Verify.aspx

Processed by: bod

Reliable Respiratory, Inc.
Officer Info

Name	Title
Michael Falkson	President
Michael Falkson	Treasurer
Michael Falkson	Secretary
Michael Falkson	Director

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Drug Manufacturer or Drug Distributor Controlled Substance Registration to:

RELIABLE RESPIRATORY, INC.
1502 PROVIDENCE HIGHWAY, SUITE 10 AND 12
NORWOOD, MA 02062

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: MA0086822

Type: Distribute

Schedules: VI

Issue Date: 12/15/2025

Expiration Date: 01/17/2027

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Reliable Respiratory, Inc.

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

Physical Address: 1502 Providence Hwy, Ste 12

City: Norwood State: MA Zip: 02062

Mailing Address (if different from physical address): 1502 Providence Hwy Ste, 10

City: Norwood State: MA Zip: 02062

Telephone: 781-551-3335 Website: www.reliablerespiratory.com

Licensing Company Email: ap@reliablerespiratory.com

Section 2: Personal Information

First: Michael Middle: David Last: Falkson

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

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

Mailing Address: [redacted]

City: Dedham State: MA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Westwood High School		09/77-05/81	
Address	**City**	**State**	**Zip**
200 Nahatan Street	Westwood	MA	02090
Diploma/Degree obtained, if any			
High school diploma			

School Name		From - To (MM/YY – MM/YY)	
University of Rhode Island		09/81-05/86	
Address	**City**	**State**	**Zip**
45 Upper College Road	Kingston	RI	02881
Diploma/Degree obtained, if any			
Bachelor of Science in Pharmacy			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/12-Current	[redacted]	Dedham	MA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Reliable Respiratory, Inc.			06/07-Present	
Business Address	**City**		**State**	**Zip**
1502 Providence Hwy, Ste 12	Norwood		MA	02062
Phone	**Title**			
781-551-3335	CEO/President			
Description of Duties				
CEO/President; overseeing company operations.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

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

Michael Falkson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/5/26

Date

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

State of Massachusetts, ss. County of Norfolk

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

Original Signature

3/5/26

Date

Subscribed and Sworn to before me this 5th day of March.

Notary Public Signature

ERIC LEVITT
NOTARY PUBLIC
COMMONWEALTH OF MASSACHUSETTS
My Comm. Expires August 6, 2032

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Reliable Respiratory Inc. MDEG License # (if applicable): _____

Physical Address: 1502 Boston Providence TRKE, Suite 12

City: Norwood State: MA Zip: 02062-4643

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 781-551-3335 Website: https://reliablerespiratory.com/

Licensing Company Email: Contracting@reliablerespiratory.com

Section 2: Personal Information

First: Michael Middle: D Last: Falkson

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

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

Mailing Address: [redacted]

City: Dedham State: MA Zip: [redacted]

Telephone: [redacted] Email: contracting@reliablerespiratory.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Westwood Highschool		09/77 - 06/81	
Address	**City**	**State**	**Zip**
200 Nahatan street	Westwood	MA	02090
Diploma/Degree obtained, if any			
High school Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
University of Rhode Island		09/81 - 06/86	
Address	**City**	**State**	**Zip**
45 Upper College Rd	North Kingston	RI	02881
Diploma/Degree obtained, if any			
BS of Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/16 - current	[redacted]	Dedham	MA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
Reliable respiratory Inc			09/01/1999 - present
Business Address	**City**	**State**	**Zip**
1502 Boston Providence TRKE, Suite 12	Norwood	MA	02062
Phone	**Title**		**Number of Employed Hours**
781-551-3335	CEO and founder		40
Description of Duties			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

I, Michael Falkson, **certify that as the MDEG Administrator for**

Reliable Respiratory Inc.,

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

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

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

Michael Falkson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Board Use Only	Date Received:

Michael Falkson, RPh
CEO Reliable Respiratory
Dedham, MA [redacted]
[redacted]

Work Experience:

Staff Pharmacist	1986 – 2003
Founder and CEO	2007 – to current

Reliable Respiratory, Inc. - direct to patient medical products distributor

Education:

B.S. University of Rhode Island School of Pharmacy	1985
Northeastern University	1985 – 1987

Course Concentration in Respiratory Care

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

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

MAURA T. HEALEY
Governor
KIMBERLEY DRISCOLL
Lieutenant Governor

KIAME MAHANIAH, MD, MBA
Secretary
ROBERT GOLDSTEIN, MD, PhD
Commissioner

Verification of Licensure

03/13/2026

To Whom It May Concern:

The individual named below was issued the following in the Commonwealth of Massachusetts:
Pharmacist License

Name of Registrant: Michael D Falkson
Registration Number: PH19885
Registration Status: Current
Issue Date: 06/24/1986
Expiration Date: 12/31/2026
Disciplinary Actions: There are no disciplinary actions against this license.

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

Michael J. Godek
Executive Director

fb234758-669d-4c4c-8608-78ad2d579629

4J

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Shield California Health Care Center, Inc.

MDEG Physical Address: 27911 Franklin Parkway

City: Valencia State: CA Zip: 91355

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (661) 294-4200 Website: https://www.shieldhealthcare.com

Email: licensure@shieldhealthcare.com

Name of MDEG Administrator (NAC 639.694): Gilbert Herrera

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

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

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Medicare: 0374890002	WA Medicaid: 9049263
Medi-Cal: PHA368480	
HI Medicaid: 811093	
OR Medicaid: 231764	

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

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): Henry Schein, Inc.

Corporation Name: Shield California Health Care Center, Inc.

Mailing Address: 27911 Franklin Parkway

City: Valencia State: CA Zip: 91355

Telephone: (661) 294-4200 Email: licensure@shieldhealthcare.com

Contact Person Name: Susan Kado

Date of SEC Registration: 11/3/1995	SEC Registration Number: 0000102909	Stock Exchange Symbol: HSIC

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

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

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

Gilbert Herrera

Print Name of Authorized Person Submitting Application

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

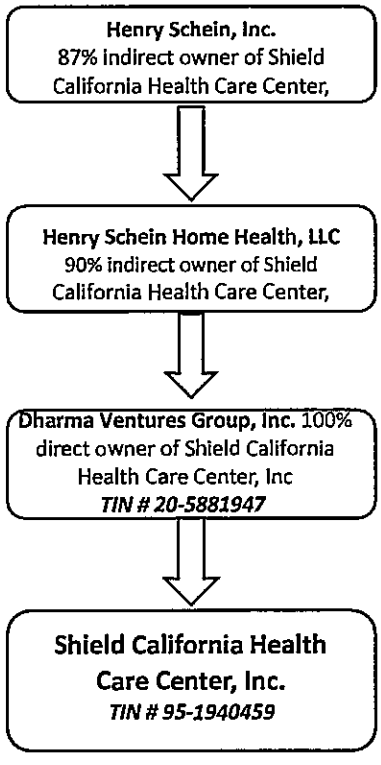
2/12/26

Date

Board Use Only	Date Received: _____	Amount: _____

Shield California Health Care Center, Inc.

Ownership Organization



Individuals and entities with an ownership interest of less than 5% are not included on this chart. Henry Schein, Inc. is a publicly traded company. A full list of Henry Schein, Inc.'s institutional shareholders can be found in the company's annual 10K report that is filed with the SEC.

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Shield California Health Care, Inc. MDEG License # (if applicable) N/A

Physical Address 27911 Franklin Parkway

City Valencia State CA Zip 91355

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

City _____ State _____ Zip _____

Telephone (661) 294-4200 Website https://www.shieldhealthcare.com

Licensing Company Email licensure@shieldhealthcare.com

Section 2: Personal Information

First Gilbert Middle _____ Last Herrera

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

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

Mailing Address [redacted]

City Valencia State CA Zip [redacted]

Telephone [redacted] Email gherrera@shieldhealthcare.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
College of Business		08/99 - 05/00	
Address	**City**	**State**	**Zip**
1801 Panorama Drive	Bakersfield	CA	93305
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
University of California, Riverside		08/95 - 05/98	
Address	**City**	**State**	**Zip**
900 University Ave	Riverside	CA	92521
Diploma/Degree obtained, if any			
Undergraduate			

School Name		From - To (MM/YY – MM/YY)	
Saugus High School		08/90 - 05/94	
Address	**City**	**State**	**Zip**
21900 Centurion Way	Santa Clarita	CA	91350
Diploma/Degree obtained, if any			
HS Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/24 - Present	[redacted]	Castaic	CA	[redacted]
11/05 - 06/24	[redacted]	Castaic	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
Shield Healthcare			09/08 - Present
Business Address	**City**	**State**	**Zip**
27911 Franklin Parkway	Valencia	CA	91355
Phone	**Title**		**Number of Employed Hours**
(661) 294-4217	Vice President of Government Affairs & Secretary		32,000
Description of Duties			
Manage cash collections, utilization management, government, regulatory and quality affairs and compliance.			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12/10/25
Date

I, Gilbert Herrera, **certify that as the MDEG Administrator for**

Shield California Health Care Center, Inc.,

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

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

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

Gilbert Herrera
Print Name (First, Last)

[signature]
Original Signature (electronic, copies or stamps not accepted)

12/10/25
Date

Board Use Only	Date Received: 12/15/25

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 05/28/2025

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

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

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

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Shield California Healthcare Center Inc 27911 Franklin Parkway Valencia CA 91355 USA	INSURER A: QBE Specialty Insurance Company	11515
	INSURER B: ProAssurance Specialty Insurance Company	17400
	INSURER C: Liberty Insurance Corporation	42404
	INSURER D: Liberty Mutual Fire Ins Co	23035
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570112801025 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
D	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY [ ] PRO-JECT [X] LOC OTHER:			TB2621093363035	06/01/2025	06/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $100,000 $5,000 $1,000,000 $3,000,000 Excluded
D	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			AS2-621-093363-045	06/01/2025	06/01/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$1,000,000
C	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION			TH7621093363075	06/01/2025	06/01/2026	EACH OCCURRENCE AGGREGATE	$10,000,000 $10,000,000
C C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			WA762D093363015 AOS WC7621093363025 WI	06/01/2025 06/01/2025	06/01/2026 06/01/2026	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	$1,000,000 $1,000,000 $1,000,000
B	Products Liability			N25NY380022 Products Liability Claims	06/01/2025	06/01/2026	Each Occurence Aggregate	$10,000,000 $10,000,000

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

Re: 27911 Franklin Pkwy Valencia, CA 91355. Certificate Holder is included as Additional Insured in accordance with the policy provisions of the General Liability policy. Druggist Liability is under, The Products Liability policy Medical Professional Services Endorsement

CERTIFICATE HOLDER

NPE West
Attn Jordan Ellison
PO Box 100142
Columbia SC 29202-9652 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

Holder Identifier : CA

Certificate No : 570112801025

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AGENCY CUSTOMER ID: 570000025511
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Shield California Healthcare Center Inc
POLICY NUMBER: See Certificate Number: 570112801025	
CARRIER: See Certificate Number: 570112801025 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

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

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
A	E&O - Miscellaneous Professional-Primary			130003732 E&O SIR applies per policy terms & conditions	12/01/2024	12/01/2025	Prof Liab Agg	$10,000,000

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AGENCY CUSTOMER ID: 570000025511
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Shield California Healthcare Center Inc
POLICY NUMBER: See Certificate Number: 570112801025	
CARRIER: See Certificate Number: 570112801025 / NAIC CODE:	EFFECTIVE DATE:

ADDITIONAL REMARKS

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

Additional Named Insured

Best Buy Care Supplies Inc
dba Total Home Care Supplies
Dharma Venture Group Inc and Subsidiaries
Lorraine Surgical Supply Inc.
Shield Texas Healthcare Inc
Shield-California Health Care Center Inc.
Shield-Denver Healthcare Center Inc
dba My Care Supplies
ACORD

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Shield-California Health Care Center, Inc. Corporate Officers

Name (full legal name)	Business Address and Phone	Title(s)	Professional Licenses? If yes, license type and license #	Place of Birth City, State, Country	Email Address	Work Phone Number	Effective date became officer
Adam Bries	135 Duryea Road, Melville, NY 11747 Phone: 631-843-5360	CEO & President	N/A	[redacted]	adam.bries@henryschein.com	319-321-1230	9/5/2025
Eileen Rosenbaum	135 Duryea Road, Melville, NY 11747 Phone: 631-843-5908	CFO & Vice President	N/A		Eileen.Rosenbaum@henryschein.com	661-294-4200	10/2/2023
Laura Jadezuk	135 Duryea Road, Melville, NY 11747 Phone: 513-659-1820	Vice President Global Tax	N/A		laura.jadezuk@henryschein.com	631-843-5962	9/5/2025
Michael Amodio	135 Duryea Road, Melville, NY 11747 Phone: 513-659-1820	Vice President and Treasurer	N/A		Michael.Amodio@henryschein.com	661-294-4200	10/2/2023
Michael Suor	27911 Franklin Pkwy, Valencia, CA 91355	Vice President and General Manager	N/A		msuor@shieldhealthcare.com	661-294-4200	10/18/2024
Gilbert Herrera	27911 Franklin Pkwy, Valencia, CA 91355	Vice President of Government Affairs and Secretary	N/A		gherrera@shieldhealthcare.com	661-294-4217	10/18/2024

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	SHIELD-CALIFORNIA HEALTH CARE CENTER, INC.
Entity No.:	0338105
Registration Date:	05/13/1957
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of October 13, 2025.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 377649132

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

HOME MEDICAL DEVICE RETAIL LICENSE

Shield California Health Care Center Inc
27911 Franklin Parkway
Valencia, CA 91355

LICENSE NUMBER: 119714
EXPIRATION DATE: 8/28/2026

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

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

4K

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Shield Denver Health Care Center, Inc.

MDEG Physical Address: 2450 Airport Blvd, Unit H

City: Aurora State: CO Zip: 80011

Mailing Address (if different from physical address): 27911 Franklin Parkway

City: Valencia State: CA Zip: 91355

Telephone: 661-294-4200 Website: https:\\shieldhealthcare.com

Email: licensure@shieldhealthcare.com

Name of MDEG Administrator (NAC 639.694): David Rangel

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

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

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))	
Medicare: 0388130001	NM Medicaid: 32270747
CO Medicaid: 08701831	WY Medicaid: 1962516989
IL Medicaid: 222466968002	
NE Medicaid: 10026764500	

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

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): Henry Schien, Inc.

Corporation Name: Shield Denver Health Care Center, Inc.

Mailing Address: 27911 Franklin Parkway

City: Valencia State: CA Zip: 91355

Telephone: 661-294-4200 Email: licensure@shieldhealthcare.com

Contact Person Name: Susan Kado

Date of SEC Registration: 11/3/1995	SEC Registration Number: 0000102909	Stock Exchange Symbol: HSIC

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

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

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

Gilbert Herrera

Print Name of Authorized Person Submitting Application

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

Date 1/30/26

Board Use Only	Date Received: 2/3/26	Amount: $500 471054

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY)
05/28/2025

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

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

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

INSURED	INSURER(S) AFFORDING COVERAGE		NAIC #
Shield California Healthcare Center Inc 27911 Franklin Parkway Valencia CA 91355 USA	INSURER A:	QBE Specialty Insurance Company	11515
	INSURER B:	ProAssurance Specialty Insurance Company	17400
	INSURER C:	Liberty Insurance Corporation	42404
	INSURER D:	Liberty Mutual Fire Ins Co	23035
	INSURER E:		
	INSURER F:		

COVERAGES **CERTIFICATE NUMBER:** 570112801123 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
D	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [ ] [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY [ ] PRO-JECT [X] LOC OTHER:			TB2621093363035	06/01/2025	06/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $100,000 $5,000 $1,000,000 $3,000,000 Excluded
D	AUTOMOBILE LIABILITY [X] ANY AUTO [ ] OWNED AUTOS ONLY [ ] HIRED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] NON-OWNED AUTOS ONLY			AS2-621-093363-045	06/01/2025	06/01/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$1,000,000
C	X UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED RETENTION			TH7621093363075	06/01/2025	06/01/2026	EACH OCCURRENCE AGGREGATE	$10,000,000 $10,000,000
C C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			WA762D093363015 AOS WC7621093363025 WI	06/01/2025 06/01/2025	06/01/2026 06/01/2026	X PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	$1,000,000 $1,000,000 $1,000,000
B	Products Liability			N25NY380022 Products Liability Claims	06/01/2025	06/01/2026	Each Occurence Aggregate	$10,000,000 $10,000,000

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

RE: 2450 Airport Blvd., Unit H, Aurora, CO 80011-7724. Certificate holder is included as Additional Insured in accordance with the policy provisions of the General Liability policy. Druggist Liability is under, The Products Liability policy Medical Professional Services Endorsement

CERTIFICATE HOLDER

NPE West
PO Box 100142
Columbia SC 29202-9652 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

Holder Identifier :

Certificate No : 570112801123

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AGENCY CUSTOMER ID: 570000025511
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Shield California Healthcare Center Inc
POLICY NUMBER: See Certificate Number: 570112801123	
CARRIER: See Certificate Number: 570112801123 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

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

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
A	E&O - Miscellaneous Professional-Primary			130003732 E&O SIR applies per policy terms & conditions	12/01/2024	12/01/2025	Prof Liab Agg	$10,000,000

ACORD 101 (2008/01)
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AGENCY CUSTOMER ID: 570000025511
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Shield California Healthcare Center Inc
POLICY NUMBER: See Certificate Number: 570112801123	
CARRIER: See Certificate Number: 570112801123 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

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

Additional Named Insured

Best Buy Care Supplies Inc
dba Total Home Care Supplies
Dharma Venture Group Inc and Subsidiaries
Lorraine Surgical Supply Inc.
Shield Texas Healthcare Inc
Shield-California Health Care Center Inc.
Shield-Denver Healthcare Center Inc
dba My Care Supplies
ACORD

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OFFICE OF THE SECRETARY OF STATE
OF THE STATE OF COLORADO

CERTIFICATE OF FACT OF GOOD STANDING

I, Jena Griswold, as the Secretary of State of the State of Colorado, hereby certify that, according to the records of this office,

SHIELD-DENVER HEALTH CARE CENTER, INC.

is a

Corporation

formed or registered on 07/15/1983 under the law of Colorado, has complied with all applicable requirements of this office, and is in good standing with this office. This entity has been assigned entity identification number 19871530452 .

This certificate reflects facts established or disclosed by documents delivered to this office on paper through 01/02/2026 that have been posted, and by documents delivered to this office electronically through 01/07/2026 @ 10:00:42 .

I have affixed hereto the Great Seal of the State of Colorado and duly generated, executed, and issued this official certificate at Denver, Colorado on 01/07/2026 @ 10:00:42 in accordance with applicable law. This certificate is assigned Confirmation Number 18054248 .

Jena Griswold

Secretary of State of the State of Colorado

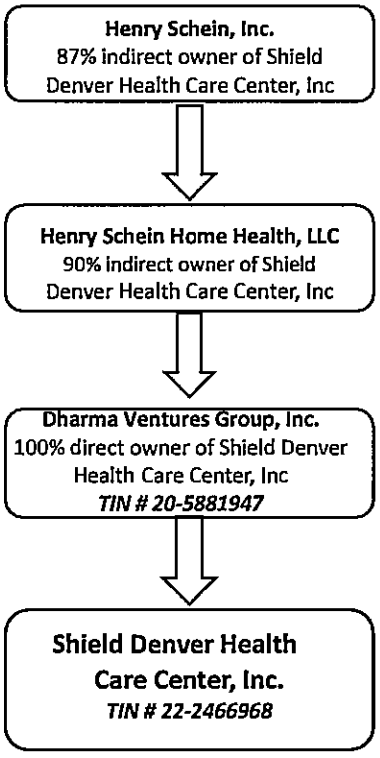
**********End of Certificate**********

Notice: A certificate issued electronically from the Colorado Secretary of State's website is fully and immediately valid and effective. However, as an option, the issuance and validity of a certificate obtained electronically may be established by visiting the Validate a Certificate page of the Secretary of State's website, https://www.coloradosos.gov/biz/CertificateSearchCriteria.do entering the certificate's confirmation number displayed on the certificate, and following the instructions displayed. Confirming the issuance of a certificate is merely optional and is not necessary to the valid and effective issuance of a certificate. For more information, visit our website, https://www.coloradosos.gov click "Businesses, trademarks, trade names" and select "Frequently Asked Questions."

Shield Denver Health Care Center, Inc. Officers					
Name (full legal name)	**Business Address and Phone**	**Title(s)**	**Professional Licenses?**	**Email Address**	**Effective date became officer**
Darma Ventures Group, Inc.	27911 Franklin Pkwy. Valencia, CA 91355 Phone: 661-294-4200	Owner	No	licensure@shieldhealthcare.com	N/A
Adam Bries	135 Duryea Road, Melville, NY 11747 Phone: 631-843-5360	CEO & President	No	adam.bries@henryschein.com	9/5/2025
Eileen Rosenbaum	135 Duryea Road, Melville, NY 11747 Phone: 631-843-5908	CFO & Vice President	No	Eileen.Rosenbaum@henryschein.com	10/2/2023
Laura Jadezuk	135 Duryea Road, Melville, NY 11747 Phone: 513-659-1820	Vice President Global Tax	No	laura.jadezuk@henryschein.com	9/5/2025
Michael Suor	27911 Franklin Pkwy. Valencia, CA 91355 Phone: 661-294-4200	Vice President and General Manager	No	msour@shieldhealthcare.com	10/18/2024
Gilbert Herrera	27911 Franklin Pkwy. Valencia, CA 91355 Phone: 661-294-4217	Vice President of Government Affairs and Secretary	No	gherrera@shieldhealthcare.com	10/18/2024

Shield Denver Health Care Center, Inc.

Ownership Organization



Individuals and entities with an ownership interest of less than 5% are not included on this chart. Henry Schein, Inc. is a publicly traded company. A full list of Henry Schein, Inc.'s institutional shareholders can be found in the company's annual 10K report that is filed with the SEC.

STATE OF COLORADO

DEPARTMENT OF STATE

Durable Medical Equipment Supplier License

I, Jena Griswold, Secretary of State of the State of Colorado, hereby certify that, in accordance with section 24-21-115, C.R.S., the following person or entity is licensed as a Durable Medical Equipment Supplier by the State of Colorado, effective as of 12/22/2025, term to expire 12/22/2026 unless sooner terminated for cause:

Shield Denver Health Care Inc.

License # 20256001327

Issued 10/28/2025

Jena Griswold

Secretary of State of the State of Colorado

City of Aurora
www.auroragov.org
CITY OF AURORA
LICENSING DIVISION

April 22, 2024

SHIELD DENVER HEALTH CARE CENTER INC
27911 FRANKLIN PKWY
VALENCIA CA 91355-4110

Tax Account	License Account 20004410-004-LIC
Letter	L1036681856

Dear Licensee:

Thank you for applying for an Aurora Business License. Your license has been approved. City code requires that the licensee display the license below in a conspicuous place at the business location, and please adhere to any conditions listed.

The tax filing roles and frequencies for the business can be seen in the lower right of the license.

Resources:

- The Aurora Tax Portal can be found at: https://AuroraTaxPortal.gentaxcpc.net.
- Tax and Licensing can be reached by phone at (303) 739-7800.
- Correspondence with tax and licensing staff can be sent through the Aurora Tax Portal or by email at Tax@auroragov.org or Licensing@auroragov.org.
- Website for more information on tax, www.auroragov.org/tax, or licensing, www.auroragov.org/bl.

Sincerely,

City of Aurora Tax & Licensing Division

LICENSE NUMBER
S20004410-0002

COMMENCE DATE
May 13, 2024

EXPIRATION DATE
May 13, 2026

THIS CERTIFIES THAT THE LICENSEE SHOWN HEREON IS AUTHORIZED TO COLLECT OR PAY CITY OF AURORA SALES OR USE TAX FOR THE LOCATION. ANY ALTERATION MADE ON THIS LICENSE WILL AUTOMATICALLY MAKE IT NULL AND VOID

CITY OF AURORA

BUSINESS LICENSE

SHIELD DENVER HEALTH CARE CENTER INC
SHIELD DENVER HEALTH CARE CENTERS INC
2450 N AIRPORT BLVD UNIT H
AURORA CO 80011-7724

TAX TYPE(S)	FILING
Occupational Privilege	Quarterly
Sales and Use	Quarterly

NATURE OF BUSINESS:
456199 - All Other Health and Personal Care Retailers

THIS LICENSE MUST BE CONSPICUOUSLY DISPLAYED AT THE ADDRESS SHOWN AND IS NOT TRANSFERABLE

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Shield Denver Health Care Center, Inc. MDEG License # (if applicable): _____

Physical Address: 2450 Airport Blvd, Unit H

City: Aurora State: CO Zip: 80011

Mailing Address (if different from physical address): 27911 Franklin Parkway

City: Valencia State: CA Zip: 91355

Telephone: (661) 294-4200 Website: https:\\shieldhealthcare.com

Licensing Company Email: licensure@shieldhealthcare.com

Section 2: Personal Information

First: David Middle: _____ Last: Rangel

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

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

Mailing Address: [redacted]

City: Aurora State: CO Zip: [redacted]

Telephone: [redacted] Email: drangel@shieldhealthcare.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Indiana University		09/08-06/09	
Address	**City**	**State**	**Zip**
107 S Indiana Ave	Bloomington	IN	47405
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Loyola Marymount University		01/06-06/08	
Address	**City**	**State**	**Zip**
1 LMU Drive	Los Angeles	CA	90045
Diploma/Degree obtained, if any			
Bachelors of Science			

School Name		From - To (MM/YY – MM/YY)	
Santa Monica College		09/01-06/05	
Address	**City**	**State**	**Zip**
1900 Pico Blvd	Santa Monica	CA	90405
Diploma/Degree obtained, if any			
Associate of Arts Degree			

School Name		From - To (MM/YY – MM/YY)	
Culver City High School		09/97 - 06/01	
Address	**City**	**State**	**Zip**
4401 Elenda Street	Culver City	CA	90230
Diploma/Degree obtained, if any			
High School Diploma			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/20-Current	[redacted]	Highlands Ranch	CO	[redacted]
From - To (MM/YY – MM/YY)		City	State	
06/14-03/20		Highlands Ranch	CO	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Shield Healthcare			04/25-Current	
Business Address		**City**	**State**	**Zip**
2450 Airport Blvd, Unit H		Aurora	CO	80011
Phone	**Title**		**Number of Employed Hours**	
800-525-8049	Area Manager		1700	
Description of Duties				
Responsible for the sales and operations of the sales office including daily activities of sales office staff.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

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

I, David Rangel, **certify that as the MDEG Administrator for**

Shield Healthcare,

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

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

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

David Rangel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/29/2026

Date

Board Use Only	Date Received:

4L

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Urological Supplies, Inc

MDEG Physical Address: 9841 Bernwood Place Dr Ste 130

City: Fort Myers State: FL Zip: 33966

Mailing Address (if different from physical address): Same

City: _____ State: _____ Zip: _____

Telephone: 239-985-9327 Website: usicares.com

Email: bill@urologicalsuppliesinc.com

Name of MDEG Administrator (NAC 639.694): William Stafford

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	■ Others: Urological supplies - mail order
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____ Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8:30 - 4:30	■ Tue: 8:30 - 4:30	■ Wed: 8:30 - 4:30	■ Thurs: 8:30 - 4:30	■ Fri: 8:30 - 4:30
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare: 6490090001
Medicaid: 015970300

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: _____	Credentials: _____	%: _____
Name: _____	Credentials: _____	%: _____
Name: N/A	Credentials: N/A	%: N/A
Name: _____	Credentials: _____	%: _____
Name: _____	Credentials: _____	%: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): _____

Corporation/Organization Name: Urological Supplies, Inc

Mailing Address: 9841 Bernwood Place DR. Ste 130

City: Fort Myers State: FL Zip: 33966

Telephone: 239-985-9327 Email: bill@urologicalsuppliesinc.com

Contact Person Name: William (Bill) Stafford

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

N/A

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Stafford

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

2/24/26

Date

Board Use Only	Date Received: 3/2/26	Amount: $500

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 10/9/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER: VGM Insurance Services, Inc. 1111 Van Miller Way Waterloo IA 50701	CONTACT NAME: Shawn Joblinske PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS: shawn.joblinske@vgm.com
INSURED: Urological Supplies Inc 9841 Bernwood Place Dr #130 Fort Myers FL 33966	INSURER(S) AFFORDING COVERAGE / NAIC # INSURER A: STATE NATIONAL INSURANCE CO 12831 INSURER B: STATE NATIONAL INSURANCE CO 12831 INSURER C: STATE NATIONAL INSURANCE CO 12831 INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			VGM D1025 G5273-11	11/1/2025	11/1/2026	EACH OCCURRENCE	$	1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	100,000
	X Professional Liability						MED EXP (Any one person)	$	10,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$	1,000,000
	X POLICY PRO-JECT LOC						GENERAL AGGREGATE	$	3,000,000
	OTHER:						PRODUCTS - COMP/OP AGG	$	3,000,000
								$	
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$	
	ANY AUTO						BODILY INJURY (Per person)	$	
	ALL OWNED AUTOS / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS / NON-OWNED AUTOS						PROPERTY DAMAGE (Per accident)	$	
								$	
B	UMBRELLA LIAB X OCCUR			VGM UM1025 7263-2	11/1/2025	11/1/2026	EACH OCCURRENCE	$	1,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	1,000,000
	DED RETENTION $							$	
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						PER STATUTE OTH-ER		
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N / A						E.L. EACH ACCIDENT	$	
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	
							E.L. DISEASE - POLICY LIMIT	$	
C	Cyber Liability			VGM D1025 G5273-11	11/1/2025	11/1/2026	Aggregate		1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Locations:
9841 Bernwood Place Dr #130 Fort Myers, FL 33966
9861 Bernwood Place DR. Ste 175 Fort Myers, FL 33966
13271 Metro Parkway Fort Myers, FL 33966

CERTIFICATE HOLDER

EVIDENCE OF INSURANCE

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE



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State of Florida
Department of State

I certify from the records of this office that UROLOGICAL SUPPLIES, INC. is a corporation organized under the laws of the State of Florida, filed on April 26, 2010, effective April 25, 2010.

The document number of this corporation is P10000035611.

I further certify that said corporation has paid all fees due this office through December 31, 2025, that its most recent annual report/uniform business report was filed on February 11, 2025, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-eighth day of January, 2026

Secretary of State

Tracking Number: 0886337287CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

9841 Bernwood Place Dr. Ste 130
Fort Myers, FL 33966
239-985-9327, F 239-985-9614
www.urologicalsuppliesinc.com

List of Management / Owners

1. William Stafford, President & Operations Manager
2. Lawrence Vetter, Secretary & Sales Manager

BACK

Select State(s):

FL

Select Product(s): *

PD09

SEARCH

CLEAR ALL

Export CSV

Florida (FL) - Licensure Information

Collapse All

Product Listing

Urological Supplies (PD09)

License Required (In-state)	No License Required
Req. for Suppliers (Out-of-state)	No
Licensing Agency	--
Verify Online	No
Req. for Pharmacies (In-state)	No
Notes	N/A

Print | Close Window

Subject: RE: Licensing
From: "Lawrence, Noel" <Noel.Lawrence@ahca.myflorida.com>
Date: Mon, Sep 27, 2010 2:19 pm
To: "bill@urologicalsupplies.us" <bill@urologicalsupplies.us>
Attach: image001.jpg
image004.png
image005.png

Dear Mr. Stafford:

I am responding to your inquiry as I supervise the licensure of Florida home medical equipment providers.

Florida Administrative Code (F.A.C.) offers the following exemption from home medical equipment provider licensure:

59A-25.002(2), F.A.C. "Home medical equipment locations that do not require a license: Diabetic monitors and disposable supplies, e.g., diabetic, ostomy, urological and wound care supplies have been identified as equipment and supplies that do not require services as defined in Section 400.925(11), F.S.; therefore, locations that supply these items only will not require a HME license."

You will find this 'Frequently Asked Question' and other useful information on the Agency's website at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Home_Care/Home_Medical_Equipment.shtml. If you need further assistance regarding home medical equipment provider licensure after reviewing this website, please contact Mary Boortz at (850) 412-4403. She is responsible for licensure of home medical equipment providers in your geographic area.

Thank you for your inquiry,

Noël Cronin Lawrence
Program Administrator
Home Care Unit
Agency for Health Care Administration
2727 Mahan Drive MS 34
Tallahassee FL 32308-5407
850.412.4403
850.922.6059 fax

Click for more information:





From: Weaver, Polly
Sent: Monday, September 27, 2010 9:03 AM
To: bill@urologicalsupplies.us
Cc: Menard, Anne
Subject: RE: Licensing

Mr. Stafford, I am putting you in touch with Ms. Anne Menard, the manager of the unit which, among other

9841 Bernwood Place Dr. Ste 130
Fort Myers, FL 33966
239-985-9327, F 239-985-9614
www.urologicalsuppliesinc.com

State Licenses required for Urological Supplies

Arizona	License #C001274, expires 10/31/2026
California	License #76789, expires 7/3/2026
Connecticut	License # CSW.0004337 expires 06/30/2026
Georgia	License # PHDME000305 expires 06/30/2027
Idaho	License DME 43108, Expires 12/31/2026
Kentucky	License # 244959 expires 9/30/2026
Louisiana	License #DME000823, expires 8/31/2026
New Hampshire	License # 8353, Expires 06/30/2027
North Carolina	License # 03210 Expires 12/31/2026
South Carolina	License # 19775 6/30/6
Tennessee	License # 1545 2/28/2027
Utah	License # 14270400-1714 Expires 09/30/2027
Virginia	License # 0237000125, expires 02/28/2027

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Urological Supplies, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): n/a

Physical Address: 9841 Bernwood Place Dr., Suite 130

City: Fort Myers State: FL Zip: 33966

Mailing Address (if different from physical address): Same

City: State: Zip:

Telephone: 239-985-9327 Website: www.usicares.com

Licensing Company Email: bill@urologicalsuppliesinc.com

Section 2: Personal Information

First: Lawrence Middle: C Last: Vetter

Alias(es, nicknames, name changes, etc.): Larry Vetter

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Fort Myers State: FL Zip: [redacted]

Telephone: [redacted] Email: larry@urologicalsuppliesinc.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Toledo		1987-1991	
Address	**City**	**State**	**Zip**
2801 W. Bancroft St.	Toledo	OH	43606
Diploma/Degree obtained, if any			
Associates in Health and Sciences Respiratory Care			

School Name		From - To (MM/YY – MM/YY)	
Hicksville High School			
Address	**City**	**State**	**Zip**
958 E High St	Hicksville	OH	43526
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10-2003-present	[redacted]	Fort Myers	FL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
Urological Supplies, Inc.		06-2013 - present	
Business Address	**City**	**State**	**Zip**
9841 Bernwood Place Dr., Suite 130	Fort Myers	FL	33966
Phone	**Title**		
239-985-9327	Owner, Vice President - Secretary		
Description of Duties			
Sales and Business Development			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

February 24 2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lawrence C. Vetter
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

February 24, 2026
Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Lee

I, Lawrence C Vetter, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2-24-26
Date

Subscribed and Sworn to before me this 24th day of February

Notary Public Signature

William P Stafford

WILLIAM P. STAFFORD
MY COMMISSION # HH 613470
EXPIRES: November 17, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Urological Supplies, Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 9841 Bernwood Place Dr Ste 130

City: Fort Myers State: FL Zip: 33966

Mailing Address (if different from physical address): Same

City: State: Zip:

Telephone: 239-985-9327 Website: usicares.com

Licensing Company Email: bill@urologicalsuppliesinc.com

Section 2: Personal Information

First: William Middle: Paschall Last: Stafford

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Fort Myers State: FL Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Ben- Hill Irwin Vocational School			From - To (MM/YY – MM/YY): 08/83 - 08/85
Address	City: Fitzgerald	State: GA	Zip
Diploma/Degree obtained, if any: Computer - Electronics Associate Degree			
School Name: Bowens Mill Christian School			From - To (MM/YY – MM/YY): 07/80 - 05/83
Address	City: Fitzgerald	State: GA	Zip
Diploma/Degree obtained, if any: High School Diploma			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/17 - Present	[redacted]	Fort Myers	FL	[redacted]
02/14 - 03/17		Fort Myers	FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Urological Supplies, Inc			04/10 - Present	
Business Address		**City**	**State**	**Zip**
9841 Bernwood Place Dr Ste 130		Fort Myers	FL	33966
Phone	**Title**			
239-208-7447	President			
Description of Duties				
President / Owner. Started Business in 2010. Oversee all operations				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

None

Original Signature (electronic, copies or stamps not accepted)

2/24/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Stafford

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/24/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Lee

I, William Stafford, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/24/26

Date

Subscribed and Sworn to before me this 24th day of February.

Notary Public Signature

YOLANDA VARGAS
Notary Public - State of Florida
Commission # HH 706983
My Comm. Expires Aug 5, 2029

(seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Urological Supplies, Inc MDEG License # (if applicable): _____

Physical Address: 9841 Bernwood Place Dr Ste 130

City: Fort Myers State: FL Zip: 33966

Mailing Address (if different from physical address): Same

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Licensing Company Email: _____

Section 2: Personal Information

First: William Middle: Paschall Last: Stafford

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Fort Myers State: FL Zip: [redacted]

Telephone: [redacted] Email: bill@urologicalsuppliesinc.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Ben-Hill Vocational School		08/83 - 08/85	
Address	**City**	**State**	**Zip**
	Fitzgerald	GA	
Diploma/Degree obtained, if any			
Computer - Electronics Associate Degree			

School Name		From - To (MM/YY – MM/YY)	
Bowens Mill Christian School		07/80 - 05/83	
Address	**City**	**State**	**Zip**
	Fitzgerald	Ga	
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/17 - Present	[redacted]	Fort Myers	FL	[redacted]
02/14 - 03/17		Fort Myers	FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Urological Supplies, Inc			04/10 - Present	
Business Address		**City**	**State**	**Zip**
9841 Bernwood Place Dr Ste 130		Fort Myers	FL	33966
Phone	**Title**		**Number of Employed Hours**	
239-985-9327	President		15 years - Full Time	
Description of Duties				
President / Owner - Started Business in 2010 and oversee all operations.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NONE **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

NONE

Original Signature (electronic, copies or stamps not accepted)

2-24-26

Date

I, William Stafford, **certify that as the MDEG Administrator for**

Urological Supplies, Inc,

that I (initial that you have read and meet the following requirements):

1. WPS Have a high school diploma or its equivalent;
2. WPS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. WPS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. WPS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Stafford

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/24/2026

Date

Board Use Only	Date Received: 3/2/26

4M

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Watkins-Conti Products, Inc.

MDEG Physical Address: 3841 E Danforth Road, Suite 109

City: Edmond State: OK Zip: 73034

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 405-697-3334 Website: www.watkinscontiproducts.com / www.yonifit.com

Email: bwigley@watkinscontiproducts.com

Name of MDEG Administrator (NAC 639.694): Brooke Wigley

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	■ Others: Medical Device (Vaginal Insert)
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8am-5pm CST	■ Tue: 8am-5pm CST	■ Wed: 8am-5pm CST	■ Thurs: 8am-5pm CS	■ Fri: 8am-5pm CST
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
N/A

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): N/A

Corporation/Organization Name: Watkins-Conti Products, Inc

Mailing Address: 3841 E Danforth Rd., Ste 109

City: Edmond State: OK Zip: 73034

Telephone: 405-697-3334 Email: bwigley@watkinscontiproducts.com

Contact Person Name: Brooke Wigley

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brooke Wigley

Print Name of Authorized Person Submitting Application

Brooke Wigley

Original signature of Authorized Person (copies or stamps not accepted)

11/17/2025

Date

Board Use Only	Date Received: 11/19/25	Amount: $500 ck 1028

WATKPRO-01 MBRANDNER

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 7/21/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER License # 1017969 INSURICA 5100 N. Classen Blvd, #300 Oklahoma City, OK 73118	CONTACT NAME: Michelle Brandner, CISR Elite PHONE (A/C, No, Ext): (405) 556-2219 FAX (A/C, No): E-MAIL ADDRESS: Michelle.Brandner@INSURICA.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Great Northern Insurance Co.	20303
INSURED Watkins-Conti Products Inc. 3841 E Danforth Road Suite 109 Edmond, OK 73034	INSURER B : National Casualty Company	11991
	INSURER C : Federal Insurance Company	20281
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR			3608-51-84 WUC	6/27/2025	6/27/2026	DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$
	OTHER:						GLOBAL AGGREGAT	$ 2,000,000
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N/A						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
B	Directors and Office			EKO3582951	8/1/2025	8/1/2026	Aggregate	4,000,000
C	Products/Completed O			9951-08-87 WUC	6/27/2025	6/27/2026	Aggregate	5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Directors & Officers Liability $4,000,000 Maximum Aggregate Limit of Liability / $25,000 Retention / Continuity Date 6-1-21
Employment Practices Liability $2,000,000 maximum aggregate Limit of Liability / $10,000 Retention / Continuity Date: 8-1-24

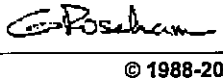
CERTIFICATE HOLDER

Proof of Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE



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OFFICE OF THE SECRETARY OF STATE

STATE OF OKLAHOMA

CERTIFICATE OF GOOD STANDING

FOREIGN FOR PROFIT BUSINESS CORPORATION

I, THE UNDERSIGNED, Secretary of State of the State of Oklahoma, do hereby certify that I am, by the laws of said State, the custodian of the records of the state of Oklahoma relating to the right of certain business entities to transact business in this state and am the proper officer to execute this certificate.

I FURTHER CERTIFY that WATKINS-CONTI PRODUCTS, INC., a Foreign For Profit Business Corporation organized and existing by virtue of the laws of the state of DE, whose registered agent is ALLISON CONTI, with its registered office at 3841 E DANFORTH RD STE 109 EDMOND 73034 USA Oklahoma, is duly qualified as a Foreign For Profit Business Corporation to transact business within the state of Oklahoma and is in good standing according to the records of this office. This certificate is not to be construed as an endorsement, recommendation or notice of approval of the entity's financial condition or business activities and practices. Such information is not available from this office.

GREAT SEAL OF THE STATE OF OKLAHOMA 1907

IN TESTIMONY WHEREOF, I hereunto set my hand and affixed the Great Seal of the State of Oklahoma, done at the City of Oklahoma City, this 17th, day of November, 2025.

Benjamin Lepak

Secretary Of State

Watkins-Conti Products List of Directors

Name	Title	Address
Allison Watkins-Conti	Founder/CEO	Edmond, OK
Jennie R. Martel	Director	Bronxville, NY
John H. Marmaduke	Director	Amarillo, TX
Ross Watkins	President	Millsap, TX
Mike Pintek	Director	Austin, TX
Anula Jayasuriya	Director	Palo Alto, CA
Brooke Wigley	COO	Edmond, OK

OKLAHOMA
State Board of Pharmacy
2920 N Lincoln Blvd Ste A, Oklahoma City, OK 73105
405-521-3815 • Fax 405-521-3758

#1-E-9219

DME Supplier
EXPIRES SEP 30, 2026

Mailing Address:

WATKINS-CONTI PRODUCTS, INC
3841 E DANFORTH ROAD, STE 109
EDMOND OK 73034

Issued to:

WATKINS-CONTI PRODUCTS, INC
3841 E DANFORTH ROAD, STE 109
EDMOND OK 73034

Inspection:	$200.00
Lic. Fee:	$200.00
Receipt No.:	14768605
Date:	9/15/2025

2026

This License is not transferable.
License must be conspicuously displayed in the location to which it is issued.

Important Information

- **Change of Location:** This license is not transferable for a change of location. A new license is required.
- **Change of Name:** This license is not transferable for a change of name. A new license is required.
- **Change of Owner:** This license is not transferable for a change of owner. A new license is required when the ownership changes by 20% or more.
- **Forms & Applications, Current Announcements and Laws & Rules are available at the Board's website:** www.pharmacy.ok.gov
- **Board Contact:**

  Email: pharmacy@pharmacy.ok.gov

  Phone: 405-521-3815

  Fax: 405-900-8365

Caution! If you ship Controlled Dangerous Substances (CDS) into Oklahoma you must register with the Oklahoma Bureau of Narcotics and Dangerous Drugs Control (OBNDD).
OBNDD Phone: 405-521-2885 and Website: www.ok.gov/obndd

All changes in any information required for the licensure must be reported to the Board within ten (10) days.

It is your responsibility to keep this license current.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

4

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Watkins-Conti Products, Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 3841 East Danforth Rd., Suite 109

City: Edmond State: OK Zip: 73034

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (405)330-3550 Website: www.WatkinsContiProducts.com

Licensing Company Email: bwigley@Watkinscontiproducts.com

Section 2: Personal Information

First: Allison Middle: Lee Last: Watkins

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Edmond State: OK Zip: [redacted]

Telephone: [redacted] Email: Allison@WatkinsContiProducts.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Randall High School		graduated 1999	
Address	City	State	Zip
	Amarillo	TX	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2013	[redacted]	Edmond	OK	[redacted]
2020-current		Edmond	OK	

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
Watkins-Conti Products, Inc		August 2015-current	
Business Address	**City**	**State**	**Zip**
3841 East Danforth Rd, Suite 109	Edmond	OK	73034
Phone	**Title**		
(405)330-3550	Founder/CEO		
Description of Duties			
Founded and manages medical device company that has FDA distributes Vaginal inserts for the management of Stress urinary incontinence.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
January27 2025	January2 82025	Oklahoma	Edmond	Oklahoma
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
FEI: 3031788248		FDA		
Reason/Charge				
Routine onsite insepction				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
N/A		N/A		
Name of Business/Industry/Entity				
Watkins-Conti Products, Inc.				

Provide explanation below:

FDA auditor conducted a routine on-site audit of our Quality Management System and complaint handling. FDA toured the facility and conducted the routine audit over the period of two days. The company received NO 483's and NO observations making this a clean audit with no disciplinary action necessary.

Original Signature (electronic, copies or stamps not accepted)

11/24/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Allison Watkins

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

~~11/21/2025~~ 11/24/25 AW

Date

Please have this section completed in the presence of a Notary Public.

State of Oklahoma, ss. County of Oklahoma

I, Ayden Jonah Fletcher, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/24/25

Date

Subscribed and Sworn to before me this 24th day of November.

Notary Public Signature

Notary Public
State of Oklahoma
AYDEN JONAH FLETCHER
OKLAHOMA COUNTY
COMMISSION #25008105
Comm. Exp. 07-10-2029
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Watkins-Conti Products, Inc MDEG License # (if applicable): _____

Physical Address: 3841 E Danforth Rd. Ste 109

City: Edmond State: OK Zip: 73034

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 405-697-3334 Website: www.watkinscontiproudcts.com / www.yonifit.com

Licensing Company Email: wcp@watkinscontiproducts.com

Section 2: Personal Information

First: Angela Middle: Brooke Last: Wigley

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Edmond State: OK Zip: [redacted]

Telephone: [redacted] Email: bwigley@watkinscontiproducts.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Memorial High School			
Address	City	State	Zip
1000 E 15th St	Edmond	OK	73034
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Western Governors University			
Address	City	State	Zip
4001 S 700 E, #300	Salt Lake City	UT	84107
Diploma/Degree obtained, if any			
Bachelor of Science - Accounting			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2023-current	[redacted]	Edmond	OK	[redacted]
From - To (MM/YY – MM/YY)		City	State	
2018-2023		Edmond	OK	
From - To (MM/YY – MM/YY)		City	State	
2014-2018		Edmond	OK	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Watkins-Conti Products			2016-current	
Business Address		**City**	**State**	**Zip**
3841 E Danforth Rd		Edmond	OK	73034
Phone	**Title**		**Number of Employed Hours**	
405-697-3334	Chief Operating Officer		40/week	
Description of Duties				
Oversee quality systems and operations and ensure compliance with regulatory bodies.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

1/17/2025
Date

I, Brooke Wigley, **certify that as the MDEG Administrator for**

Watkins-Conti Products,

that I (initial that you have read and meet the following requirements):

1. BW Have a high school diploma or its equivalent;
2. BW Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. BW Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. BW Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brooke Wigley
Print Name (First, Last)

Brooke Wigley
Original Signature (electronic, copies or stamps not accepted)

11/17/2025
Date

Board Use Only	Date Received: 12/9/25

4N

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) * If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: McKesson Medical-Surgical Inc.

Physical Address: 40 Lackey Dam Road

City: Uxbridge State: MA Zip: 01569

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (774) 781-6100 Website: https://mms.mckesson.com/

Name of Designated Representative (DR): Paul Reget

Licensing Company Email: mckessonlicensing@mckesson.com DR Email: paul.reget@mckesson.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☒ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Clinics		☒ Others: Distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Virginia

Parent Company (if any): McKesson Medical-Surgical Holdings Inc. - ultimate owner McKesson Corporation (publicly traded)

Corporation Name: McKesson Medical Surgical Inc.

Mailing Address: 6555 State Highway 161

City: Irving State: TX Zip: 75039

Telephone: 972.446.4800 Email: mckessonlicensing@mckesson.com

Contact Person Name: Daniel Wright

Date of SEC Registration: 07/07/1994 | SEC Registration Number: 2417015 | Stock Exchange Symbol: MCK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: B. Braun Medical Inc.
Address: 824 12th Avenue City: Bethlehem State: PA Zip: 18018
Name: Abbott Rapid DX N America LLC
Address: 1101 Greenwood Blvd. City: Lake Mary State: FL Zip: 32746
Name: Pfizer Pharmaceutical
Address: 1855 Shelby Oaks Drive N City: Memphis State: TN Zip: 38134
Name: Amgen Inc.
Address: One Amgen Center Drive City: Thousand Oaks State: CA Zip: 91320

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Virginia
Parent Company (if any): McKesson Medical-Surgical Holdings Inc.
Corporation/Organization Name: McKesson Medical-Surgical Inc.
Mailing Address: 9954 Mayland Drive, Suite 4000
City: Richmond State: VA Zip: 23233
Telephone: 804.264.7500 Email: mckessonlicensing@mckesson.com
Contact Person Name: Angela Phillips

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

McKesson Medical-Surgical Inc.

Facility Name

Daniel Wright

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

01 OCT 2025

Date

Board Use Only	Date Received: 11/4/25	Amount: 400.00 - CC

OFFICERS AND OWNER

McKesson Medical-Surgical Inc. – Additional Details

Virginia company incorporated on February 27th, 1980.

Applicant:

McKesson Medical-Surgical Inc.
40 Lackey Dam Rd., Uxbridge, MA 01569
Phone: 774-781-6100
FEIN: 94-2640465

Corporate Office:

McKesson Medical-Surgical, Inc.
9954 Mayland Drive, Suite 4000, Richmond, VA 23233
FEIN: 94-2640465

Parent Company – 100% Shareholder:

McKesson Medical-Surgical Holdings Inc.
9954 Mayland Drive, Suite 4000, Richmond, VA 23233
FEIN: 13-3734754

Corporate Officers:

Stanton J. McComb, President, Director
9954 Mayland Drive, Suite 4000, Richmond, VA 23233

Gregory S. Keyes, Vice President & Treasurer; Director
9954 Mayland Drive, Suite 4000, Richmond, VA 23233

Steven Tarantino III, Vice President
9954 Mayland Drive, Suite 4000, Richmond, VA 23233

Daniel R. Wright, Vice President
9954 Mayland Drive, Suite 4000, Richmond, VA 23233

Saralisa C. Brau, Secretary
6555 State Highway 161 Irving, TX 75039

Application Contact:

Angela Phillips, Lead Regulatory Specialist, Enterprise Quality Management
Email: mckessonlicensing@mckesson.com
Phone: 839-201-2917

Confidentiality Notice: This document, including any attachments, is for the sole use of its intended recipients and may contain confidential, proprietary and/or privileged information of McKesson Corporation or its affiliates. Any unauthorized review, use, disclosure, or distribution is prohibited.

McKESSON

CERTIFICATE OF GOOD STANDING

Commonwealth of Virginia

State Corporation Commission

CERTIFICATE OF GOOD STANDING

I Certify the Following from the Records of the Commission:

That McKesson Medical-Surgical Inc. is duly incorporated under the law of the Commonwealth of Virginia;

That the corporation was incorporated on February 27, 1980;

That the corporation's period of duration is perpetual; and

That the corporation is in existence and in good standing in the Commonwealth of Virginia as of the date set forth below.

Nothing more is hereby certified.

Signed and Sealed at Richmond on this Date:

August 21, 2025

Bernard J. Logan, Clerk of the Commission

CERTIFICATE NUMBER : 2025082122217749

McKESSON

COPY OF LICENSE

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Drug Manufacturer or Drug Distributor Controlled Substance Registration to:

McKesson Medical-Surgical Inc.
40 Lackey Dam Road
Uxbridge, MA 01569

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: RMD400187

Type: Distribute

Schedules: VI

Issue Date: 07/24/2025

Expiration Date: 07/24/2026

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

McKESSON

CERTIFICATE OF INSURANCE

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY)
06/20/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Insurance Services West, Inc. Seattle WA Office 1420 Fifth Avenue Suite 3020 Seattle WA 98101-4030 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Old Republic Insurance Company	24147
INSURER B:		
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
McKesson Corporation and
all its subsidiaries
6555 North State Highway 161
Irving TX 75039 USA

COVERAGES **CERTIFICATE NUMBER:** 570113398855 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY319292	07/01/2025	07/01/2026	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
							MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$2,000,000
	OTHER:							
A	AUTOMOBILE LIABILITY			MWTB 319291 Self Insured for Phys Dam	07/01/2025	07/01/2026	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / HIRED AUTOS ONLY / SCHEDULED AUTOS / NON-OWNED AUTOS ONLY						BODILY INJURY (Per accident)	
							PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	Y / N: N	N / A	MWC31382625	07/01/2025	07/01/2026	X PER STATUTE OTH-ER	
							E.L. EACH ACCIDENT	$1,000,000
							E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
EVIDENCE OF INSURANCE ONLY.

CERTIFICATE HOLDER

MCKESSON CORPORATION
6555 STATE HIGHWAY 161
IRVING TX 75039 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Insurance Services West, Inc.

Holder Identifier :

Certificate No : 570113398855

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG McKesson Medical-Surgical Inc. MDEG License # (if applicable) _____

Physical Address 40 Lackey Dam Road

City Uxbridge State MA Zip 01569

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (774) 781-6100 Website https://mms.mckesson.com/

Licensing Company Email mckessonlicensing@mckesson.com

Section 2: Personal Information

First Paul Middle Alan Last Regel

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 40 Lackey Dam Road

City Uxbridge State MA Zip 01569

Telephone [redacted] Email paul.regel@mckesson.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Aquinas High School		-05/79	
Address	**City**	**State**	**Zip**
315 11th St S	La Crosse	WI	54601
Diploma/Degree obtained, if any			
High School Graduate			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/96 - Current	[redacted]	Bellingham	MA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Exel Inc. dba DHL Supply Chain (USA)			02/2026 - Present	
Business Address		**City**	**State**	**Zip**
700 Killinger Road		Annville	PA	17050
Phone	**Title**		**Number of Employed Hours**	
717-901-1379	Operations Manager		600	
Description of Duties				
Billing and reporting for daily, weekly and monthly operations. Bridging gaps in QA and Operational opportunities to ensure no service failure. Assist with serialization implementation and process flow. Develop Supervisors and provide necessary tools for future growth				

Business Name			From - To (MM/YY – MM/YY)	
Exel Inc. dba DHL Supply Chain (USA)			03/2022-01/2026	
Business Address		**City**	**State**	**Zip**
260 Salem Church Rd		Mechanicsburg	PA	17050
Phone	**Title**		**Number of Employed Hours**	
717 901 1379	Operations Manager		6000+	
Description of Duties				
To manage and promote a safety-first culture where teams are encouraged to be flexible and to strive for continuous improvement while innovating to address the needs of multiple stakeholders. Participates in RFP and customer pursuits. Financially responsible for Facility. Leads network charters for volume volatility and order profile improvements.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted) Date

I, Paul Reget, certify that as the MDEG Administrator for

McKesson Medical-Surgical Inc.,

that I (initial that you have read and meet the following requirements):

1. PR Have a high school diploma or its equivalent;
2. PR Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. PR Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. PR Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul Regel

Print Name (First, Last)

Paul L Reget

Original Signature (electronic, copies or stamps not accepted)

Oct. 31, 2025

Date

Board Use Only	Date Received: 11/4/25

Not Required

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler McKesson Medical-Surgical Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 40 Lackey Dam Road

City Uxbridge State MA Zip 01569

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website www.mckesson.com

Licensing Company Email mckessonlicensing@mckesson.com

Section 2: Personal Information

First Paul Middle Alan Last Reget

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 40 Lackey Dam Road

City Uxbridge State MA Zip 01569

Telephone [redacted] Email paul.reget@mckesson.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Aquinas High School		- 05/79	
Address	City	State	Zip
315 11th St S	La Crosse	WI	54601
Diploma/Degree obtained, if any			
High School Graduate			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
March 1996 - current	[redacted]	32 Dorothy Avenue	MA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Exel Inc. dba DHL Supply Chain (USA)			02/2026 - Present
Business Address	**City**	**State**	**Zip**
700 Killinger Road	Annville	PA	17050
Phone	**Title**	**Number of Employed Hours**	
717-901-1379	Operations Manager	600	

Description of Duties

Billing and reporting for daily, weekly and monthly operations. Bridging gaps in QA and Operational opportunities to ensure no service failure. Assist with serialization implementation and process flow. Develop Supervisors and provide necessary tools for future growth.

Business Name			From - To (MM/YY – MM/YY)
Exel Inc. dba DHL Supply Chain (USA)			03/2022-01/2026
Business Address	**City**	**State**	**Zip**
260 Salem Church Rd	Mechanicsburg	PA	17050
Phone	**Title**	**Number of Employed Hours**	
717 901 1379	Operations Manager	6000+	

Description of Duties

To manage and promote a safety-first culture where teams are encouraged to be flexible and to strive for continuous improvement while innovating to address the needs of multiple stakeholders. Participates in RFP and customer pursuits. Financially responsible for Facility. Leads network charters for volume volatility and order profile improvements.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Paul A. Rapt
Original Signature (electronic, copies or stamps not accepted)

Sept. 16 2025
Date

I, Paul Alan Reget, **certify that as the designated representative for**

McKesson Medical-Surgical Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. P.R. I am at least 21 years of age;
3. P.R. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. P.R. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. P.R I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. P.R I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. P.R. I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Paul Reget

Print Name (First, Last)

Paul A. Reget

Original Signature (electronic, copies or stamps not accepted)

Sept. 16 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul Reget

Print Name (First, Last)

Paul A. Reget

Original Signature (electronic, copies or stamps not accepted)

Sept. 16 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Massachusetts, ss. County of Norfolk

I, PAUL A. Reget, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Paul A. Reget

Original Signature

Sept. 10 2025

Date

Subscribed and Sworn to before me this 10 day of September 2025

Victoria Arenas

Notary Public Signature

VICTORIA ARENAS
Notary Public
Commonwealth of Massachusetts
My Commission Expires
April 2, 2032

(Seal)

McKESSON

SURETY BOND

- Not required for Publicly Traded

VERIFICATION CERTIFICATE FOR INDEFINITE TERM SURETY BOND

THIS IS TO CERTIFY that Bond Number 070022483 issued by

Liberty Mutual Insurance Company , as Surety, dated the 15th

day of September , 2016 , in the amount of

One Hundred Thousand & 00/100 ($ 100,000.00), on behalf

of McKesson Corporation , as Principal,

and in favor of State of Nevada and to the State Board of Pharmacy , as Obligee,

covers a term which began on the 15th day of September , 2016 ,

and ends only with the cancellation of said bond or other legal termination thereof; and that the said bond remains in effect, subject to all its agreements, conditions and limitations.

Current Renewal Term: 09/15/2025 to 09/15/2026.

Signed, sealed and dated this 29th day of September , 2025 .

Liberty Mutual Insurance Company

Surety

By: Amanda R. Turman-Avina

Amanda R. Turman-Avina, Attorney-in-Fact

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

Liberty Mutual SURETY

POWER OF ATTORNEY

Certificate No: 8204866

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Amanda R. Turman-Avina

all of the city of Houston, state of TX each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of July, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 1st day of July, 2024, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 29th day of September, 2025

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Liberty Mutual
SURETY

Liberty Mutual Surety
1001 4th Ave Ste 3800
Office: 206-473-3533

As part of its business continuity efforts during the pendency of the COVID-19 pandemic, Liberty Mutual Insurance Company ("LMIC") on behalf of itself and the companies listed below has authorized its Attorneys-in-Fact to affix its corporate seal for surety obligations in a digital format in lieu of its traditional raised seal to any bond issued on its behalf by any such Attorney-in-Fact:

Liberty Mutual Insurance Company
Liberty Mutual Fire Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company
Safeco Insurance Company of America
American States Insurance Company

Please note that the digital seal utilized by our authorized agents will also include their agency specific reference number.

LMIC agrees and affirms on behalf of itself and the other companies listed herein, that the digital corporate seal referenced above has the same binding effect when affixed to a bond or a Power of Attorney document as if it were a raised corporate seal.

Effective this 23rd day of March, 2020.

By: _____
Renee C. Llewellyn, Assistant Secretary

LIBERTY MUTUAL INSURANCE COMPANY
INCORPORATED
1912
MASSACHUSETTS

CHANGE RIDER

To be attached to and form a part of Bond No. 070022483

in the amount of $100,000.00 issued by Liberty Mutual Insurance Company

on behalf of McKesson Corporation

in favor of State of Nevada and to the State Board of Pharmacy

It is understood and agreed that the bond described above is hereby modified so as to

Affirm coverage for the following location:

McKesson Medical-Surgical Inc., 40 Lackey Dam Road, Uxbridge, MA 01569

It is further expressly understood and agreed that the aggregate liability of the Liberty Mutual Insurance Company under said bond to the obligee herein mentioned shall not exceed the amount stated above.

Nothing herein contained shall be held to vary, alter, waive, or extend any of the terms, agreements, conditions or limitations of the above-mentioned bond, other than as above stated.

Signed, sealed and dated this 29th day of September, 2025.

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

Liberty Mutual Insurance Company

BY: Amanda R. Turman-Avina

Amanda R. Turman-Avina, Attorney-in-Fact

POWER OF ATTORNEY

Certificate No: 8204866

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Amanda R. Turman-Avina all of the city of Houston, state of TX each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of July, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 1st day of July, 2024, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 29th day of September, 2025.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Liberty Mutual
SURETY

Liberty Mutual Surety
1001 4th Ave Ste 3800
Office: 206-473-3533

As part of its business continuity efforts during the pendency of the COVID-19 pandemic, Liberty Mutual Insurance Company ("LMIC") on behalf of itself and the companies listed below has authorized its Attorneys-in-Fact to affix its corporate seal for surety obligations in a digital format in lieu of its traditional raised seal to any bond issued on its behalf by any such Attorney-in-Fact:

Liberty Mutual Insurance Company
Liberty Mutual Fire Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company
Safeco Insurance Company of America
American States Insurance Company

Please note that the digital seal utilized by our authorized agents will also include their agency specific reference number.

LMIC agrees and affirms on behalf of itself and the other companies listed herein, that the digital corporate seal referenced above has the same binding effect when affixed to a bond or a Power of Attorney document as if it were a raised corporate seal.

Effective this 23rd day of March, 2020.

By: _____
Renee C. Llewellyn, Assistant Secretary

LIBERTY MUTUAL INSURANCE COMPANY
INCORPORATED
1912
MASSACHUSETTS

McKESSON

EMPLOYEE LIST

This is a list of personnel currently employed at McKesson Medical-Surgical facility located at 55 Lyman Street, Northborough, MA that intend to transfer to the applicant facility once it is fully operational.

Roster			
Aaron Almonte	Dan Lewis	Jiwan Mishra	Nahir Yustis
Abraham Veliz	Daniel De Barros	Joe Vargas	Nawar Noori
Agustin Lopez	Daniel Salgado	John Asante	Nicholas Mattress
Aida Yaffarly Cuellar Yara	Darrin Lefevre	John Dzanku	Nicholas Wood
Aimee Oliver (On Leave)	Darryll Rosemond	John Gruslin (On Leave)	Omaya Cabral Rivera
Alejandro Villodas	Dave Folta	John Kierstead	Pamela Lanctot
Alex Tirado	Dave Smith	John West	Parrish Hyde
Alexander Carrasco (On Leave)	Dawn Tuliano	Jonathan Mercado	Paul Reget
Alexander Coutinho	Deborah Patten	Jose Barreiro	Peter Kaval
Alexandro Andino	Delourde Aristil (On Leave)	Jose Cotto	Placide Jn Francois
Ali Alfadaghee	Denis Robitaille	Jose Pozo-Campos	Rebeca Souza Da
Alissa Young	Dennis Agyei	Josephine Osei Oduro	Reuben Tetteh Azu
Allison Blaser	Derek Haley	Josephine Rivera	Richard Reyes
Alondra Regalado	Diana Pereira	Josue Cotto	Rigoberto Rodriguez
Amaurys de Jesus Devora Tejada	Djibril Diagne	Juan Bermudez	Robert Bellucci
Andrew Murphy (On Leave)	Dominic Faiola	Juan Rosa	Robert Kuczmiec
Andrew StJean	Donny Cornish	Julio Cesar Peraza	Rochener Altidort
Andy Rodriguez	Doreen Laporte	Justice Damoah	Rodlyne Pierre Victor
Angela Rodriguez	Douglas Montgomery	Justin Shekleton	Ronaldo Baptiste
Annie Sutkowski	Douglas Wright	Kaitlyn Oconnor	Roosbert Peralta
Anny Quelix Vargas	Edgar Jacob	Karina V. Haidar de	Rose maria Atwi
Anthony Tamburro	Eduardo Perez	Katherine Minaya	Ryan Rodriguez
Ariel Lara	Eimis Hernandez	Kathyria Pérez Rivera	Sam Parke
Artur Dibra	Elianise Sejour	Kausila Bastola	Samantha Sicola
Austin Reed	Elis Murati	Kelvin Martinez	Santa Rai
Belinda Sackeyfio Quaye	Elvia Urizar	Kenneth Murray	Scott Kennedy
Benjamin Calderon	Eric Berlo	Keren Castillo	Shawn McCollim
Brad Rheaume	Eric Trznadel	Kevin Infante	Sonal Patel
Brandon Brodeur	Esteban Contreras	Kym Sizemore	Sonia Samedy
Brandon Leung	Fabiana Semeco	Lia Olsborg	Steve Pennie
Brian Gagnon	Fabiola Semeco	Lina Santos (On Leave)	Suk Tamang
Brian Jimenez	Francis Anim [C]	Lisa Barney	Taylor Peak
Brian Marron	Francis Maleakas	Louis Piscitani (On	Theodore Walker (On
Brian Silbor (On Leave)	Francis Wiafe	Lucas Arantes	Thiago Calmon
Brian Tokarski	Frankie Andujar	Luis Pereira	Thomas Decoste
Bryan Brunelle (On Leave)	George Eazsol	Malary Jean François	Thomas Evers
Bryan Ketron	German Giovanni Garcia Narvaez	Marcia Da Silva Sena	Thomas Rivers
Carlos Fernandez	Gisela Sierra (On Leave)	Margli Orellana	Tiffany Preston
Carlos Paez	Godson Keteni	Maria Asuaje	Todd Benoit
Cedric Jones	Hanin Noori	Maria del Pilar Duran	Travis Morton
Celia Lucas Monteiro	Hansen Romey	Maria Guaman (On	Umberto Dias
Chakira Sena	Harshad Patel	Marta Lopez	Vladimir Rojas
Charles Murray (On Leave)	Heather Henning	Matthew Silverman	Walter Dimeo
Christopher Henault	Hirenkumar Patel	Matthew von Jess	Wayne Pare
Christopher OBrien	Hon Heng	Maximo Jimenez	Wes Boazman
Chudamuni Bhujel	Ian Decew	Melodie Dean	Williams Ababio
Cinthia Made	Inoel Paula-Molina	Michael Christian	Winfred Abbey
Claudia Hoyos	Jamie Weldin	Michael Legere	Yaw Boakye
Cliff Gerring	Jared Washburn	Michael Panagiotou	Yoselyn Andrea Cueto
Cody Stone	Jarvey Ruiz Morales	Miquel Alejos	Yudi Barrero
Craig Baird	Jeffrey Reynolds	Mike Pyle	
Craig Mayer	Jeremy Urella	Mohammad Khan	
Cristopher Pillco	Jerome Jusler	Moises Vasquez	
Dan Fedler	Jeronimo Macario	Monica Freitas	

COPY OF McKESSON CORPORATION SEC 10K

*McKesson Corporation is the ultimate parent company of the applicant entity

**Excerpt only. Full report is available online: https://investor.mckesson.com/quarterly-results

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended March 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from_____ to_____

Commission File Number: 1-13252



McKESSON CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**94-3207296**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

6555 State Hwy 161,
Irving, TX 75039

(Address of principal executive offices, including zip code)

(972) 446-4800

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

(Title of each class)	*(Trading Symbol)*	*(Name of each exchange on which registered)*
Common stock, $0.01 par value	MCK	New York Stock Exchange
1.500% Notes due 2025	MCK25	New York Stock Exchange
1.625% Notes due 2026	MCK26	New York Stock Exchange
3.125% Notes due 2029	MCK29	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter, September 30, 2024, was approximately $62.7 billion.

Number of shares of common stock outstanding on April 30, 2025: 125,112,236

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its calendar year 2025 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

McKESSON CORPORATION

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McKESSON CORPORATION

PART I

Item 1. Business.

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General

McKesson Corporation together with its subsidiaries (collectively, the "Company," "McKesson," "we," "our," or "us" and other similar pronouns), which traces its business roots to 1833, is a diversified healthcare services leader dedicated to advancing health outcomes for patients everywhere. Our teams partner with biopharma companies, care providers, pharmacies, manufacturers, governments, and others to deliver insights, products, and services to help make quality care more accessible and affordable.

The Company's fiscal year begins on April 1 and ends on March 31. Unless otherwise noted, all references in this document to a particular year refers to the Company's fiscal year. The Company was incorporated on July 7, 1994 in the State of Delaware.

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), are available free of charge on the Company's website (www.mckesson.com under the "Investors — Financials — SEC Filings" caption) as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission ("SEC"). The content on any website referred to in this Annual Report on Form 10-K ("Annual Report") is not incorporated by reference into this report, unless expressly noted otherwise. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC. The address of the website is www.sec.gov.

Business Segments

The Company operates its business in four reportable segments: U.S. Pharmaceutical, Prescription Technology Solutions ("RxTS"), Medical-Surgical Solutions, and International.

Our U.S. Pharmaceutical segment distributes branded, generic, specialty, biosimilar and over-the-counter ("OTC") pharmaceutical drugs, and other healthcare-related products in the United States ("U.S."). This segment also provides practice management, technology, clinical support, and business solutions to community-based oncology and other specialty practices. In addition, the segment sells financial, operational, and clinical solutions to pharmacies (retail, hospital, alternate sites) and provides consulting, outsourcing, technological, and other services.

Our RxTS segment helps solve medication access, affordability and adherence challenges for patients by working across healthcare to connect patients, pharmacies, providers, pharmacy benefit managers, health plans, and biopharma companies. RxTS serves our biopharma and life sciences partners, delivering innovative solutions that help people get the medicine they need to live healthier lives. RxTS offers technology services, which includes electronic prior authorization, prescription price transparency, benefit insight, and dispensing support services, in addition to third-party logistics and wholesale distribution support designed to benefit stakeholders.

Our Medical-Surgical Solutions segment provides medical-surgical supply distribution, logistics, and other services to healthcare providers, including physician offices, surgery centers, nursing homes, hospital reference labs, and home health care agencies. We offer more than 245,000 national brand medical-surgical products as well as McKesson's own line of high-quality products through a network of distribution centers in the U.S.

Our International segment provides distribution and services to wholesale, institutional, and retail customers in Canada and Norway where we own, partner, or franchise with retail pharmacies, and support better, safer patient care by delivering vital medicines, supplies, and information technology solutions. During fiscal 2025, we completed the sale of Rexall and Well.ca businesses in Canada. Refer to Financial Note 2, "Business Acquisitions and Divestitures," to the consolidated financial statements included in this Annual Report for more information.

U.S. Pharmaceutical Segment:

Our U.S. Pharmaceutical segment provides distribution and logistics services for branded, generic, specialty, biosimilar, and OTC pharmaceutical drugs along with other healthcare-related products to customers. This business provides solutions and services to pharmacies, hospitals, oncology and other specialty practices, pharmaceutical manufacturers, biopharma partners, physicians, payors, and patients throughout the U.S. We also source generic pharmaceutical drugs through our ClarusONE Sourcing Services LLP joint venture with Walmart Inc. ("ClarusONE").

Our U.S. Pharmaceutical segment operates and serves customers through a network of 27 distribution centers in the U.S., including two strategic redistribution centers. We invest in technology and other systems at all of our distribution centers to enhance safety, reliability, and product availability. For example, we offer McKesson Connect℠, an internet-based ordering system that provides item look-up and real-time inventory availability as well as ordering, purchasing, third-party reconciliation, and account management functionality. We make extensive use of technology as an enabler to ensure customers have the right products at the right time in the right place.

To maximize distribution efficiency and effectiveness, we follow the Six Sigma methodology, which is an analytical approach that emphasizes setting high-quality objectives, collecting data, and analyzing results to a fine degree in order to improve processes, reduce costs, and enhance service accuracy and safety. We provide solutions to our customers including supply management technology, world-class marketing programs, managed care, repackaging products, and services to help them meet their business and quality goals. We continue to implement information systems to help achieve greater consistency and accuracy both internally and for our customers, as well as make investments to increase capacity and automation.

We have four primary customer pharmaceutical distribution channels: (i) retail national accounts, which include national and regional retail chains, food and drug combinations, mail order pharmacies, and mass merchandisers, (ii) community pharmacies and health (formerly described as independent, small, and medium chain retail pharmacies), (iii) institutional healthcare providers such as hospitals, health systems, integrated delivery networks, and long-term care providers, and (iv) oncology, biopharma, and other specialty partners.

Retail National Accounts: We provide business solutions that help our retail national account customers increase revenues and profitability. Solutions include:

- Central Fill℠ – Prescription refill service that enables pharmacies to more quickly refill prescriptions remotely, more accurately, and at a lower cost, while reducing inventory levels and improving customer service.
- Strategic Redistribution Centers – Two facilities totaling over 740,000 square feet that offer access to inventory for single source warehouse purchasing, including pharmaceuticals and biologics. These distribution centers also provide the foundation for a two-tiered distribution network that supports best-in-class direct store delivery.
- McKesson SynerGx® – Generic pharmaceutical purchasing program and inventory management that helps pharmacies maximize their cost savings with a broad selection of generic drugs, competitive pricing, and one-stop shopping.
- Inventory Management – An integrated solution comprised of forecasting software and automated replenishment technologies that reduce inventory-carrying costs.
- ExpressRx Track™ – Pharmacy automation solution featuring state-of-the-art robotics, upgraded imaging, and expanded vial capabilities, and industry-leading speed and accuracy in a small footprint.

Community Pharmacy and Health: We strengthen the overall health of community pharmacies and elevate the role they play in people's lives. We accomplish this by providing supply chain excellence, pharmacy and patient solutions, as well as supporting independent pharmacies through industry and legislative advocacy. Our pharmacy and patient solutions include:

- Health Mart® – A national network of approximately 4,400 independently-owned pharmacies and one of the industry's most comprehensive pharmacy franchise programs. Health Mart provides solutions for franchisees to promote excellence in business operations, team development, patient health, marketing and merchandising, and protects financial health through proactive audit support.
- Health Mart Atlas® and Atlas Specialty – Comprehensive managed care services that connect the continuum of care to help community pharmacies, health systems and physician practices save time, access competitive reimbursement rates, and improve cash flow.
- McKesson Reimbursement Advantage℠ ("MRA") – MRA is one of the industry's most comprehensive reimbursement optimization packages, comprising financial services (automated claim resubmission), analytic services, and customer care.
- McKesson Provider Pay® – Provider Pay is an automated reconciliation and payment management solution designed to maximize third-party cash flow and pursue unpaid claims.
- McKesson Amplify – Provides resources for state pharmacy associations in all 50 states, including dedicated support funding, resources, and opportunities to participate in best practice sharing consortia. The funding helps to support advocacy initiatives that address the unique challenges faced by independent pharmacies and promote their sustainability and growth.
- McKesson OneStop Generics® – Generic pharmaceutical purchasing program that helps pharmacies maximize their cost savings with a broad selection of generic drugs, competitive pricing, and one-stop shopping.
- Pinpoint Community Solutions – McKesson's perpetual inventory management system targeted to independent pharmacy owners with five or fewer stores. The solution provides customers the opportunity to improve cash flow and increase efficiency with inventory visibility to help maximize operational performance.
- FrontEdge™ – Strategic planning, merchandising, and price maintenance program that helps community pharmacies maximize store profitability.
- McKesson RxOwnership Program – A confidential, no-fee resource for pharmacists and pharmacy owners interested in buying, starting, or selling an independent pharmacy, regardless of their pharmacy affiliation.

Institutional Healthcare Providers: At McKesson, we are relentless in our pursuit of opportunities to achieve operational efficiency, reduce waste, and improve the financial performance of our customers so they can achieve more of their goals today and into the future. Solutions include:

- Professional and Advisory Services – Comprehensive suite of advisory and consulting services designed to support health system business of pharmacy initiatives, including patient care, business operations, ambulatory services, inpatient operations, data and digitization, pharmacy workforce management, leadership, and compliance with safety, quality, and regulatory standards. Specialized consulting areas include 340B optimization, orphan drug support and retail pharmacy payer solutions.
- McKesson Plasma and Biologics – Specialty and plasma drug distributor that leads in market exclusive drug access; partner to health systems customers in navigating the complexities of limited distribution drug; and optimization of McKesson Distribution benefits.
- Outpatient, Retail, and Specialty Pharmacy – A portfolio of services and solutions customized to each customer's business and clinical strategy.
- Contracting and Contract/Purchasing Optimization – Solutions across generics, specialty, branded products, biosimilars, and 340B products, for inpatient and outpatient settings.
- Supply Assurance – Solutions and strategies to enhance product availability and proactively manage inventory of critical items.

The U.S. Pharmaceutical segment also offers solutions which enable its customers to drive greater efficiencies in their day-to-day operations, effectively managing their inventories and complying with complex government regulations. Solutions include McKesson Pharmacy Systems, MacroHelix, and Supply Logix, all of which provide innovative software technology and services that support retail pharmacies and hospitals.

Oncology, Biopharma, and Other Specialty Partners:

The U.S. Pharmaceutical segment provides a range of solutions to oncology and other specialty practices and offers community specialists (oncologists, rheumatologists, ophthalmologists, urologists, neurologists, and other specialists) an extensive set of customizable solutions and services designed to strengthen core practice operations, enhance value-based care delivery, and expand their service offering to patients. Community-based physicians in this business have broad flexibility and discretion to select the products and commitment levels that best meet their practice needs. Services in provider solutions include specialty drug distribution, group purchasing organizations ("GPO") like Onmark®, technology solutions, practice consulting services, and vaccine distribution, including our exclusive distributor relationship with the Centers for Disease Control and Prevention's ("CDC") Vaccines for Children program.

This business provides a variety of solutions, including practice operations, healthcare information technology, revenue cycle management and managed care contracting solutions, evidence-based guidelines, and quality measurements to support The U.S. Oncology Network ("USON"), one of the nation's largest networks of physician-led, integrated, community-based oncology practices dedicated to advancing high-quality, evidence-based cancer care. SCRI Oncology, LLC, an oncology research business in which we own a 51% controlling interest, is one of the nation's largest research networks and specializes in enhancing clinical trial access and availability across the country.

This segment includes Ontada®, McKesson's oncology technology and insights business providing software to support the clinical, financial, and operational needs of our oncology practice customers. Ontada also partners with oncology providers and biopharma partners to perform real-world evidence studies, retrospective research, and to provide clinical data insights, advisory solutions and education opportunities.

When we discuss specialty products or services, we consider the following factors: diseases requiring complex treatment regimens such as cancer and rheumatoid arthritis; plasma and biologics products; ongoing clinical monitoring requirements, high-cost, special handling, storage, and delivery requirements and, in some cases, exclusive distribution arrangements. Our use of the term "specialty" may not be comparable to that used by other industry participants, including our competitors.

Prescription Technology Solutions Segment:

Our Prescription Technology Solutions segment works across healthcare to connect patients, pharmacies, providers, pharmacy benefit managers, health plans, and biopharma to deliver medication access solutions that support patients from first prescription fill to ongoing therapy, regardless of their insurance coverage. RxTS has connections with most electronic health record systems, over 50,000 pharmacies, approximately 950,000 providers, most pharmacy benefit managers and health plans, and has supported over 650 biopharma brands representing most therapeutic areas. Through its industry connections and ability to navigate the healthcare ecosystem, RxTS offers innovative solutions created to benefit healthcare stakeholders. Its comprehensive solution suites and technology services span across the entire patient journey, including medication access and affordability, prescription decision support, prescription price transparency, benefit insight and dispensing support services, as well as third-party logistics and wholesale distribution support, to help increase speed to therapy, reduce prescription abandonment, and support improved health outcomes for the patient. In the past year, RxTS helped patients save more than $10 billion on brand and specialty medications, helped to prevent an estimated 12 million prescriptions from being abandoned due to affordability challenges, and helped patients access their medicine more than 100 million times.

Medical-Surgical Solutions Segment:

Our Medical-Surgical Solutions segment delivers medical-supply distribution, logistics, biomedical maintenance, and other services to healthcare providers across the alternate-site spectrum. Our more than 340,000 customers include physician offices, surgery centers, post-acute care facilities, hospital reference labs, and home health agencies. We partner with manufacturers and channel partners to support our key target end-markets, including primary care, extended care, government, and other markets. We distribute medical-surgical supplies (such as gloves, needles, syringes, and wound care products), infusion pumps, laboratory equipment, and pharmaceuticals. Through a network of distribution centers in the U.S., we offer more than 245,000 products from national brand manufacturers and McKesson's own brand of high-quality products. Through the right mix of products and services, we help improve efficiencies, profitability, and compliance. We also never lose focus on helping customers improve patient and business outcomes. We develop customized plans to address the product, operational, and clinical support needs of our customers, including inventory management, reducing administrative burdens, and training and educating clinical staff. We deliver for our customers, so they can deliver and care for their patients. In May 2025, the Company announced its intention to separate this segment into an independent company.

International Segment:

Our International segment includes operations in Canada and Norway. McKesson Canada is one of the largest pharmaceutical wholesale and retail distributors in Canada. The wholesale business delivers products to retail pharmacies, hospitals, long-term care centers, clinics and institutions in Canada through a national network of distribution centers and provides logistics and distribution services for manufacturers.

Beyond wholesale pharmaceutical logistics and distribution, McKesson Canada provides automation and technology solutions to its retail and hospital customers. Additionally, McKesson Canada provides comprehensive specialty health services to Canadians and provides biopharma services to manufacturers, including a national network of specialty pharmacies, personalized patient care and support programs, and INVIVA, Canada's first and largest accredited network of private infusion clinics. McKesson Canada also owns and operates PDCI, Canada's leading market access consultancy, supporting manufacturers as they introduce new products into the Canadian market.

The Canada retail business includes approximately 2,700 banner pharmacies under the IDA®, Guardian®, The Medicine Shoppe®, Remedy'sRx®, Proxim®, and Uniprix® banners. During fiscal 2025, we completed the previously announced transaction to sell our Rexall and Well.ca businesses. This divestiture is further described in Financial Note 2, "Business Acquisitions and Divestitures," to the consolidated financial statements included in this Annual Report.

In July 2021, we announced our intention to exit our businesses in Europe. We divested the majority of our European businesses during fiscal 2022 and fiscal 2023. Our remaining operations in Europe provide distribution and services to wholesale and retail customers in Norway where we own, partner, or franchise with retail pharmacies. We continue to evaluate suitable exit alternatives for our retail and distribution businesses in Norway. Refer to Financial Note 2, "Business Acquisitions and Divestitures," to the consolidated financial statements included in this Annual Report for additional information on our European divestitures.

Investments, Restructuring, Business Combinations, and Divestitures

We invest in new and existing distribution centers to increase scale and capacity, improve efficiency through automation and technology, and enhance regulatory compliance capabilities. Additionally, we invest in data and analytics to support our growth priorities, including artificial intelligence ("AI"). We are in the early stages of exploring potential AI capabilities and related data and analytics across our enterprise to improve productivity and efficiency, as well as enhance our products and services to better support patients, employees, and customers.

We have undertaken additional strategic initiatives in recent years designed to increase operational efficiencies, focus on our core healthcare businesses, execute our business strategy, and enhance our competitive position. These initiatives are detailed in Financial Note 2, "Business Acquisitions and Divestitures," and Financial Note 3, "Restructuring, Impairment, and Related Charges, Net," to the consolidated financial statements included in this Annual Report.

Competition

We operate in highly competitive environments in North America and Norway. In recent years, the healthcare industry has been subject to increasing consolidation. In the pharmaceutical distribution environment in which our U.S. Pharmaceutical and International segments operate, we face strong competition from international, national, regional, and local full-line, short-line, and specialty distributors, service merchandisers, self-warehousing chain drug stores, manufacturers engaged in direct distribution, third-party logistics companies, and large payer organizations. We consider our largest competitors in distribution, wholesaling, and logistics to be Cencora, Inc. and Cardinal Health, Inc.

Our RxTS business experiences substantial competition from many companies, including other biopharma services companies, software services firms, consulting firms, shared service vendors, and internet-based companies with technology applicable to the healthcare industry. Competition in this business varies in size from large to small companies, in geographical coverage, and in scope and breadth of products and services offered.

Our Medical-Surgical Solutions segment experiences competition from a wide range of national and regional medical supply and equipment distributors throughout the U.S.

In addition, we compete with other service providers and healthcare manufacturers, as well as other potential customers of our businesses, which may from time to time decide to develop, for their own internal needs, supply management capabilities that might otherwise be provided by our businesses. We believe that our scale and diversity of product and service offerings are our primary competitive advantages. In all areas, key competitive factors include price, quality of service, breadth of product lines, innovation, adoption of new and evolving technologies, and, in some cases, convenience to the customer.

Patents, Trademarks, Copyrights, and Licenses

McKesson and its subsidiaries hold patents, copyrights, trademarks, and trade secrets related to McKesson products and services. We pursue patent protection for our innovations and obtain copyright protection for our original works of authorship when such protection is advantageous. Through these efforts, we have developed a portfolio of patents and copyrights in the U.S. and worldwide. In addition, we have registered or applied to register certain trademarks and service marks in the U.S. and in foreign countries.

We believe that, in the aggregate, McKesson's confidential information, patents, copyrights, trademarks, and intellectual property licenses are important to its operations and market position, but we do not consider any of our businesses to be dependent upon any one patent, copyright, trademark, or trade secret, or any family or families of the same. We cannot guarantee that our intellectual property portfolio will be sufficient to deter misappropriation, theft, or misuse of our technology, nor that we can successfully enjoin infringers. We periodically receive notices alleging that our products or services infringe on third-party patents and other intellectual property rights. These claims may result in McKesson entering settlement agreements, paying damages, discontinuing use or sale of accused products, or ceasing other activities. While the outcome of any litigation or dispute is inherently uncertain, we do not believe that the resolution of any of these infringement notices would have a material adverse impact on our results of operations.

We hold inbound licenses for certain intellectual property that is used internally, and in some cases, utilized in McKesson's products or services. While in the future it may be necessary to seek or renew licenses relating to various aspects of our products and services, we believe, based upon past experience and industry practice, such licenses generally can be obtained on commercially reasonable terms. We believe our operations as well as our products and services are not materially dependent on any single license or other agreement with any third party.

Human Capital

Everything we do at McKesson begins with our employees, who bring our mission and purpose to life every day. As of March 31, 2025, we had approximately 45,000 employees worldwide, which includes 2,000 part-time employees. We had approximately 36,000 employees in the U.S., 5,000 employees in Canada, and 4,000 employees in the rest of the world. We also supplement our work-force with contractors and/or consultants for certain business projects, processes, and/or operations as demand requires.

Culture and Leadership: One of McKesson's defining characteristics is our strong culture. We take pride in fostering a sense of belonging, finding meaning in our work, and caring for each other, our customers, and all those who depend on us. Our I^{2}CARE values (Integrity, Inclusion, Customer-First, Accountability, Respect, Excellence) and ILEAD leadership behaviors (Inspire, Leverage, Execute, Advance, Develop) are at the core of our daily actions – from how we interact with each other and our customers, to how we make decisions, both big and small. We also offer all employees the opportunity to join employee resource groups ("ERGs"), which are voluntary, employee-led, company-sponsored networks that aim to make a positive impact on our employees' lives. Each ERG is non-exclusive and open to every employee. Our ERGs focus on helping employees make authentic connections, celebrate and learn from each other, showcase leadership skills and find ways to nurture and support belonging and empowerment.

Investment in Employees: We are committed to investing in our employees, so that they, in turn, can focus on furthering our purpose of Advancing Health Outcomes for All®. We offer employees health and wellness benefits focused on physical, mental, and social well-being, savings programs to help prepare them for retirement and flexible work arrangements, and other offerings. We also offer employees regular training, coaching, and 360-degree assessments, and financial assistance programs for higher education opportunities.

We seek to attract and retain the best talent through competitive compensation and pay for performance, while prioritizing recognition of merit and compliance with laws. Our compensation philosophy is rooted in a fair and transparent program that regularly conducts benchmarking to assess market rates for talent, based on geography and other factors.

We solicit employee feedback through annual and mid-year employee opinion surveys, which assesses our employees' levels of engagement, commitment and overall satisfaction using industry benchmarks, and then design action plans to improve those metrics. We also seek feedback on our people leaders through our annual manager quality survey, which is an opportunity for employees to help their managers grow professionally and build valuable leadership skills that help to promote a positive and productive workplace.

Health and Safety: Our security and safety teams employ systems designed to continually monitor our facilities and work environment to help identify and prevent or mitigate risks. This includes having procedures and investing in equipment for both physical and electronic security. Our employees receive specialized training related to their role, work setting, and equipment used in their work environment.

Government Regulation

We operate in many highly regulated environments and are subject to oversight by various federal, state, and local governmental entities in the U.S. and elsewhere. We incur significant expense and make large capital expenditures and investments to enable us to comply with laws and guidance promulgated by governmental entities.

The regulatory framework affecting our business and industry is continuously evolving and influenced by conditions such as public policy developments; shifts in governmental priorities, initiatives, and focus areas, including due to changes in federal, state, and local representation; and varied interpretations of laws and agency rulemaking conventions. These conditions create uncertainties for our business, and we are unable to predict the impact of future changes to the regulatory framework, or any prolonged uncertainty, on our operations and compliance costs.

See "Risk Factors" in Item 1A of Part I below for information regarding material risks associated with our compliance with governmental regulations.

Operational Licenses and Permits; Controlled Substances: We are subject to the operating and security standards of the U.S. Drug Enforcement Administration ("DEA"), the U.S. Food and Drug Administration ("FDA"), the U.S. Department of Health and Human Services ("HHS"), the Centers for Medicare & Medicaid Services ("CMS"), various state boards of pharmacy, state health departments, and comparable agencies in the U.S. and other countries. Certain of our businesses may be required to register for permits and/or licenses with governmental agencies, depending upon the type of operations and location of product development, manufacture, distribution, and sale. For example, we are required to hold valid DEA and state-level registrations and licenses, meet various security and operating standards, and comply with the Controlled Substances Act and its accompanying regulations governing the sale, marketing, packaging, holding, distribution, and disposal of controlled substances. We maintain extensive controlled substance monitoring and reporting programs at considerable expense in order to help us meet those standards.

Government Contracts: Our contracts with governmental entities typically are subject to procurement laws that include socio-economic, employment practices, environmental protection, recordkeeping and accounting, and other requirements. These statutory and regulatory requirements complicate our business and increase our compliance burden. We are subject to audits, investigations, and oversight proceedings about our compliance with contractual and legal requirements.

Healthcare Program Regulation: Federal, state, and local governmental entities in the U.S. and elsewhere continue to strengthen their position on, and scrutiny of, practices that may indicate fraud, waste, and abuse affecting government healthcare programs such as Medicare and Medicaid. Our relationships with pharmaceutical and medical-surgical product manufacturers, healthcare providers, and other companies and individuals, as well as our provision of products and services to governmental entities, subject our business to statutes, regulations, and government guidance that are intended to prevent fraud and abuse. Among other things, those laws: (1) prohibit persons from soliciting, offering, receiving, or paying any remuneration in order to induce the referral of an individual for, or to induce the ordering or purchasing of, items or services that are in any way paid for by Medicare, Medicaid, or other government healthcare programs; (2) prohibit physicians from referring certain "designated health services" to an entity with which they have a financial relationship, unless an exception applies; and (3) prohibit knowingly submitting, or causing to be submitted, a false or fraudulent claim for payment to the government; and (4) require certain entities to report and return an overpayment by Medicare or Medicaid within 60 days of identifying the overpayment.

Many of these healthcare fraud and abuse laws are vague or indefinite and are often subject to varied and evolving interpretations by courts, regulators, and enforcing agencies and, as such, may be interpreted or applied by a prosecutorial, regulatory, or judicial authority in a manner that could require us to make changes in our operations at added expense.

In the U.S., the Patient Protection and Affordable Care Act ("ACA") significantly expanded health insurance coverage to uninsured Americans and changed the way healthcare is financed by both governmental and private payors. The implementation of the Inflation Reduction Act of 2022 ("IRA") has begun to change benefit design and how Medicare pays for drugs, which are all intended to reduce the price of drugs. Three central features of the IRA have authorized the government to negotiate drug prices for certain Parts B and D drugs over time, establish an inflation rebate program, and cap patient cost sharing under Medicare Part D.

Provincial governments in Canada that provide partial funding for the purchase of pharmaceuticals and independently regulate the sale and reimbursement of drugs have sought to reduce the costs of publicly funded health programs. For example, provincial governments have taken steps to reduce consumer prices for generic pharmaceuticals and, in some provinces, change professional allowances paid to pharmacists by generic drug manufacturers.

McKesson continues to advocate for policies that would improve drug cost transparency under a patient's drug plan to better inform prescribing decisions, and also address access to care, affordability, and treatment regimen adherence, all designed to improve clinical outcomes and reduce the health spending burden.

FDA Regulation and Supply Chain Integrity: In the U.S., the FDA is the principal federal authority that regulates the safety, efficacy, quality, testing, premarket approval, manufacture, labeling, storage, distribution, and post-market surveillance of healthcare products, such as drugs and medical devices, foods, and cosmetics.

Federal and state laws regulate the pharmaceutical drug supply chain in order to prevent the distribution of counterfeit, stolen, contaminated, or otherwise harmful prescription drugs in interstate commerce. At the federal level, the Drug Supply Chain Security Act ("DSCSA"), among other things, requires standardized, unit-level traceability of pharmaceutical products along the entire drug supply chain and requires all trading partners to cooperate in an electronic, interoperable prescription drug traceability system. In October 2024, the FDA extended the compliance deadlines for the DSCSA interoperable unit-level traceability requirements to May 27, 2025, for manufacturers, August 27, 2025 for distributors, and November 27, 2025 for dispensers. The FDA stated that these extensions apply to trading partners who meet certain conditions. The Company believes its businesses are eligible for the extensions. The DSCSA also sets forth national standards for the licensure of wholesale drug distributors and third-party logistic providers and other requirements applicable to these entities and the FDA has issued a proposed rule with respect to these requirements. These federal and state regulatory requirements have increased, and may further increase, our compliance burden and distribution costs.

Additionally, federal and state governments may adopt other laws intended to protect the integrity of the supply chain, and those laws could affect our distribution business. For example, the Federal Trade Commission ("FTC") and HHS issued a request for public comment in 2024 on how the practices of pharmaceutical wholesalers and group purchasing organizations impact generic drug shortages. Various industry stakeholders responded to this request, but no further action has been taken by the FTC or HHS.

Cybersecurity, Data Security, Privacy, and AI: We are subject to many cybersecurity, privacy, and data protection laws that change frequently and have requirements that vary from jurisdiction to jurisdiction. Our efforts to comply with these laws complicate our operations and add to our costs. We are subject to significant compliance obligations under privacy laws such as the Health Insurance Portability and Accountability Act of 1996, the General Data Protection Regulation in the European Union, the Personal Information Protection and Electronic Documents Act in Canada, and an expanding list of comprehensive state privacy laws in the U.S. Some privacy laws may prohibit the transfer of personal information to certain other jurisdictions or otherwise limit our use and disclosure of data. Many of these laws also require us to provide access or other data rights (modification, deletion, portability, etc.) to consumers' and patients' individual personal data records within specified periods of time. Cybersecurity laws such as the federal Cyber Incident Reporting for Critical Infrastructure Act of 2022, proposed changes to the Federal Acquisition Regulation, and SEC reporting requirements may require us to provide notifications of certain cybersecurity incidents within short timeframes. Regulations and guidance targeting critical infrastructure entities, including McKesson, continue to be a focus of regulators. We are subject to privacy and data protection compliance audits or investigations by various governmental agencies. There is also an emerging trend of governmental entities proposing and providing regulatory guidance related to AI, including generative AI. If we or our third-party providers are restricted from using AI as a result of any regulatory views, laws or other measures, it could impact our operations, increase our compliance expense and burden, and cause us to incur costs to replace or modify our use of AI.

Environmental Regulation: We are subject to various federal, state, local, and foreign laws concerning the environment, including laws addressing the discharge of pollutants into the air and water, the management and disposal of hazardous substances and wastes, and the cleanup of contaminated sites, as well as laws governing the operation of radiation-emitting equipment at U.S. Oncology Network practices.

We sold our chemical distribution operations in 1987 and retained responsibility for certain environmental obligations. Agreements with the U.S. Environmental Protection Agency and certain states have required and may require environmental assessments and cleanups at several closed sites. These matters are described further in Financial Note 17, "Commitments and Contingent Liabilities," to the consolidated financial statements included in this Annual Report.

Climate Change Regulation: Governments in the U.S. and abroad have adopted or are considering new or expanded policies and laws to address climate change. Such policies and laws may necessitate reductions in greenhouse gas ("GHG") emissions; mandate that companies implement processes and controls to monitor and disclose climate-related matters; and impose additional taxes or offset charges on specified energy sources, among other requirements. Compliance with climate-related policies and laws may be further complicated by disparate regulatory approaches in various jurisdictions. Methodologies for reporting climate-related information may change and previously reported information may be retroactively adjusted, if required. New or expanded climate-related policies and laws could impose costs on us, including capital expenditures to develop data gathering and reporting systems, third-party attestations, and additional GHG reduction measures. Until the timing and extent of climate-related policies and laws are clarified, including due to legal challenges, we cannot predict their potential effect on our capital expenditures, results of operations, or competitive position.

Antitrust Laws: Antitrust and competition laws in the U.S. and elsewhere prohibit types of conduct deemed to be anti-competitive. Antitrust enforcement in the healthcare industry remains a focus of the FTC and the U.S. Department of Justice. Some of our strategic transactions may require review by competition regulators, with inherent delays. Violations of the antitrust laws can result in sanctions and other adverse actions, including criminal and civil penalties. Private plaintiffs also may bring civil lawsuits for alleged antitrust law violations, including claims for treble damages. These laws contribute to our compliance efforts and expense, and their enforcement might materially adversely affect our operations and growth strategy.

Other Information about the Business

Customers: During fiscal 2025, sales to our ten largest customers, including group purchasing organizations ("GPOs") accounted for approximately 72% of our total consolidated revenues. Sales to our largest customer, CVS Health Corporation ("CVS"), accounted for approximately 24% of our total consolidated revenues in fiscal 2025. In fiscal 2023, we extended our pharmaceutical distribution partnership with CVS to June 2027. Our ten largest customers comprised approximately 48%, and CVS was approximately 23% of our total trade accounts receivable at March 31, 2025. We also have agreements with GPOs, each of which functions as a purchasing agent on behalf of member hospitals, pharmacies, and other healthcare providers, as well as with government entities and agencies. The accounts receivable balances are with individual members of the GPOs, and therefore no significant concentration of credit risk exists. Substantially all of these revenues and accounts receivable are included in our U.S. Pharmaceutical segment.

Suppliers: We obtain pharmaceutical and other products from manufacturers and our largest supplier accounted for 11% of our total purchases in fiscal 2025. The loss of a supplier could adversely affect our business if alternate sources of supply are unavailable. We believe that our relationships with our suppliers are generally sound. The ten largest suppliers in fiscal 2025 accounted for approximately 69% of our total purchases.

Some of our distribution arrangements with manufacturers provide us consideration based on a percentage of our purchases. In addition, we have certain distribution arrangements with pharmaceutical manufacturers that include an inflation-based consideration component whereby we benefit when the manufacturers increase their prices as we sell our existing inventory at the new higher prices. For these manufacturers, a reduction in the frequency and magnitude of price increases, as well as restrictions in the amount of inventory available to us, could have an adverse impact on our gross profit margin.

Research and Development: Research and development expenses were $91 million, $77 million, and $89 million for the years ended March 31, 2025, 2024, and 2023, respectively.

Financial Information About Foreign and Domestic Operations: Certain financial information relating to foreign and domestic operations is discussed in Financial Note 20, "Segments of Business," to the consolidated financial statements included in this Annual Report as well as in "Foreign Operations" in Item 7 of Part II of this Annual Report. See "Risk Factors" in Item 1A of Part I below for information regarding risks associated with our foreign operations.

Forward-Looking Statements

This Annual Report, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of Part II of this report and the "Risk Factors" in Item 1A of Part I of this report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 ("Securities Act") and Section 21E of the Exchange Act. Forward-looking statements may be identified by their use of terminology such as "believes," "expects," "anticipates," "may," "will," "should," "seeks," "approximately," "intends," "projects," "plans," "estimates," "targets," or the negative of these words or other comparable terminology. The discussion of trends, strategy, plans, prospects, assumptions, expectations, or intentions may also include forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected, anticipated, or implied. Although it is not possible to predict or identify all such risks and uncertainties, they include, but are not limited to, the factors discussed in Item 1A of Part I of this report under "Risk Factors" and in our publicly available SEC filings and press releases. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date such statements were first made. Except to the extent required by federal securities laws, we undertake no obligation to publicly release the result of any revisions to any forward-looking statements to reflect events or circumstances after the date the statements are made, or to reflect the occurrence of unanticipated events.

Available Information

We routinely post on our company website, and via our social media channels, information that may be material to investors, including details and updates to information disclosed elsewhere, which may include business developments, earnings and financial performance, sustainability matters, details regarding upcoming events, and materials for presentations to investors and financial analysts. Investors are encouraged to monitor our website www.mckesson.com. Interested parties can sign up on our website, including our Investor Relations site, to receive automated e-mail alerts, such as via RSS newsfeed, when we post certain information. Interested parties can also follow our social media feed @McKesson on X, formerly known as Twitter. The content on any website or social media channel is not incorporated by reference into this report, unless expressly noted otherwise.

Item 1A. Risk Factors.

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The discussion below identifies certain representative risks that might cause our actual business results to materially differ from our estimates. It is not practical to identify or describe all risks and uncertainties that might materially impact our business operations, reputation, financial position, or results of operations. Our business could be materially affected by risks that we have not yet identified or that we currently consider to be immaterial. This is not a complete discussion of all potential risks and uncertainties.

Litigation and Regulatory Risks

We experience costly and disruptive legal disputes.

We are routinely named as a defendant in litigation or regulatory proceedings and other legal disputes, which may include asserted class action litigation, such as those described in Financial Note 17, "Commitments and Contingent Liabilities," to the consolidated financial statements included in this Annual Report. Regulatory proceedings involve allegations such as false claims, healthcare fraud and abuse, and antitrust violations. Civil litigation proceedings involve commercial, employment, environmental, intellectual property, tort, and other claims. Despite valid defenses that we assert, legal disputes are often costly, time-consuming, distracting to management, and disruptive to normal business operations. The uncertainty and expense associated with unresolved legal disputes might harm our business and reputation even if the matter ultimately is favorably resolved. The outcome of legal disputes is difficult to predict, and outcomes may occur that we believe are not justified by the evidence or existing law. Outcomes include monetary damages, penalties and fines, and injunctive or other relief that requires us to change our business operations and incur significant expense. Accordingly, legal disputes might have a materially adverse impact on our reputation, our business operations, and our financial position or results of operations.

We experience losses not covered by insurance or indemnification.

Our business exposes us to risks that are inherent in the distribution, manufacturing, dispensing, and administration of pharmaceuticals and medical-surgical supplies, the provision of ancillary services, the conduct of our payer businesses, practice support services, and the provision of products that assist clinical decision-making and relate to patient medical histories and treatment plans. For example, pharmacy operations are exposed to risks such as improper filling of prescriptions, mislabeling of prescriptions, inadequacy of warnings, unintentional distribution of counterfeit drugs, and expiration of drugs. Although we seek to maintain adequate insurance coverage, such as property insurance for inventory and professional and general liability insurance, coverages on acceptable terms might be unavailable, or coverages might not cover our losses. We generally seek to limit our contractual exposure, but limitations of liability or indemnity provisions in our contracts may not be enforceable or adequately protect us from liability. Uninsured or non-indemnified losses might have a materially adverse impact on our business operations and our financial position or results of operations.

We experience costly legal disputes, government actions, and adverse publicity regarding our role in distributing controlled substances such as opioids.

The Company is a defendant in many litigation matters alleging claims related to the distribution of controlled substances (opioids), as described in Financial Note 17, "Commitments and Contingent Liabilities," to the consolidated financial statements in this Annual Report. We are sometimes named as a defendant in similar, new cases. The plaintiffs in those cases include governmental entities (such as states, provinces, counties, and municipalities) as well as businesses, groups, and individuals. The cases allege violations of controlled substance laws and other laws, and they make common law claims such as negligence and public nuisance. Many of these cases raise novel theories of liability and can have unexpected outcomes that we believe are not justified by evidence or existing law. Legal proceedings such as these often involve significant expense, management time and distraction, and risk of loss that can be difficult to predict or quantify. It is not uncommon for claims to be resolved over many years. Outcomes include monetary damages, penalties and fines, and injunctive or other relief that requires us to change our business operations and incur significant expense. Although the Company has valid defenses and is vigorously defending itself, some proceedings have been, and others may be, resolved by negotiated outcome. For example, we are subject to consent decrees issued by state courts that govern our distribution of controlled substances. Not all proceedings, however, are resolved by settlement. Our reputation has been and may continue to be impacted by publicity regarding opioids litigation and related allegations. An adverse outcome of any such legal proceedings might have a materially adverse impact on our business operations and our financial position or results of operations.

We experience increased costs to distribute controlled substances such as opioids.

Legislative, regulatory, or industry measures related to the distribution of controlled substances such as prescription opioids could affect our business in ways that we may not be able to predict. For example, some states have passed legislation that could require us to pay taxes or assessments on the distribution of opioid medications in those states and other states have considered similar legislation. Liabilities for taxes or assessments or other costs of compliance under any such laws might have a materially adverse impact on our reputation, our business operations, and our financial position or results of operations.

We are subject to extensive, complex, and challenging healthcare, environmental, and other laws.

As described in "Government Regulation" in Item 1 of Part I above, our industry is highly regulated, and further regulation of our distribution businesses, technology products, and services could impose increased costs, negatively impact our profit margins and the profit margins of our customers, delay the introduction or implementation of our new products, or otherwise negatively impact our business and expose the Company to litigation and regulatory investigations. We incur cleanup costs under environmental laws and may incur additional costs under environmental laws. Additionally, we are subject to various routine and ad hoc inspections and requests for information by governmental agencies to determine compliance with various statutes and regulations. Any noncompliance by us with applicable laws, or the failure to maintain, renew, or obtain necessary permits and licenses, could lead to enforcement actions or litigation and might have a materially adverse impact on our business operations and our financial position or results of operations.

We are subject to extensive and frequently changing laws relating to healthcare fraud, waste, and abuse.

As described in "Government Regulation" in Item 1 of Part I above, federal, state, and local governmental entities in the U.S. and elsewhere continue to strengthen their position on, and scrutiny of, practices that may indicate fraud, waste, and abuse affecting government healthcare programs such as Medicare and Medicaid. Those laws may be interpreted or applied in a manner that could require us to make changes in our operations at added expense. Alleged failures to comply with those laws, including the federal Anti-Kickback Statute, expose us to federal or state government investigations or qui tam actions, and to liability for damages and civil and criminal penalties. Such failures might result in the loss of licenses or our ability to participate in Medicare, Medicaid, or other federal and state healthcare programs, or pursue government contracts. These sanctions might have a materially adverse impact on our business operations and our financial position or results of operations.

We might lose our ability to purchase, store, or distribute pharmaceuticals, including controlled substances, and medical products.

As described in "Government Regulation" in Item 1 of Part I above, we are subject to the operating, quality, regulatory, and security requirements of the DEA, the FDA, various state boards of pharmacy, state health departments, CMS, and other agencies. Noncompliance with these requirements can result in inspectional observations, warning letters, product recalls, withdrawals or other market action, fines, seizures, injunctions, and other administrative, civil, and criminal enforcement actions. Noncompliance, enforcement actions or adverse decisions by regulators, or the inability to obtain, maintain, or renew permits, licenses, or other regulatory approvals needed for the operation of our businesses might have a materially adverse impact on our reputation, our business operations and our financial position or results of operations.

Privacy, cybersecurity, data protection, and AI laws increase our compliance burden.

As described in "Government Regulation" in Item 1 of Part I above, we are subject to a variety of privacy, cybersecurity, data protection, and AI laws that change frequently and have requirements that vary from jurisdiction to jurisdiction. Failure to comply with these laws subjects us to potential regulatory enforcement activity, fines, private litigation including class actions, reputational impacts, and other costs. We also have contractual obligations that might be breached if we fail to comply with privacy and data security laws. The use of AI solutions by our employees or third parties on which we rely could also lead to the misuse of data or public disclosure of confidential information (including personal data or proprietary information) in contravention of our internal policies, applicable laws, contractual requirements, or third-party intellectual property rights. Our efforts to comply with privacy, data security, and AI laws complicate our operations and add to our costs. A significant cybersecurity and/or privacy breach or failure to comply with privacy and data security laws, by us or by external service providers, vendors, or other third parties with which we do business, might have a materially adverse impact on our reputation, our business operations, and our financial position or results of operations.

Anti-bribery and anti-corruption laws increase our compliance burden.

We are subject to laws prohibiting improper payments and bribery, including the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act, and similar regulations in other jurisdictions. Our failure to comply with these laws might subject us to civil and criminal penalties that might have a materially adverse impact on our reputation, our business operations, and our financial position or results of operations.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Please see the attached summary of disciplinary actions and the related settlement agreements.

Original Signature (electronic, copies or stamps not accepted)

01OCT2025

Date

Please note that the disciplinary actions described below do NOT pertain to operations at the location set forth in this application.

McKesson Corporation and its wholly owned subsidiaries (hereinafter "McKesson") delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 100 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. We have limited this summary to disciplinary actions taken against these facilities during the time frame specified in the question or the last six years in accordance with McKesson Corporation's Records and Information Management (RIM) Policy. ***The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions. This statement does not include any fines that are deemed non-disciplinary by the issuing state (for example, it does not include non-disciplinary Citations and Fines issued by California). Please let us know if your state requires information regarding non-disciplinary fines.***

On January 7, 2020, **McKesson Corporation** entered into a Consent Agreement and Final Order with the Iowa Board of Pharmacy regarding pseudoephedrine products that had not been included in the McKesson's Clear Lake, IA facility's annual controlled substance inventory and butalbital products that continued to be treated as legend drugs after such products became schedule III products in the state on June 26, 2019 (the "2020 Clear Lake Consent").

On February 20, 2020, in response to the DEA Settlement, McKesson Corporation entered into a final agreement with the Indiana Board of Pharmacy. The agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Indiana has been placed on indefinite probation until the facility's DEA Registration is fully re-instated on or about February 16, 2021. The suspension period imposed by Indiana aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 22, 2021, in response to the DEA Settlement, **McKesson Corporation** entered into a final agreement with the Illinois Department of Financial and Professional Regulation. The Illinois Consent Order applies to the McKesson distribution centers located in Aurora, Colorado, Livonia, Michigan and Washington Court House, Ohio.

- Aurora, Colorado - the facility's Illinois controlled substance was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2020 except for various exceptions that mirror exceptions in the DEA settlement;

- Livonia, Michigan - the facility's Illinois controlled substance was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2019 except for various exceptions that mirror exceptions in the DEA settlement; and

- Washington Court House, Ohio - the facility's Illinois controlled substance was restricted. The facility was prohibited from distributing controlled substances into the state until 1/18/2021 except for various exceptions that mirror exceptions in the DEA settlement.

On May 27, 2021, **McKesson Corporation** entered into a consent agreement with the Maine Board of Pharmacy regarding its Aurora, IL distribution center failing to report the Colorado disciplinary action to the Maine Board of Pharmacy within 10 days as required. The Colorado disciplinary action is now reported to the Maine Board of Pharmacy. The terms of the consent agreement included a fine in the amount of $500.00.

On October 1, 2021, **McKesson Corporation** ("McKesson") entered into a non-disciplinary agreement with the Connecticut Department of Consumer Protection, regarding its Memphis, TN distribution center. The agreement resolves allegations that, from January 2015 - January 2021, McKesson sold controlled substances to a practitioner that did not have an active Connecticut Controlled Substances Certificate of Registration. McKesson made no admission of liability and there were no findings of any violation of law. A monetary penalty of $4,500 was imposed.

On October 14, 2021, in response to the DEA Settlement, **McKesson Corporation** entered into a Settlement Agreement with the Ohio Board of Pharmacy (the "WCH Ohio Settlement"). The WCH Ohio Settlement applies to the McKesson distribution center located in Washington Court House, Ohio. The Ohio Settlement also resolved allegations of suspicious order reporting violations related to sales occurring between 2011 and 2017. Under the terms of terms of the WCH Ohio Settlement, there were no findings of any violation of law and McKesson made no admissions to the same. McKesson was subject to a reprimand and a fine of twenty-thousand dollars ($20,000).

On December 20, 2021, **McKesson Corporation** entered into a Consent Order with the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation (the "IDFPR") based on reciprocal state action from the 2020 Clear Lake Consent. The Illinois Consent applied to McKesson's Clear Lake, IA distribution center. Under the terms of the Illinois Consent Order, the facility was subject to a public reprimand by the IDFPR.

On March 24, 2022, **McKesson Corporation** and the California Board of Pharmacy (the "Board") entered into a settlement agreement which resolved allegations against McKesson relating to the sale of controlled substances in 2017 and 2018 to an outpatient hospital pharmacy that the pharmacy discovered were being stolen by a pharmacy employee. Pursuant to the settlement agreement, the Board publicly reproved McKesson's Santa Fe Springs distribution center permit, and McKesson agreed to pay the board's costs related to the investigation and enforcement of the matter. As set forth in the settlement agreement, McKesson denies any allegation that it violated California laws regarding the distribution of controlled substances and there are no findings of any violation of state or federal laws.

On July 22, 2023, **McKesson Corporation**'s Santa Fe Springs, CA distribution center entered into a Consent Order with the Alabama Board of Pharmacy. The Consent Order constitutes reciprocal disciplinary action that was based entirely on a February 22, 2022, Decision and Order from the California Board of Pharmacy. There were no new facts giving rise to the Alabama Consent. Your office was notified of the California Order on or about 03/25/2022. Pursuant to the terms of the Alabama Consent, McKesson agreed to pay a fine of $25,000.

On April 12, 2024, **McKesson Corporation**'s Duluth, GA distribution center entered into a Public Consent Agreement with the Georgia State Board of Pharmacy. McKesson Corporation was disciplined for failure to maintain prescription drugs securely and assessed a fine of $10,000.

On August 29, 2024, the Ohio Board of Pharmacy issued a Final Order to **McKesson Corporation** for activities that occurred at McKesson's former distribution center previously located in Washington Courthouse, OH for purchases of dangerous drugs from an unlicensed entity from July 2019 to April 2021. The Board imposed a monetary fine in the amount of $2,750.00.

On September 25, 2024, **McKesson Corporation's** Montgomery, NY facility entered into a Settlement Agreement with the Connecticut Department of Consumer Protection Drug Control Division. Pursuant the terms of the Agreement, the Department of Consumer Protection alleged that McKesson's contracted courier failing to maintain prescription drugs securely in violation of Section 21a-115-32(b)(4) of the Regulations of Connecticut State Agencies. The Settlement Agreement shall neither be considered an admission of liability or a violation of law for any purpose, nor as evidence supporting the allegations of the Department of Consumer Protection. Per the Settlement Agreement,

McKesson Corporation shall submit a payment of One Thousand Five Hundred Dollars ($1,500) to the Department of Consumer Protection and shall be issued a Letter of Reprimand.

On November 14, 2024, **McKesson Corporation's** Montgomery, NY facility entered into a Settlement Agreement with the Connecticut Department of Consumer Protection Drug Control Division. Pursuant the terms of the Agreement, the Department of Consumer Protection alleged that McKesson's contracted courier failing to maintain prescription drugs securely in violation of Section 21a-115-32(b)(4) of the Regulations of Connecticut State Agencies. The Settlement Agreement shall neither be considered an admission of liability or a violation of law for any purpose, nor as evidence supporting the allegations of the Department of Consumer Protection. Per the Settlement Agreement, McKesson Corporation shall submit a payment of Five Thousand Dollars ($5,000) to the Department of Consumer Protection and shall be issued a Letter of Reprimand.

On August 20, 2025, the Michigan Board of Pharmacy issued a Consent Order and Stipulation resolving disciplinary action against **McKesson Corporation** distribution center located in Holt, MI, resulting in a fine of $1,000. The Michigan Board of Pharmacy found violations of Mich Admin Code R 338.3141(1) and MCL 333.17768(2)(e), which require effective controls against theft and diversion of controlled substances.

Pending Actions

McKesson Corporation's Jeffersonville, OH facility has a pending action in Ohio that hasn't reached final disposition. McKesson Corporation will supplement this information once final disposition determined.

BEFORE THE IOWA BOARD OF PHARMACY

RE: Wholesaler License and Controlled Substances Act Registration of **MCKESSON DRUG COMPANY** License No. 7987 Registration No. 2212001 Respondent	CASE NO. 2019-0047 **COMBINED STATEMENT OF CHARGES, SETTLEMENT AGREEMENT, AND FINAL ORDER**

COME NOW the Iowa Board of Pharmacy ("Board") and McKesson Drug Company ("Respondent"), 2101 12th Ave S, Clear Lake IA 50428, and enter into this Combined Statement of Charges, Settlement Agreement, and Final Order ("Order") pursuant to Iowa Code sections 17A.10 and 272C.3(4), and 657 IAC 35.5. The Board has jurisdiction over Respondent and the subject matter of this case pursuant to Iowa Code chapters 17A, 124, 155A, and 272C (2019), and 657 IAC 36.

A. STATEMENT OF CHARGES

COUNT I
FAILURE TO TAKE COMPLETE INVENTORY

1. Respondent is charged with failing to comply with the requirements in 657 IAC 10.19 to take a complete and accurate inventory of all stocks of controlled substances, and may be disciplined pursuant to Iowa Code sections 124.304(1)(d) and 155A.17(4), and 657 IAC 10.44(5), 36.6(28).

B. FACTUAL CIRCUMSTANCES

2. Respondent's wholesaler license number 7987 is currently active through December 31, 2019. Respondent's Controlled Substances Act registration number 2212001 is currently active through January 31, 2021.

3. Respondent failed to include pseudoephedrine products in the annual controlled substance inventory.

4. Respondent failed to take an initial inventory of butalbital products after such products became schedule III controlled substances on June 26, 2019.

C. SETTLEMENT AGREEMENT AND FINAL ORDER

5. The Board has jurisdiction over the parties and the subject matter of these proceedings.

6. Respondent acknowledges that the allegations in the Statement of Charges, if proven in a contested case hearing, would constitute grounds for the discipline agreed to in this Order.

7. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.

8. Respondent acknowledges that it has the right to be represented by counsel on this matter.

9. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.

10. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.

11. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

12. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank. These reports shall be the only reports or publications the Board will make regarding this settlement.

13. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

14. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

15. Respondent is hereby **CITED** for failing to comply with the requirements in 657 IAC 10.19 to take a complete and accurate inventory of all stocks of controlled substances and **WARNED** that future violations of the laws and rules governing wholesalers can result in further disciplinary action.

16. Respondent shall pay a **CIVIL PENALTY** in the amount of five thousand dollars ($5,000) within sixty (60) days of this Order. The check shall be made payable to the "Treasurer of Iowa" and shall be deposited in the general fund. The civil penalty should be mailed to the Iowa Board of Pharmacy, Attn: Amanda Woltz, 400 SW 8th St, Ste E, Des Moines IA 50309.

17. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 155A and 272C and 657 IAC 36.

By the signature below, Ammie McAsey acknowledges s/he is the SVP Prescription Operations for Respondent and is authorized to sign this Combined Statement of Charges, Settlement Agreement, and Final Order on behalf of Respondent.

1-2-2020
Date

Ammie McAsey
MCKESSON DRUG COMPANY
Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is approved by the Iowa Board of Pharmacy on the 7 day of January, 2020.

Tasia Hoard
Chairperson
Iowa Board of Pharmacy

Iowa Board of Pharmacy

ANDREW FUNK, PHARM.D.
EXECUTIVE DIRECTOR

ACCEPTANCE OF SERVICE BY ATTORNEY

I, Roger Morris,
(Print name)

as attorney for McKesson Drug Company, acknowledge that I received a copy of the Combined Statement of Charges, Settlement Agreement, and Final Order dated January 7, 2020 and am authorized to accept service of this document on behalf of McKesson Drug Company.

By signing this form, I acknowledge that I am accepting service of the document described above.

(Signature) 1/15/2020 (Date)

Please return this form by mail to the address below, by fax to the number below, or by scanning and sending by email to Amanda.woltz@iowa.gov.

400 S.W. EIGHTH STREET, SUITE E • DES MOINES, IA 50309-4688
PHONE: 515-281-5944 • https://pharmacy.iowa.gov • FAX: 515-281-4609

BEFORE THE INDIANA BOARD OF PHARMACY
CAUSE NUMBER: 2019-IBP-0041

IN THE MATTER OF THE LICENSE OF:)
)
McKESSON DRUG COMPANY)
LICENSE NO: 48000550A)

FILED
FEB 12 2020
Indiana Professional Licensing Agency

FINAL ORDER ACCEPTING PROPOSED FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

The State of Indiana ("Petitioner"), by counsel Timothy M. Weber, Deputy Attorney General, and McKesson Drug Company ("Respondent"), by counsel Randall Fearnow, signed a Proposed Settlement Agreement ("Agreement") which purports to resolve all issues involved in the action regarding Respondent's license before the Indiana Board of Pharmacy ("Board"), and which Agreement has been submitted to the Board for approval.

The Board, after reviewing the Agreement at the January 13, 2020 meeting held in Room W064 of the Indiana Government Center South, 402 West Washington Street, Indianapolis, Indiana, now finds it has been entered into fairly and without fraud, duress, or undue influence, and is fair and equitable between the parties. The Board hereby incorporates the Agreement which is attached hereto and incorporated herein as **Exhibit A** and approves and adopts in full the Agreement as a resolution of this matter. The Board approved this Agreement by a vote of 6-0-0. Incorporated into the Agreement was the consensus of both parties to Findings of Fact, Conclusions of Law, and Order.

WHEREFORE, the Board hereby accepts and approves the Agreement, settling all matters in this case consistent with the terms of the Agreement between the parties, and Respondent is hereby **ORDERED** to abide by all the terms of the Agreement as set forth below:

1. Respondent's license to practice as a wholesale drug distributor in the state of Indiana shall be placed on **INDEFINITE PROBATION**. As a term of this probation, and with the exception of the activities discussed in Paragraph 3 below, Respondent may not distribute controlled substances into Indiana effective as of the effective date of the Agreement until Respondent's DEA Registration is fully re-instated on or about February 16, 2021. In the event that Respondent's DEA Registration will remain suspended beyond February 16, 2021, Respondent shall notify the Board prior to the date of the continued suspension of its DEA Registration and the date that the suspension of its DEA Registration will terminate.

2. After the DEA Registration is fully re-instated, Respondent may submit a Petition to Withdraw the Probation to request that the probation be lifted.

3. The restriction of Respondent's ability to distribute controlled substances in the state of Indiana shall not apply to or limit Respondent's authority to distribute, or Respondent's operations involving, List 1 chemical products at or from Respondent which are authorized under Respondent's DEA Registration. Respondent is permitted, at its option, to possess and distribute controlled substances to federal customers under Respondent's exclusive contract with the United States Department of Veteran Affairs.

4. Respondent shall fully comply with the 2017 Agreements and any amendments or modifications thereto, entered into by Respondent and the United States Department of Justice and Drug Enforcement Administration, and effective on January 17, 2017.

5. Within **NINETY (90) DAYS** of the final order in this matter, Respondent shall pay a **FINE** in the amount of **ONE THOUSAND DOLLARS ($1,000.00)**. This fine shall be paid by check or money order payable to the Indiana Professional Licensing Agency, and submitted to the following address:

Indiana Professional Licensing Agency
Attn: Board of Pharmacy
402 W. Washington Street, Room W072
Indianapolis, IN 46204

6. Within **NINETY (90) DAYS** of the final order in this matter, Respondent shall, pursuant to Ind. Code § 4-6-14-10(b), pay a **FEE** in the amount of **FIVE DOLLARS ($5.00)** to be deposited into the Health Records and Personal Identifying Information Protection Trust Fund. This fee shall be paid by check or money order payable to the State of Indiana, and submitted to the following address:

Office of the Indiana Attorney General
Attn: Executive Assistant, Consumer Protection Division
302 West Washington Street, 5th Floor
Indianapolis, IN 46204

7. A violation of the Final Order, any non-compliance with the statutes or regulations regarding the practice of wholesale drug distribution, or any violation of this Agreement may result in Petitioner requesting a summary suspension of Respondent's license, an Order to Show Cause as may be issued by the Board, or a new cause of action pursuant to Ind. Code § 25-1-9-4, any or all of which could lead to additional sanctions, up to and including a revocation of Respondent's license.

SO ORDERED, this 19th day of February 2020.

INDIANA BOARD OF PHARMACY

By: Maureen Bennett
for Matt Balla, R. Ph., President

CERTIFICATE OF SERVICE

I certify that a copy of the "Final Order Accepting Proposed Findings of Fact, Conclusions of Law, and Order" has been duly served upon:

McKesson Drug Company
3000 Kenskill Ave
Washington Court House, OH 43160
Service by U.S. Mail

Randall Fearnow
QUARLES & BRADY, LLP
300 N. LaSalle Street, Suite 4000
Chicago, Illinois 60654-3406
Service by U.S. Mail

Timothy M. Weber
OFFICE OF THE INDIANA ATTORNEY GENERAL
Indiana Government Center South, Fifth Floor
302 West Washington Street
Indianapolis, Indiana 46204-2770
Service by Email: timothy.weber@atg.in.gov

2-19-2020
Date

Nathaniel Black Jr., Litigation Specialist

Indiana Board of Pharmacy
Indiana Government Center South
402 West Washington St., Room W072
Indianapolis, IN 46204
Phone: 317-234-2067
Fax: 317-233-4236
Email: pla4@pla.in.gov

Explanation of Service Methods
Personal Service: by delivering a true copy of the aforesaid document(s) personally.
Service by U.S. Mail: by serving a true copy of the aforesaid document(s) by First Class U.S. Mail, postage prepaid.
Service by Email: by sending a true copy of the aforesaid document(s) to the individual's electronic mail address.

BEFORE THE INDIANA
BOARD OF PHARMACY
CAUSE NO: 2019 IBP 0041

IN THE MATTER OF THE LICENSE OF:)
)
McKESSON DRUG COMPANY)
LICENSE NO: 48000550A)

FILED
JAN 08 2020
Indiana Professional Licensing Agency

SETTLEMENT AGREEMENT

The State of Indiana ("Petitioner"), by Timothy M. Weber, Deputy Attorney General, and McKesson Drug Company ("Respondent"), by counsel, Randall Fearnow, hereby execute this Settlement Agreement ("Agreement") to resolve all issues raised by the filing of the Petitioner's Complaint in the above captioned matter and the Respondent's objections thereto. This Agreement is subject to the review and approval of the Indiana Board of Pharmacy ("Board") pursuant to Ind. Code § 25-1-9 and Ind. Code § 4-21.5-3.

STIPULATED FACTS

1. Respondent is a licensed wholesale drug distributor in the State of Indiana having been issued license number 48000550A.

2. Respondent's address is 2000 Kenskill Ave., Washington Court House, Ohio 43160.

3. Respondent is one of several wholesale distribution centers operated by its parent company, McKesson Corporation (parent company hereinafter referred to as "McKesson").

4. On January 17, 2017, McKesson entered into a Settlement Agreement and Release and an Administrative Memorandum of Agreement (collectively, the "2017 Agreement") with the Drug Enforcement Agency ("DEA") and the Department of Justice ("DOJ"). Pursuant to the terms of the 2017 Agreement, the parties agreed in relevant part.

EXHIBIT A

a. At times relevant to the 2017 Agreement, McKesson's distribution centers were required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801 *et seq.* ("CSA"), and the regulations promulgated thereunder, 21 C.F.R. Part 1300 *et seq.*

b. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation.

c. In 2006 and 2007, the DEA sent letters to every entity in the United States that was registered with the DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The letters contained guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b).

d. In 2008, McKesson entered into a settlement with the DOJ and a Memorandum of Agreement with the DEA (collectively referred to as the "2008 Agreements").

e. The 2017 Agreement covers the time period of January 1, 2009 through the date of the last signatory to the 2017 Agreement, which was on January 17, 2017 ("Covered Time Period").

5. Pursuant to the 2017 Agreement, Respondent's DEA Certificate of Registration ("DEA Registration") will be suspended between February 16, 2019 and February 16, 2021 with a partial exception to possess and distribute controlled substances related to servicing federal customers that purchase from Respondent under an exclusive contract with the United States Department of Veterans

Affairs. The suspension does not apply to or limit McKesson's authority to distribute, or operations involving List 1 Chemical products.

6. Indiana Code § 25-1-9-4(a)(3) allows the Board to discipline a practitioner if the Board finds that the practitioner has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question.

7. Indiana Code § 25-26-14-17(10) requires a wholesale distributor, if involved in the distribution of controlled substances, to maintain registration with the federal Drug Enforcement Agency.

STIPULATED CONCLUSION OF LAW

The parties further stipulate Respondent's Indiana license is subject to discipline in accordance with Indiana Code § 25-1-9-4(a)(3) because Respondent's DEA Registration was suspended; therefore, it did not maintain registration with the DEA as required by Indiana Code § 25-26-14-17(10).

AGREED DISPOSITION

It is now therefore agreed by Respondent and Petitioner as follows:

1. Both parties voluntarily waive their rights to a public hearing on the Complaint and all other proceedings in this action to which either party may be entitled by law, including judicial review and appeal.

2. This Agreement resolves any and all pending claims or allegations relating to disciplinary action against the Respondent's Indiana wholesale drug distributor license.

3. Respondent's license to practice as a wholesale drug distributor in the state of Indiana is hereby placed on INDEFINITE PROBATION. As a term of this probation, and with the exception of the activities discussed in Paragraph 5 below, Respondent may not distribute controlled substances into Indiana effective as of the effective date of this Agreement until Respondent's DEA Registration is fully

re-instated on or about February 16, 2021. In the event that Respondent's DEA Registration will remain suspended beyond February 16, 2021, Respondent shall notify the Board prior to the date of the continued suspension of its DEA Registration and the date that the suspension of its DEA Registration will terminate.

4. After the DEA Registration is fully re-instated, Respondent may submit a Petition to Withdraw the Probation to request that the probation be lifted.

5. The restriction of Respondent's ability to distribute controlled substances in the state of Indiana shall not apply to or limit Respondent's authority to distribute, or Respondent's operations involving, List 1 chemical products at or from Respondent which are authorized under Respondent's DEA Registration. Respondent is permitted, at its option, to possess and distribute controlled substances to federal customers under McKesson's exclusive contract with the United States Department of Veterans Affairs.

6. Respondent shall fully comply with the 2017 Agreement and any amendments or modifications thereto, entered into by Respondent and the United States Department of Justice, Drug Enforcement Administration and effective on January 17, 2017.

7. Within ninety (90) days of the Board's Final Order accepting this Agreement, Respondent shall pay a **FINE** in the amount of **ONE THOUSAND DOLLARS ($1,000.00).** This fine shall be paid by check or money order payable to the Indiana Professional Licensing Agency, and submitted to the following address:

Indiana Professional Licensing Agency
Attn: Board of Pharmacy
402 W. Washington Street, Room W072
Indianapolis, Indiana 46204

8. Within **NINETY (90) DAYS** of the Final Order, Respondent shall, pursuant to Ind. Code § 4-6-14-10(b), pay a **FEE** in the amount of **FIVE DOLLARS ($5.00)** to be deposited into the Health Records and Personal Identifying Information Protection Trust Fund. This fee shall be paid by check or money order payable to the State of Indiana, and submitted to the following address:

Office of the Indiana Attorney General
Attn: Teresa Henson
302 West Washington Street, 5th Floor
Indianapolis, IN 46204

9. Respondent has carefully read and examined this Agreement and fully understands its terms and that, subject to approval by the Board, this Agreement is a final disposition of the Allegations.

10. The hearing set in this matter shall be vacated upon approval of the Board.

IN WITNESS WHEREOF, the undersigned, authorized representatives of the parties, affix their signatures hereto evidencing their acceptance of this Agreement.

Dennie McKsey — 1-6-2020
Representative for Respondent — Date

1-7-2020
Randall R. Fearnow — Date
Counsel for Respondent

1-7-2020
Timothy M. Weber — Date
Deputy Attorney General

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

DIVISION OF PROFESSIONAL REGULATION OF THE ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION,	Complainant,	) Case No. 2017-03162
v.		
MCKESSON CORPORATION, License No. 004.002044, License No. 004.001511, License No. 004.000755,	Respondent.	

CONSENT ORDER

The Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation ("Department"), by attorney Brandon R. Thom, and Respondent McKesson Corporation ("Respondent"), by attorney Roger N. Morris of Quarles & Brady LLP, agree to the following:

STIPULATIONS

Respondent holds multiple Wholesale Drug Distributor licenses in the State of Illinois, including license numbers 004.002044 (Aurora, Colorado), 004.001511 (Livonia, Michigan), and 004.000755 (Washington Court House, Ohio). On January 17, 2017, Respondent entered into a Settlement Agreement and Administrative Memorandum of Agreement with the U.S. Department of Justice-Drug Enforcement Administration ("DEA"). The January 17, 2017 Memorandum of Agreement is attached herein as **Exhibit 1.** The DEA alleged various conduct which the DEA alleged would constitute violations of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 et sequ (the "Act") and regulations promulgated under the Act at 21 C.F.R. Part 1300 *et seq.* To resolve the matter, Respondent made no admissions of liability but agreed to pay a settlement payment of one hundred fifty million dollars ($150,000,000) and agreed to a time-limited suspension of the DEA Certification of Registrations of four (4) of Respondent's distribution centers, including those listed herein. Respondent's actions and/or omissions, if proven true, would constitute violations of the Illinois Wholesale Drug Distribution Licensing Act, 225 ILCS 120/55(a)(1) and (5).

At all times material to the matter set forth in this Consent Order, the Department had jurisdiction over the subject matter and parties herein. Respondent acknowledges that Respondent has entered into this Consent Order freely and of Respondent's own will without threat or coercion by the Department or any person and has not relied upon any representation made by or on behalf of the Department other than those specifically included

herein. Respondent has been advised of the right to accept or reject this Consent Order. Respondent has been advised of the right to a hearing on the Petition for Restoration, the right to contest any charges brought, and the right to administrative review of any Order resulting from a hearing. Respondent knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by either the Board of Pharmacy ("Board") or Director. Respondent acknowledges that the Department attorney may be requested to communicate with the Board or Director in furtherance of the approval of this Consent Order. Respondent has been informed that this Consent Order will be presented to the Director for final approval. If this Consent Order is not approved, Respondent waives any right to raise any prejudice resulting from the Director's consideration of this Consent Order. Respondent understands that this Consent Order is not effective unless and until it is adopted by the Director. A copy of any original signature(s) shall be given the full force and effect of any original signature(s) affixed to this Consent Order.

Respondent and the Department have agreed, in order to resolve this matter, that Respondent be permitted to enter into a Consent Order with the Department.

CONDITIONS

Wherefore, the Department, by attorney Brandon R. Thom, and Respondent, by attorney Roger N. Morris of Quarles & Brady LLP, agree:

A Respondent's Illinois Wholesale Drug Distributor license no. 004.002044 (Aurora, Colorado), shall be placed on probation for a definite period of three (3) years, effective January 17, 2017 to January 17, 2020. Throughout the term of this probation, Respondent's Illinois Wholesale Drug Distributor license no. 004.002044 (Aurora, Colorado) shall be prohibited from distributing controlled substances in the State of Illinois. This probationary restriction shall not apply to or limit Respondent's authority to distribute, or operations involving, List 1 Chemical products at or from Respondent's Aurora, Colorado distribution center.

B Respondent's Illinois Wholesale Drug Distributor license no. 004.001511 (Livonia, Michigan), shall be placed on probation for a definite period of two (2) years, effective January 17, 2017 to January 17, 2019.

Throughout the term of this probation, Respondent's Illinois Wholesale Drug Distributor license no. 004.001511 (Livonia, Michigan) shall be prohibited from distributing controlled substances in the State of Illinois. This probationary restriction shall not apply to or limit Respondent's authority to distribute, or operations involving, List I Chemical products at or from Respondent's Livonia, Michigan distribution center. Respondent's Livonia, Michigan distribution center is permitted, at its option, to possess and distribute controlled substances to federal customers under McKesson's exclusive contract with the U.S. Department of Veterans Affairs.

C. Respondent's Illinois Wholesale Drug Distributor license no. 004.000755 (Washington Court House, Ohio), shall be placed on probation for a definite period of two (2) years, effective February 16, 2019 to February 16, 2021. Throughout the term of this probation, Respondent's Illinois Wholesale Drug Distributor license no. 004.000755 (Washington Court House, Ohio) shall be prohibited from distributing controlled substances in the State of Illinois. This probationary restriction shall not apply to or limit Respondent's authority to distribute, or operations involving, List I Chemical products at or from Respondent's Washington Court House, Ohio distribution center. Respondent's Washington Court House, Ohio distribution center is permitted, at its option, to possess and distribute controlled substances to federal customers under McKesson's exclusive contract with the U.S. Department of Veterans Affairs.

D. Respondent shall comply with all terms and conditions imposed upon Respondent in the January 17, 2017 DEA Memorandum of Agreement, attached hereto as Exhibit 1. Any violation of the Memorandum of Agreement by Respondent shall be deemed a violation of this Consent Order.

E. Respondent shall comply with all terms and conditions of the Wholesale Drug Distribution Licensing Act 225 ILCS 120/1 et seq. and the Rules enacted in furtherance thereof. Respondent's failure to do so shall be deemed a violation of the terms of this Consent Order.

F. Failure by Respondent to comply fully with the terms and conditions of this Consent Order may be grounds for the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation to issue an Order mandating the immediate and automatic indefinite suspension of Respondent's Illinois Wholesale Drug Distributor Licenses, numbers 004.002044, 004.001511, and 004.000755. Respondent may file an appropriate Petition within thirty (30) days from date the order was entered to contest the

underlying factual basis of the indefinite suspension. Respondent shall be afforded a hearing on the merits following the filing of the Petition. Respondent waives any statute of limitations defense in any hearing on the indefinite suspension.

G. This Consent Order is a public disciplinary action and will be reported to all applicable public indexes. This Consent Order will be available to the general public.

H. This Consent Order shall become effective upon the Director's approval and signature, as dated below.

April 21, 2021
Date

Department Attorney Brandon R. Thom

April 12, 2021
Date

Respondent McKesson Corporation

April 12, 2021
Date

Roger N. Morris of Quarles & Brady LLP
Attorney for Respondent

4/20/21
Date

Illinois Board of Pharmacy Member

The foregoing Consent Order is approved in full.

Dated this 22nd day of May, 2021.

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
ACTING SECRETARY MARIO TRETO, JR.

Acting Director Cecilia Abundis
Division of Professional Regulation

Case No. 2017-03162
License Nos. 004.002044
004.001511
004.000755

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and McKesson Corporation ("McKesson") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to McKesson and any facility owned or operated by McKesson US Pharmaceutical registered, or who may become registered, with DEA to distribute, or otherwise handle controlled substances. The current list of applicable facilities is identified in Appendix A.

BACKGROUND

1. McKesson is registered with DEA at the facilities listed in Appendix A as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.*, ("CSA" or "the Act"). *See* Appendix A. Collectively, the distribution centers listed in Appendix A and the former Landover, Maryland distribution center are referred to herein as the "McKesson Distribution Centers."

2. In May 2008, McKesson entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA") with DEA. *See* Appendix B.

3. McKesson's Aurora, Colorado, distribution facility ("McKesson Aurora"), located at 14500 East 39th Ave., Aurora, Colorado 80011, is registered with DEA as a distributor of Schedule II-V controlled substances pursuant to DEA Certificate of Registration PM0018425.

4. On March 12, 2013, DEA executed an Administrative Inspection Warrant ("AIW") at McKesson Aurora.

5. Between March 2013 and the present, DEA executed one (1) additional AIW and served numerous administrative subpoenas and conducted a number of cyclic inspections at various McKesson US Pharmaceutical distribution centers nationwide including McKesson's Washington Court House, Ohio, distribution center ("McKesson WCH"), DEA Certificate of Registration RM0220688, located at 3000 Kenskill Avenue, Washington Court House, Ohio 43160; McKesson's Livonia, Michigan, distribution center ("McKesson Livonia"), DEA Certificate of Registration 0030849, located at 38220 Plymouth Road, Livonia, Michigan 48150; McKesson's Lakeland, Florida, distribution center ("McKesson Lakeland"), DEA Certificate of Registration PM0000771, located at 1515 Kendrick Lane, Lakeland, Florida 33805; McKesson's Methuen distribution center ("McKesson Methuen"), DEA Certificate of Registration PM0020850, located at 9 Aegean Drive, Methuen, Massachusetts 01844; McKesson's Chicago distribution center ("McKesson Chicagoland"), DEA Certificate of Registration RM0380484, located at 1955 McKesson Street, Suite 101, Aurora, Illinois 60502; McKesson's Delran, New Jersey, distribution center ("McKesson Delran"), DEA Certificate of Registration RM0173055, located at 400 Delran Parkway, Delran, New Jersey 08075; McKesson's LaCrosse, Wisconsin

distribution center, ("McKesson LaCrosse"), DEA Certificate of Registration RM0220537, located at 3003 Airport Road, LaCrosse, Wisconsin 54603; McKesson's La Vista, Nebraska, distribution center ("McKesson La Vista"), DEA Certificate of Registration PM0038693, located at 7009 South 108th Street, La Vista, Nebraska 68128; McKesson's Ruther Glen, Virginia, distribution center ("McKesson Ruther Glen"), DEA Certificate of Registration RM0424363, located at 10504 McKesson Drive, Ruther Glen, Virginia 22546; and McKesson's West Sacramento, California, distribution center ("McKesson West Sacramento"), DEA Certificate of Registration PM0021535, located at 3775 Seaport Boulevard, West Sacramento, California 95691.

6. On or about August 13, 2014, McKesson received a letter from the U.S. Attorney for the District of Colorado (the "August 13, 2014 Letter") setting forth allegations that McKesson failed to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b). This letter described certain civil penalties that the U.S. Attorney for the District of Colorado could seek in Colorado and elsewhere in connection with that alleged conduct.

7. On or about November 14, 2014, McKesson received a letter (dated November 4, 2014) from the DEA Office of Chief Counsel, Diversion Regulatory and Litigation Section, stating that DEA was separately pursuing administrative action against McKesson Aurora for the conduct outlined in the August 13, 2014 Letter. DEA also stated that the allegations regarding McKesson's failure to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failure to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b) was national in scope, and that DEA was also pursuing administrative investigations of such alleged failures at McKesson WCH, McKesson Livonia, McKesson Lakeland, McKesson Methuen, McKesson Chicagoland, McKesson Delran, McKesson LaCrosse, McKesson La Vista, McKesson Ruther Glen, and McKesson West Sacramento.

8. As of the date of this Agreement, DEA has not issued Orders to Show Cause ("OTSCs") against any of McKesson's DEA-registered distribution centers.

STIPULATION AND AGREEMENT

In lieu of commencing and pursuing administrative litigation against the DEA registrations of an unknown number of McKesson's distribution centers, McKesson and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further

below. The Parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this matter.

2. Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following conduct alleged by the Government for the Covered Time Period:

a. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers, including the following:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
LaCrosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;

Washington Courthouse, Ohio; and
West Sacramento, California.

b. In 2008, McKesson entered into a Settlement Agreement with the Department of Justice and a Memorandum of Agreement with DEA (collectively referred to herein as the "2008 Agreements") related to, among other things, McKesson's failure to report suspicious orders of controlled substances to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP"), in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the Act, and 21 C.F.R. § 1301.74(b);

c. McKesson failed to follow the procedures and policies set forth in the McKesson CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP;

d. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. § 1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;

e. McKesson failed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters; and

f. The McKesson Distribution Centers distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

4. Effect of 2008 MOA. To the extent that there are obligations contained in the 2008 MOA that survived the expiration of the stated term of the 2008 MOA, those terms are superseded by the obligations contained in this Agreement.

5. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

II. Terms and Conditions

1 Obligations of McKesson.

a. McKesson agrees to maintain a compliance program intended to detect and prevent diversion of controlled substances as required under the CSA and applicable implementing regulations. McKesson acknowledges and agrees that the obligations undertaken in this Agreement and the Compliance Addendum are designed, in part, to meet its obligations under the CSA and its implementing regulations.

b. Beginning on the first full calendar month after the Effective Date, McKesson shall provide DEA Headquarters with an unedited file of all transactions of non-ARCOS reportable controlled substances. This information will be in the format that Automation of Reports and Consolidated Orders System ("ARCOS") data is submitted to DEA, and will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. The files shall be due by the 15th of each calendar month for the previous calendar month's report. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable implementing regulations. The Parties agree that such report is not required under the CSA or its implementing regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

c. In satisfaction of its obligation under the CSA's implementing regulations and as agreed to pursuant to this Agreement for each McKesson distribution center registrant to "inform the Field Division Office of the Administration in [its] area of suspicious orders," 21 C.F.R. § 1301.74(b), McKesson shall transmit Suspicious Order Reports to DEA Headquarters at the end of each business day. McKesson shall submit the daily Suspicious Order Reports in the format that ARCOS data is submitted to DEA, and the reports will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. This obligation will continue during the term of this Agreement unless and until DEA advises McKesson otherwise in writing.

d. McKesson agrees that its authority to distribute all controlled substances from its McKesson Aurora distribution center, DEA Certificate of Registration PM0018425, will be suspended for a period of three (3) years commencing from the Effective Date of this Agreement (the "Aurora Suspension Period"). This suspension shall not apply to or limit McKesson's authority to distribute, or

operations involving, List I Chemical products at or from the Aurora distribution center, which are authorized under the DEA registration number PM0018425.

e. McKesson agrees that its authority to distribute all controlled substances from its McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, will be suspended for a period of two (2) years commencing from the Effective Date of this Agreement, except for orders placed by Permitted Registrants ("the Livonia Suspension Period").[1] This suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia distribution center, which are authorized under the DEA registration number PM0030849. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson Livonia distribution center, Certification of Registration PM0030849, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

f. McKesson agrees that its authority to distribute all controlled substances from its McKesson WCH distribution center, DEA Certificate of Registration RM0220688, will be suspended for a period of two (2) years commencing thirty (30) days from the date upon which the DEA Certificate of Registration for the McKesson Livonia distribution center is reinstated, except for orders placed by Permitted Registrants (the "WCH Suspension Period"). In the event the McKesson Livonia distribution center is not reinstated within one hundred and eighty (180) days of completion of the Livonia Suspension Period due to McKesson (i) failing to cure a compliance requirement as identified by DEA in its thirty (30) day advance notice letter described in Section II.2., or (ii) electing to permanently terminate the Livonia registration, the WCH Suspension Period will commence no later than two (2) years and one hundred eighty (180) days from the Effective Date of this Agreement. The McKesson WCH distribution center suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the WCH distribution center, which are authorized under the DEA registration number RM0220688. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field

[1] For purposes of this agreement "Permitted Registrants" shall include registrants identified in Appendix C. McKesson shall include updates to the Permitted Registrants in the quarterly reports provided to DEA local offices under II.1 e-g.

Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson WCH distribution center, Certification of Registration RM0220688, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

g. McKesson agrees that its authority to distribute controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, from its McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, will be suspended for a period of one (1) year commencing from the Effective Date of the Agreement, except for orders placed by Permitted Registrants (the "Lakeland Suspension Period"). McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Miami Field Division, Diversion Regulatory Unit, 2100 North Commerce Parkway, Weston, Florida 33326, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of hydromorphone (drug code 9150) from its McKesson Lakeland distribution center, Certification of Registration PM0000771, for each previous quarter. McKesson shall notify the Miami Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the hydromorphone.

h. McKesson agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by DEA or other law enforcement authorities, subject to appropriate requests, *e.g.*, administrative subpoena. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

i. Pursuant to the 2017 Settlement Agreement and Release, McKesson agrees to a settlement payment to the United States of America in the amount of $150,000,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances. McKesson agrees to execute the 2017 Settlement Agreement and Release simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said settlement payment penalties within five (5) days of the Effective Date of this Agreement.

j. Any material breach by any McKesson facility of subsections II.1.b-g of this Agreement by McKesson after the Effective Date of this Agreement, where McKesson has not cured such breach as may be allowed under relevant law, regulation, this Agreement and Compliance Addendum may be a basis upon which DEA takes administrative action seeking the revocation and/or the suspension of the DEA Certificates of Registration of any of McKesson's distribution centers. However, nothing in this Agreement or the Compliance Addendum shall be deemed a waiver of McKesson's Due Process rights.

k. In any case where a supplier inadvertently ships controlled substances to any McKesson suspended facility, McKesson shall promptly return the product to the supplier. McKesson shall maintain a record of such receipt and return for two (2) years.

l. In any case where a customer inadvertently returns controlled substances to any McKesson suspended facility, McKesson shall promptly send the product to another McKesson DC for processing. McKesson shall maintain a record of such receipt and transfer for two (2) years.

m. Any McKesson suspended facility receiving a DEA Order Form 222 shall promptly endorse such Order Form to another, non-suspended McKesson facility pursuant to 21 C.F.R. § 1305.14. McKesson shall maintain a record of any endorsement and transfer of an order form for two (2) years.

n. In the event that any controlled substance maintained at a suspended McKesson facility is no longer required to be stocked or sold to a Permitted Registrant, the suspended McKesson facility may transfer such controlled substance to another non-suspended McKesson facility. Such transaction shall be reflected in the quarterly transaction report submitted to the appropriate local DEA field office as described in subsection II.1.e-g of this Agreement.

2 Obligations of DEA.

a. DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. § 1301.74(b) or 21 U.S.C. § 823(b)(1). DEA has taken no action during the

negotiation of this Agreement, and is taking no action by entering into this Agreement, that can be interpreted to be directly or indirectly endorsing or approving the system that McKesson is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of McKesson under this Agreement, including the receipt of information and/or its participation in meetings with McKesson representatives, shall not be construed or interpreted to be directly or indirectly endorsing or approving the system that McKesson is utilizing to meet its obligations under the CSA and the implementing regulations.

b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as described in subsection II.1.c. of this Agreement.

c. In the event that DEA discovers information about conduct during the Covered Time Period that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement, the Compliance Addendum, and the civil penalties paid pursuant to the Settlement Agreement and Release; all actions taken by McKesson pursuant to this Agreement and Compliance Addendum; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility, and at other McKesson facilities.

d. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Aurora's distribution center, DEA Certificate of Registration PM0018425, and, if needed, grant any requisite registration renewal, no later than the end of the Aurora Suspension Period.

e. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, and, if needed, grant any requisite registration renewal, no later than the end of the Livonia Suspension Period.

f. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson WCH distribution center, DEA Certificate of Registration RM0220688, and, if needed, grant any requisite registration renewal, no later than the end of the WCH Suspension Period.

g. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will reinstate the ability of the McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, to distribute the controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, no later than the end of the Lakeland Suspension Period.

3. Release by DEA. In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:

a. Fully and finally release McKesson, together with its subsidiary entities, distribution facilities, and registrants, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct; and

b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date of this Agreement, and the review of the reports and records McKesson submitted to DEA prior to the Effective Date of this Agreement. This release applies only to administrative actions brought before or by DEA.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-Covered Conduct. Further, nothing in this Paragraph shall prohibit or limit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming McKesson is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

4 Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its

agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:

a. Any potential criminal liability;

b. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

c. Any administrative liability to the United States other than administrative claims released in Paragraph II.3.a. and b.

d. Any civil liability to the United States, other than the civil claims released in the 2017 Settlement Agreement and Release; or

e. Any liability based upon any obligation created by or arising under this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (*i.e.*, final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:

a. For DEA or DOJ:

Drug Enforcement Administration, Diversion Control Division, 8701 Morrissette Drive, Springfield, Virginia 22152;

Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, Virginia 22152; and

U.S. Department of Justice, Criminal Division, Narcotic and Dangerous Drug Section, 145 N St. NE (2 Constitution Square), 2nd Floor, East Wing, Washington, D.C. 20530

b. For McKesson:

Senior Vice President, US Pharmaceutical, Regulatory Affairs and Compliance
McKesson Corporation
One Post Street, 36th Floor
San Francisco, CA 94104

with copies to:

Vice President, U.S. Pharmaceutical, Regulatory Affairs & Compliance
McKesson Corporation
6535 State Highway 161
Irving, TX 75039-2402

Assistant General Counsel, US Pharmaceutical
McKesson Corporation
One Post Street, 36th Floor
San Francisco, CA 94104

7. Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.

8. Confidentiality and Designation of Information. McKesson and DEA agree that all transaction reports submitted to DEA contain information this is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of

Information Act ("FOIA"), 5 U.S.C. § 552. Such information may be exempt from disclosure under the Freedom of Information Act and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide McKesson reasonable opportunity to respond to any such requests.

9. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

10. Authorizations. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

11. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties to this Agreement shall be any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA, as amended.

[Signature page to follow]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of McKesson Corporation:

Mark Walchirk
President, US Pharmaceutical
McKesson Corporation

Dated: 1-5-17

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

By direction

Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration

Dated: 1-17-17

Louis J. Milione
Assistant Administrator, Diversion Control Division
Drug Enforcement Administration

Dated: 1-17-17

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Janet T. Mills
Governor

Anne L. Head
Commissioner

May 27, 2021

Sent via email: michele.lau@mckesson.com

McKesson Corporation
Michele Lau, VP/Secretary/Director
1 Post Street
San Francisco, CA 94104-5203

Re: Complaint No. 2021-PHA-17215

Dear Ms. Lau:

Enclosed please find the fully executed consent agreement between you, the Maine Board of Pharmacy, and the Office of the Attorney General in the above referenced matter.

This letter also acknowledges receipt of your fine payment in the amount of $500.00. Your fine is paid in full. As all conditions of the consent agreement have been fulfilled, this complaint file is now closed.

Please feel free to contact our office at (207) 624-8651 with any questions.

Sincerely,

Jessica Gowell

Jessica Gowell, Professional Licensing Supervisor

Enclosure

cc: John Nichols, Esq., Assistant Attorney General
Andrew Black, Esq., Assistant Attorney General
Geraldine L. Betts, Board Administrator & Complainant
Thomas Avery, Board Investigator

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
MCKESSON CORPORATION	)	CONSENT AGREEMENT
	)	
Case No. 2021-PHA-17215	)	

PARTIES

This document is a Consent Agreement regarding the pending application of McKesson Corporation for the renewal of its prescription drug wholesaler license. The parties to this Consent Agreement are: McKesson Corporation ("McKesson"), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since October 17, 2011, McKesson has been licensed in Maine as a prescription drug wholesaler with a registered location of 1995 McKesson Street, Suite 101, Aurora, Illinois (license number **WH70001735**).

2. On October 4, 2019, the Colorado State Board of Pharmacy imposed discipline against McKesson's Colorado registration as an out-of-state prescription drug wholesaler (Registration # WHO 7154) in Case No. 2019-5119.

3. McKesson then failed to report the Colorado disciplinary action to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

4. On November 22, 2019, McKesson submitted an application for renewal of its Maine license and reported to the Board for the first time that it had been disciplined by the Colorado State Board of Pharmacy.

5. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report a license disciplinary action to the Board within 10 days of that action.

6. At its meeting on January 7, 2021, the Board reviewed the above information and voted to preliminarily deny McKesson's application for renewal of its license to be a prescription drug wholesaler. In lieu of the denial, the Board also voted to offer McKesson this Consent Agreement. Unless McKesson either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333, by **May 16, 2021,** the preliminary denial of McKesson's application for licensure as a prescription drug wholesaler will become final.

COVENANTS

7. McKesson admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C) for failing to report disciplinary action taken in another jurisdiction against a professional license no later than 10 days after the action was taken.

8. As discipline for the violation admitted to in paragraph 7 above, McKesson agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of five hundred dollars ($500.00) payment of which shall be made payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333, and must be submitted with the signed Consent Agreement.

9. Upon receipt of the signed Consent Agreement with the enclosed payment of the civil penalty from McKesson, the Board will renew McKesson's license contingent upon it meeting all other eligibility criteria.

10. Violation of any of the terms or conditions of this Consent Agreement by McKesson shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

11. The Board and McKesson agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless McKesson fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against McKesson, and this Consent Agreement will be admitted into evidence in any future adjudicatory hearing involving McKesson. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against McKesson.

12. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

13. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

14. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

15. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

16. McKesson acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: May 5, 2021

MCKESSON CORPORATION

By: _____

Print Name: Michele Lau

Title: Senior VP & Corporate Secretary

DATED: 5/26/21

_____

BRADLEY S. HAMILTON, R.Ph., President
MAINE BOARD OF PHARMACY

DATED: 5/27/21

_____

JOHN NICHOLS
Assistant Attorney General

STATE OF CONNECTICUT
DEPARTMENT OF CONSUMER PROTECTION
BEFORE THE COMMISSIONER OF CONSUMER PROTECTION

In the Matter of
McKesson Corporation Case No. 2021-234

Agreement Concerning Connecticut Controlled Substance
Certificate of Registration

This Agreement by and between McKesson Corporation, hereinafter referred to as Respondent, and the duly authorized representative of the Commissioner of Consumer Protection, is entered into in accordance with Sections 4-177(c) and 21-322 of the Connecticut General Statutes. In accordance herewith, the parties agree that:

PARAGRAPH ONE: Respondent is the holder of Connecticut Wholesaler of Drugs, Cosmetics & Medical Devices License No. CSW.0001623 for a distribution center located at 4836 Southbridge Boulevard, Memphis, Tennessee.

PARAGRAPH TWO: The Department of Consumer Protection has alleged that between January 2015 and January 2021, Respondent sold controlled substances to a practitioner that did not have an active Connecticut Controlled Substances Certificate of Registration in violation of Section 21a-248(b) of the Connecticut General Statutes.

PARAGRAPH THREE: Respondent enters into this Agreement solely for the purposes of settlement. This Agreement shall neither be considered an admission of liability or a violation of law for any purpose, nor as evidence supporting the allegations of the Department of Consumer Protection.

PARAGRAPH FOUR: Respondent shall pay, prior to the approval of this agreement by the Commissioner, a monetary payment in the amount of Four Thousand Five Hundred Dollars ($4,500.00) into the Consumer Protection Enforcement Fund, Account No. 35125, in accordance with Section 21a-8 of the Connecticut General Statutes.

PARAGRAPH FIVE: Respondent waives:

(a) Any right to a hearing or the procedural requirements of the Uniform Administrative Procedure Act, Connecticut General Statutes, Section 4-166 et. seq.;

(b) Any requirement that this Agreement contain a statement of findings of fact and conclusions of law; and

(c) Any right to seek judicial review or otherwise challenge or contest the validity of this Agreement.

PARAGRAPH SIX: This Settlement Agreement is a revocable offer of settlement that may be modified by mutual agreement or withdrawn by the Department at any time prior to its being executed and shall not become binding unless and until it is accepted and approved by the Commissioner of Consumer Protection.

For the Respondent

Dated: 8.25.2021

Name: Ammie McAsey
Title: SVP, Customer Distribution Experience - PSaS

For the Department of Consumer Protection

Dated: 9.20.2021 By:

Kathleen Coss, Esq.
Project Manager

The above Agreement Concerning Connecticut Controlled Substance Certificate of Registration is accepted and approved this 1st day of October , 2021.

Michelle H. Seagull
Commissioner

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 22, 2022

CERTIFIED MAIL

McKesson Drug Company
Attn: Sandra Zamora
9501 S Norwalk
Santa Fe Springs, CA 90670

RE: Administrative Case No. 6850
McKesson Corporation dba McKesson Drug Company, WLS 3076

Dear Ms. Zamora:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order for Public Reproval regarding the above-referenced matter. Your attention is directed to page 4 of the document.

Effective at 5:00 p.m. on March 24, 2022, Wholesale Permit No. WLS 3076 issued to McKesson Drug Company shall be publicly reproved by the Board and shall also be subject to terms and conditions in the decision.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, at lupe.baltazar@dca.ca.gov or (916) 518-3009. Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Sincerely,

ANNE SODERGREN
Executive Officer

By Susan Cappello

Susan Cappello
Enforcement Manager

SC:lb
Enclosure(s)

cc: Christina Thomas, DAG
Amy Levine Heiserman, Esq.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 6850
McKesson Drug Company, WLS 3076

I am over 18 years of age, and not a party to the within cause; my business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. I served a copy of the:

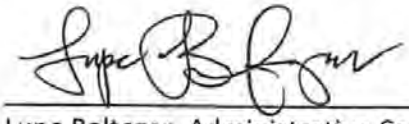
LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
McKesson Drug Company Attn: Sandra Zamora 9501 S Norwalk Santa Fe Springs, CA 90670	7017 0190 0000 4212 5618
Amy Levine Heiserman, Esq. Quarles & Brady LLP One Renaissance Square Two North Central Avenue, Suite 600 Phoenix, AZ 85004-2322	7017 0190 0000 4212 5625

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on February 22, 2022, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 22, 2022 at Sacramento, California.



Lupe Baltazar, Administrative Case Analyst

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against:

MCKESSON CORPORATION, dba
MCKESSON DRUG COMPANY,
Wholesale Permit No. WLS 3076;

and

JOHN F. BOHLINGER,
Designated Representative License No. EXC 17318,

Respondents

Agency Case No. 6850

OAH No. 2021050035

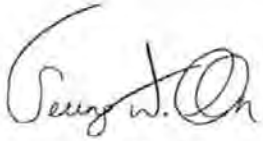
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 24, 2022.

It is so ORDERED on February 22, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General
CHRISTINA THOMAS
Deputy Attorney General
State Bar No. 171168
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6297
Facsimile: (916) 731-2126
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against: **MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY** **9501 Norwalk Boulevard** **Santa Fe Springs, CA 90670** **Wholesale Permit No. WLS 3076,** **and** **JOHN F. BOHLINGER** **9501 Norwalk Blvd.** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318** Respondents.	Case No. 6850 OAH No. 2021050035 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL (AS TO MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY, ONLY)** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Christina Thomas, Deputy Attorney General.

2. Respondent McKesson Corporation, dba McKesson Drug Company (Respondent) is represented in this proceeding by attorney Alissa Brice Castenada, whose address is: Quarles & Brady LLP One Renaissance Square Two North Central Avenue Phoenix, AZ 85004-2391

JURISDICTION

3. On or about October 2, 1995, the Board issued Wholesale Permit No. WLS 3076 to McKesson Corporation, dba McKesson Drug Company. The Wholesale Permit was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 6850 and will expire on October 1, 2022, unless renewed.

4. First Amended Accusation No. 6850 was filed before the Board of Pharmacy, Department of Consumer Affairs and is currently pending against Respondent. The First Amended Accusation and all other statutorily required documents were properly served on Respondent on January 4, 2021. Respondent timely filed its Notice of Defense contesting the First Amended Accusation. A copy of First Amended Accusation No. 6850 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 6850. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent denies the allegations in First Amended Accusation No. 6850.

9. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up its right to contest those charges.

10. Respondent agrees that its Wholesale Permit is subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified,

supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Wholesale Permit No. WLS 3076 issued to Respondent McKesson Corporation, dba McKesson Drug Company, shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of First Amended Accusation No. 6850, attached as exhibit A.

Cost Recovery. No later than 60 days from the effective date of the Decision, Respondent shall pay $147,780.00 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew its Wholesale Permit Number until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in First Amended Accusation No. 6850, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Wholesale Permit No. WLS 3076.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Alissa Brice Castaneda. I understand the stipulation and the effect it will have on my Wholesale Permit. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

MCKESSON CORPORATION, DBA
MCKESSON DRUG COMPANY
Respondent

I have read and fully discussed with Respondent McKesson Corporation, dba McKesson Drug Company the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: _____

ALISSA BRICE CASTANEDA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

CHRISTINA THOMAS
Deputy Attorney General
Attorneys for Complainant

LA2019505103
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DATED: 12/17/2021

MCKESSON CORPORATION, DBA
MCKESSON DRUG COMPANY
Respondent

I have read and fully discussed with Respondent McKesson Corporation, dba McKesson Drug Company the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 12/17/2021

ALISSA BRICE CASTANEDA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 12/17/21

Respectfully submitted,

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

CHRISTINA THOMAS
Deputy Attorney General
Attorneys for Complainant

LA2019505103
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Exhibit A

First Amended Accusation No. 6850

XAVIER BECERRA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General
CHRISTINA THOMAS
Deputy Attorney General
State Bar No. 171168
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6297
Facsimile: (916) 731-2126
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY** **9501 S. Norwalk** **Santa Fe Springs, CA 90670** **Wholesale Permit No. WLS 3076,** **and** **JOHN F. BOHLINGER** **9501 Norwalk Blvd.** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318** Respondents.	Case No. 6850 **FIRST AMENDED ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about October 2, 1995, the Board of Pharmacy issued Wholesale Permit Number WLS 3076 to McKesson Corporation, dba McKesson Drug Company (Respondent

McKesson). The Wholesale Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2021, unless renewed.

3. On or about January 21, 2004, the Board of Pharmacy issued Original Certificate Number EXC 17318 to John F. Bohlinger (Respondent Bohlinger) to act as a Designated Representative. The certificate was in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2021, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Section 4300 of the Code states:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

6. Section 4307 of the Code states:

> (a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

7. Section 4301 of the Code states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(*o*) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

///

8. California Health and Safety Code section 11153.5 states, in pertinent part:

(a) No wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, shall furnish controlled substances for other than legitimate medical purposes."

...

(c) Factors to be considered in determining whether a wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, furnished controlled substances knowing or having a conscious disregard for the fact that the controlled substances are for other than legitimate medical purposes shall include, but not be limited to, whether the use of controlled substances was for purposes of increasing athletic ability or performance, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes the product.

9. Section 4169.1 of the Code (effective January 1, 2018), states:

A wholesaler, upon discovery, shall notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the board a copy of the information that the wholesaler provides to the United States Drug Enforcement Administration. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

10. Section 4059.5, subsection (a), of the Code states:

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, or in the case of a reverse distributor a designated representative-reverse distributor, that individual shall sign for and receive the delivery.

REGULATORY PROVISIONS

11. Code of Federal Regulations, title 21, section 1301.74, subsection (b), states:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

12. California Code of Regulations, title 16, section 1783, states, in pertinent part:

(a) A manufacturer or wholesaler shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer or wholesaler shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

(b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

(c) Dangerous drugs or devices furnished by a manufacturer or wholesaler shall be delivered only to the premises listed on the permit; provided that a manufacturer or wholesaler may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer or wholesaler if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer or wholesaler by the next business day after the delivery to the pharmacy receiving area.

COST RECOVERY

13. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

CONTROLLED SUBSTANCES / DANGEROUS DRUGS

14. Section 4021 of the Code states: "'Controlled substance' means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code."

15. Section 4022 of the Code states: "'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:

(a) Any drug that bears the legend: 'Caution: federal law prohibits dispensing without prescription,' 'Rx only,' or words of similar import.

...

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

16. Phenergan with Codeine Syrup 6.25 mg – 10 mg / 5 ml is the brand name for promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C), a Schedule V controlled substance designated by California Health and Safety Code section 11058(c)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat coughing.

17. Xanax is the brand name for alprazolam, a Schedule IV controlled substance designated by California Health and Safety Code section 11057(d)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat anxiety.

FACTUAL ALLEGATIONS – CHILDREN'S MEDICAL CENTER PHARMACY

18. At all times relevant herein, the Children's Medical Center Pharmacy, also known as the Rady Children's Outpatient Pharmacy (Rady Pharmacy), was part of the Rady Children's Hospital of San Diego. According to its website, it is the only hospital in the San Diego area dedicated exclusively to pediatric healthcare.

19. Between May 7, 2017 and June 26, 2018, the Rady Pharmacy could not account for an inventory shortage of approximately 119 pints of P/C and 5,300 tablets of alprazolam 2mg. A pharmacy technician at the Rady Pharmacy had stolen these dangerous drugs and controlled substances for herself and her friends.

Promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C)

20. Based on Lexicomp Online, a collection of clinical database and clinical decision support tools, P/C is not recommended in pediatrics due to risk of adverse effects, such as slowed or difficult breathing, misuse, abuse, addiction, overdose, and death.

21. According to the pharmacy manager, the Rady Pharmacy did not use or dispense P/C because pediatric doctors did not prescribe P/C to children. On the rare occasion the doctor prescribed P/C, it would be during the winter season according to the pharmacy manager.

22. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, less than two 16-ounce bottles of P/C **per year** to the Rady Pharmacy between January 2014 and August 2017. Beginning in September 2017, the sales of P/C displayed an irregular pattern compared to the previous ordering pattern:

P/C Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (16oz) of P/C Sold**
September 2017	11
October 2017	7
November 2017	7
December 2017	10
January 2018	14
February 2018	10
March 2018	15
April 2018	10
May 2018	18
June 2018	17

23. When calculating the monthly percentage change in sales, there were sales of P/C which varied from 40% to 80% more than the sale from the previous month.

24. The orders for P/C beginning in September 2017 were significantly larger and were shipped in consecutive months from September 2017 to June 2018, which totaled approximately 119 pints or 56,287 ml of P/C.

Alprazolam 2mg

25. Alprazolam is available in dosages of 0.25 mg, 0.5 mg, 1 mg, and 2mg.

26. According to Lexicomp Online, alprazolam should be titrated and used at the lowest effective dose. Lexicomp provided the following dosing information: "*Children ≥ 7 years and Adolescents < 18 years: Limited data available... Initial: 0.005 to 0.02 mg/kg/dose 3 times daily... maximum of 0.02 mg/kg/dose.*" For example, if a child is 40 kg (about 88 pounds), the dosing range is from 0.2 to 0.8 mg per dose.

27. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, one bottle of 100-count alprazolam 2mg **per year** between January 2014 and September 2017. Beginning in October 2017, the sales of alprazolam 2mg displayed an irregular pattern compared to the previous ordering pattern:

///

///

///

///

Alprazolam 2mg Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (100-count) of alprazolam 2mg Sold**
October 2017	7
November 2017	9
December 2017	8
January 2018	4
February 2018	4
March 2018	4
April 2018	0
May 2018	15

28. When calculating the monthly percentage change in sales, there were sales of alprazolam 2mg which varied from 250% to 275% more than the sale from the previous month.

29. The orders for alprazolam 2mg beginning in October 2017 were significantly larger and were shipped in consecutive months (except April 2018) from October 2017 to May 2018, which totaled approximately 5,100 tablets of alprazolam 2 mg.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Excessive Furnishing of Controlled Substances)

30. Respondents are subject to disciplinary action under Code section 4301, subsection (e), in that Respondents clearly and excessively furnished controlled substances in violation of California Health and Safety Code section 11153.5, subsection (a), as follows:

a. Respondents furnished the Rady Pharmacy one to two pints of P/C in non-consecutive months from January 2014 to August 2017. Sales increased to seven to 18 pints ordered in consecutive months from September 2017 to June 2018.

b. Respondents furnished the Rady Pharmacy 100 to 200 tablets of alprazolam 2mg in non-consecutive months from January 2014 to September 2017. Sales increased to 400 to 1,500 tablets ordered in consecutive months from October 2017 to May 2018 (except April 2018).

c. Respondents furnished the Rady Pharmacy large quantities of controlled substances (P/C and alprazolam 2mg) that are not typically distributed to pediatric patients.

d. The P/C and alprazolam 2mg furnished by Respondents were not dispensed to patients for legitimate medical purposes but were diverted by a pharmacy technician.

Paragraphs 18 to 29 are re-alleged as if fully set forth herein.

///

FACTUAL ALLEGATIONS – CARING PHARMACY

31. On January 7, 2020, a Board inspector conducted an inspection of Caring Pharmacy (Caring Pharmacy), located at 25802 Hemingway Avenue #103, Stevenson Ranch, CA 91381. K.F. is a licensed pharmacist and the owner of Caring Pharmacy. S.F. is K.F's wife and is an unlicensed individual.

32. During this inspection at approximately 9:30 a.m., the Board inspector observed Respondent McKesson's delivery driver bring a drug tote (Drug Tote) to S.F.'s car in front of Caring Pharmacy. S.F. signed for the delivery, and the delivery driver left. S.F. subsequently brought the Drug Tote into Caring Pharmacy.

33. Shortly thereafter, the Board inspector entered Caring Pharmacy, and S.F. stated that no pharmacist was present at Caring Pharmacy at that time. The invoice that accompanied the Drug Tote revealed that the Drug Tote consisted of Emgality and Repatha, both of which are dangerous drugs under California Business and Professions Code section 4022.

SECOND CAUSE FOR DISCIPLINE

(Violation of Statute Regulating Dangerous Drugs)

34. Respondents are subject to disciplinary action under Code section 4301, subsection (j), in that Respondents committed unprofessional conduct by violating California Business and Professions Code section 4059.5, subsection (a). Specifically, on or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for or received by a pharmacist. The drugs were signed for by an unlicensed individual.

THIRD CAUSE FOR DISCIPLINE

(Violation of Pharmacy Law)

35. Respondents are subject to disciplinary action under Code section 4301, subsection (o), in that Respondents committed unprofessional conduct by violating the following Pharmacy Law and regulations:

///

///

///

a. California Business and Professions Code section 4059.5, subsection (a): On or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for and received by a pharmacist. The drugs were signed for by an unlicensed individual.

b. California Code of Regulations, title 16, section 1783: On or about January 7, 2020, Respondents delivered dangerous drugs to an unlicensed person at Caring Pharmacy who was not an "authorized person" under California Code of Regulations, title 16, section 1783, subsection (b).

DISCIPLINARY CONSIDERATIONS

36. On April 5, 2018, the Board issued Citation No. CI 2014 63111 to Respondent McKesson for violating California Health and Safety Code section 11153.5 [wholesaler furnishing controlled substance other than for legitimate medical purposes] and assessed a fine of $5,000.00. Respondent McKesson has paid the fine.

37. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

38. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

39. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

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40. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

OTHER MATTERS

41. Pursuant to Code section 4307, if discipline is imposed on Wholesale Permit Number WLS 3076 issued to McKesson Corporation, McKesson Corporation shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Wholesale Permit Number WLS 3076, issued to McKesson Corporation, dba McKesson Drug Company;

2. Revoking or suspending Designated Representative Number EXC 17318, issued to John F. Bohlinger;

3. Prohibiting McKesson Corporation from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if Wholesale Permit Number WLS 3076 issued to McKesson Corporation is revoked;

4. Ordering McKesson Corporation and John F. Bohlinger to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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5. Taking such other and further action as deemed necessary and proper.

DATED: 11/16/2020

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2020.11.16 05:53:42 -08'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 22, 2022

CERTIFIED MAIL

John F. Bohlinger
9501 Norwalk Blvd.
Santa Fe Springs, CA 90670

RE: Administrative Case No. 6850
John F. Bohlinger, EXC 17318

Dear Mr. Bohlinger:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order for Public Reproval regarding the above-referenced matter. Your attention is directed to page 4 of the document.

Effective at 5:00 p.m. on March 24, 2022, Designated Representative No. EXC 17318 issued to John F. Bohlinger shall be publicly reproved by the Board and shall also be subject to terms and conditions in the decision.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, at lupe.baltazar@dca.ca.gov or (916) 518-3009. Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Sincerely,

ANNE SODERGREN
Executive Officer

By Susan Cappello

Susan Cappello
Enforcement Manager

SC:lb
Enclosure(s)

cc: Christina Thomas, DAG
Amy Levine Heiserman, Esq.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 6850
John F. Bohlinger, EXC 17318

I am over 18 years of age, and not a party to the within cause; my business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
John F. Bohlinger 9501 Norwalk Blvd. Santa Fe Springs, CA 90670	7017 0190 0000 4212 5632
Amy Levine Heiserman, Esq. Quarles & Brady LLP One Renaissance Square Two North Central Avenue, Suite 600 Phoenix, AZ 85004-2322	7017 0190 0000 4212 5625

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on February 22, 2022, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 22, 2022 at Sacramento, California.

Lupe Baltazar, Administrative Case Analyst

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against:

MCKESSON CORPORATION, dba
MCKESSON DRUG COMPANY,
Wholesale Permit No. WLS 3076;

and

JOHN F. BOHLINGER,
Designated Representative License No. EXC 17318,

Respondents

Agency Case No. 6850

OAH No. 2021050035

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 24, 2022.

It is so ORDERED on February 22, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General
CHRISTINA THOMAS
Deputy Attorney General
State Bar No. 171168
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6297
Facsimile: (916) 731-2126
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against: **MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY** **9501 Norwalk Boulevard** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318,** **and** **JOHN F. BOHLINGER** **9501 Norwalk Blvd.** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318** Respondents.	Case No. 6850 OAH No. 2021050035 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL (AS TO JOHN F. BOHLINGER, ONLY)** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Christina Thomas, Deputy Attorney General.

2. Respondent John F. Bohlinger is represented in this proceeding by attorney Alissa Brice Castaneda, whose address is: Quarles & Brady LLP One Renaissance Square Two North Central Avenue Phoenix, AZ 85004-2391

JURISDICTION

3. On or about January 21, 2004, the Board issued Designated Representative License No. EXC 17318 to John F. Bohlinger. The Designated Representative License was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 6850 and will expire on January 1, 2023, unless renewed.

4. First Amended Accusation No. 6850 was filed before the Board of Pharmacy, Department of Consumer Affairs and is currently pending against Respondent. The First Amended Accusation and all other statutorily required documents were properly served on Respondent on January 4, 2021. Respondent timely filed his Notice of Defense contesting the First Amended Accusation. A copy of First Amended Accusation No. 6850 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 6850. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be represented by counsel at his own expense; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

///

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent denies the allegations in First Amended Accusation No. 6850.

9. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up his right to contest those charges.

10. Respondent agrees that his Designated Representative is subject to discipline and he agrees to be bound by the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified,

supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Designated Representative License No. EXC 17318 issued to Respondent John F. Bohlinger shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of First Amended Accusation No. 6850, attached as exhibit A.

Coursework. No later than six months from the effective date of the public reproval, Respondent, at his own expense, shall enroll, successfully complete and submit verification of a six- hour course relevant to the Drug Supply Chain Security as specified by the Board. Respondent shall obtain prior approval from the Board before enrolling in the course. Respondent shall submit to the Board the original transcripts or certificates of completion for the above-required course.

Full Compliance. As a resolution of the charges in First Amended Accusation No. 6850, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Designated Representative License No. EXC 17318.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Alissa Brice Castaneda. I understand the stipulation and the effect it will have on my Designated Representative License. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

JOHN F. BOHLINGER
Respondent

I have read and fully discussed with Respondent the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: _____

ALISSA BRICE CASTANEDA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

CHRISTINA THOMAS
Deputy Attorney General
Attorneys for Complainant

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DATED: 12/17/21

JOHN F. BOHLINGER
Respondent

I have read and fully discussed with Respondent the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 12/17/2021

ALISSA BRICE CASTANEDA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: December 17, 2021

Respectfully submitted,

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

CHRISTINA THOMAS
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 6850

XAVIER BECERRA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General
CHRISTINA THOMAS
Deputy Attorney General
State Bar No. 171168
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6297
Facsimile: (916) 731-2126
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY** **9501 S. Norwalk** **Santa Fe Springs, CA 90670** **Wholesale Permit No. WLS 3076,** **and** **JOHN F. BOHLINGER** **9501 Norwalk Blvd.** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318** Respondents.	Case No. 6850 **FIRST AMENDED ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about October 2, 1995, the Board of Pharmacy issued Wholesale Permit Number WLS 3076 to McKesson Corporation, dba McKesson Drug Company (Respondent

McKesson). The Wholesale Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2021, unless renewed.

3. On or about January 21, 2004, the Board of Pharmacy issued Original Certificate Number EXC 17318 to John F. Bohlinger (Respondent Bohlinger) to act as a Designated Representative. The certificate was in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2021, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Section 4300 of the Code states:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

6. Section 4307 of the Code states:

> (a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

7. Section 4301 of the Code states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(*o*) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

///

8. California Health and Safety Code section 11153.5 states, in pertinent part:

(a) No wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, shall furnish controlled substances for other than legitimate medical purposes."

...

(c) Factors to be considered in determining whether a wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, furnished controlled substances knowing or having a conscious disregard for the fact that the controlled substances are for other than legitimate medical purposes shall include, but not be limited to, whether the use of controlled substances was for purposes of increasing athletic ability or performance, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes the product.

9. Section 4169.1 of the Code (effective January 1, 2018), states:

A wholesaler, upon discovery, shall notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the board a copy of the information that the wholesaler provides to the United States Drug Enforcement Administration. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

10. Section 4059.5, subsection (a), of the Code states:

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, or in the case of a reverse distributor a designated representative-reverse distributor, that individual shall sign for and receive the delivery.

REGULATORY PROVISIONS

11. Code of Federal Regulations, title 21, section 1301.74, subsection (b), states:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

12. California Code of Regulations, title 16, section 1783, states, in pertinent part:

(a) A manufacturer or wholesaler shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer or wholesaler shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

(b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

(c) Dangerous drugs or devices furnished by a manufacturer or wholesaler shall be delivered only to the premises listed on the permit; provided that a manufacturer or wholesaler may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer or wholesaler if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer or wholesaler by the next business day after the delivery to the pharmacy receiving area.

COST RECOVERY

13. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

CONTROLLED SUBSTANCES / DANGEROUS DRUGS

14. Section 4021 of the Code states: "'Controlled substance' means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code."

15. Section 4022 of the Code states: "'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:

(a) Any drug that bears the legend: 'Caution: federal law prohibits dispensing without prescription,' 'Rx only,' or words of similar import.

...

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

16. Phenergan with Codeine Syrup 6.25 mg – 10 mg / 5 ml is the brand name for promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C), a Schedule V controlled substance designated by California Health and Safety Code section 11058(c)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat coughing.

17. Xanax is the brand name for alprazolam, a Schedule IV controlled substance designated by California Health and Safety Code section 11057(d)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat anxiety.

FACTUAL ALLEGATIONS – CHILDREN'S MEDICAL CENTER PHARMACY

18. At all times relevant herein, the Children's Medical Center Pharmacy, also known as the Rady Children's Outpatient Pharmacy (Rady Pharmacy), was part of the Rady Children's Hospital of San Diego. According to its website, it is the only hospital in the San Diego area dedicated exclusively to pediatric healthcare.

19. Between May 7, 2017 and June 26, 2018, the Rady Pharmacy could not account for an inventory shortage of approximately 119 pints of P/C and 5,300 tablets of alprazolam 2mg. A pharmacy technician at the Rady Pharmacy had stolen these dangerous drugs and controlled substances for herself and her friends.

Promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C)

20. Based on Lexicomp Online, a collection of clinical database and clinical decision support tools, P/C is not recommended in pediatrics due to risk of adverse effects, such as slowed or difficult breathing, misuse, abuse, addiction, overdose, and death.

21. According to the pharmacy manager, the Rady Pharmacy did not use or dispense P/C because pediatric doctors did not prescribe P/C to children. On the rare occasion the doctor prescribed P/C, it would be during the winter season according to the pharmacy manager.

22. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, less than two 16-ounce bottles of P/C **per year** to the Rady Pharmacy between January 2014 and August 2017. Beginning in September 2017, the sales of P/C displayed an irregular pattern compared to the previous ordering pattern:

P/C Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (16oz) of P/C Sold**
September 2017	11
October 2017	7
November 2017	7
December 2017	10
January 2018	14
February 2018	10
March 2018	15
April 2018	10
May 2018	18
June 2018	17

23. When calculating the monthly percentage change in sales, there were sales of P/C which varied from 40% to 80% more than the sale from the previous month.

24. The orders for P/C beginning in September 2017 were significantly larger and were shipped in consecutive months from September 2017 to June 2018, which totaled approximately 119 pints or 56,287 ml of P/C.

Alprazolam 2mg

25. Alprazolam is available in dosages of 0.25 mg, 0.5 mg, 1 mg, and 2mg.

26. According to Lexicomp Online, alprazolam should be titrated and used at the lowest effective dose. Lexicomp provided the following dosing information: "*Children ≥ 7 years and Adolescents < 18 years: Limited data available... Initial: 0.005 to 0.02 mg/kg/dose 3 times daily... maximum of 0.02 mg/kg/dose.*" For example, if a child is 40 kg (about 88 pounds), the dosing range is from 0.2 to 0.8 mg per dose.

27. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, one bottle of 100-count alprazolam 2mg **per year** between January 2014 and September 2017. Beginning in October 2017, the sales of alprazolam 2mg displayed an irregular pattern compared to the previous ordering pattern:

///

///

///

///

Alprazolam 2mg Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (100-count) of alprazolam 2mg Sold**
October 2017	7
November 2017	9
December 2017	8
January 2018	4
February 2018	4
March 2018	4
April 2018	0
May 2018	15

28. When calculating the monthly percentage change in sales, there were sales of alprazolam 2mg which varied from 250% to 275% more than the sale from the previous month.

29. The orders for alprazolam 2mg beginning in October 2017 were significantly larger and were shipped in consecutive months (except April 2018) from October 2017 to May 2018, which totaled approximately 5,100 tablets of alprazolam 2 mg.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Excessive Furnishing of Controlled Substances)

30. Respondents are subject to disciplinary action under Code section 4301, subsection (e), in that Respondents clearly and excessively furnished controlled substances in violation of California Health and Safety Code section 11153.5, subsection (a), as follows:

a. Respondents furnished the Rady Pharmacy one to two pints of P/C in non-consecutive months from January 2014 to August 2017. Sales increased to seven to 18 pints ordered in consecutive months from September 2017 to June 2018.

b. Respondents furnished the Rady Pharmacy 100 to 200 tablets of alprazolam 2mg in non-consecutive months from January 2014 to September 2017. Sales increased to 400 to 1,500 tablets ordered in consecutive months from October 2017 to May 2018 (except April 2018).

c. Respondents furnished the Rady Pharmacy large quantities of controlled substances (P/C and alprazolam 2mg) that are not typically distributed to pediatric patients.

d. The P/C and alprazolam 2mg furnished by Respondents were not dispensed to patients for legitimate medical purposes but were diverted by a pharmacy technician.

Paragraphs 18 to 29 are re-alleged as if fully set forth herein.

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FACTUAL ALLEGATIONS – CARING PHARMACY

31. On January 7, 2020, a Board inspector conducted an inspection of Caring Pharmacy (Caring Pharmacy), located at 25802 Hemingway Avenue #103, Stevenson Ranch, CA 91381. K.F. is a licensed pharmacist and the owner of Caring Pharmacy. S.F. is K.F's wife and is an unlicensed individual.

32. During this inspection at approximately 9:30 a.m., the Board inspector observed Respondent McKesson's delivery driver bring a drug tote (Drug Tote) to S.F.'s car in front of Caring Pharmacy. S.F. signed for the delivery, and the delivery driver left. S.F. subsequently brought the Drug Tote into Caring Pharmacy.

33. Shortly thereafter, the Board inspector entered Caring Pharmacy, and S.F. stated that no pharmacist was present at Caring Pharmacy at that time. The invoice that accompanied the Drug Tote revealed that the Drug Tote consisted of Emgality and Repatha, both of which are dangerous drugs under California Business and Professions Code section 4022.

SECOND CAUSE FOR DISCIPLINE

(Violation of Statute Regulating Dangerous Drugs)

34. Respondents are subject to disciplinary action under Code section 4301, subsection (j), in that Respondents committed unprofessional conduct by violating California Business and Professions Code section 4059.5, subsection (a). Specifically, on or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for or received by a pharmacist. The drugs were signed for by an unlicensed individual.

THIRD CAUSE FOR DISCIPLINE

(Violation of Pharmacy Law)

35. Respondents are subject to disciplinary action under Code section 4301, subsection (o), in that Respondents committed unprofessional conduct by violating the following Pharmacy Law and regulations:

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a. California Business and Professions Code section 4059.5, subsection (a): On or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for and received by a pharmacist. The drugs were signed for by an unlicensed individual.

b. California Code of Regulations, title 16, section 1783: On or about January 7, 2020, Respondents delivered dangerous drugs to an unlicensed person at Caring Pharmacy who was not an "authorized person" under California Code of Regulations, title 16, section 1783, subsection (b).

DISCIPLINARY CONSIDERATIONS

36. On April 5, 2018, the Board issued Citation No. CI 2014 63111 to Respondent McKesson for violating California Health and Safety Code section 11153.5 [wholesaler furnishing controlled substance other than for legitimate medical purposes] and assessed a fine of $5,000.00. Respondent McKesson has paid the fine.

37. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

38. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

39. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

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40. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

OTHER MATTERS

41. Pursuant to Code section 4307, if discipline is imposed on Wholesale Permit Number WLS 3076 issued to McKesson Corporation, McKesson Corporation shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Wholesale Permit Number WLS 3076, issued to McKesson Corporation, dba McKesson Drug Company;

2. Revoking or suspending Designated Representative Number EXC 17318, issued to John F. Bohlinger;

3. Prohibiting McKesson Corporation from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if Wholesale Permit Number WLS 3076 issued to McKesson Corporation is revoked;

4. Ordering McKesson Corporation and John F. Bohlinger to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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///

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///

5. Taking such other and further action as deemed necessary and proper.

DATED: 11/16/2020

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2020.11.16 05:53:42 -08'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MCKESSON DRUG COMPANY	)	**BOARD OF PHARMACY**
	)	
Wholesale Distributor Permit No. 192131	)	**CASE NO: 22-L-0252**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against **MCKESSON DRUG COMPANY** which resulted in the filing of a Notice of Hearing and Statement of Charges ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that **MCKESSON DRUG COMPANY** has violated the provisions of law based upon the conduct set out in the Statement.

2. **MCKESSON DRUG COMPANY** shall pay an administrative fine in the amount of Twenty-Five Thousand Dollars ($25,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall **MCKESSON DRUG COMPANY** attempt to discharge the same.

3. **MCKESSON DRUG COMPANY** expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and

§40-22-20 and Code of Alabama (1975), §20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. **MCKESSON DRUG COMPANY** further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, **MCKESSON DRUG COMPANY** hereby releases the Board, its members, agents, representatives, servants, and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. **MCKESSON DRUG COMPANY** acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against **MCKESSON DRUG COMPANY's** permit, including, but not limited to revocation.

6. **MCKESSON DRUG COMPANY** acknowledges and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. **MCKESSON DRUG COMPANY** acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 19th of July, 2023.

MCKESSON DRUG COMPANY

BY: Jammie McKay

ITS: SVP Customer Distribution

By: _____
Nicholas Meza,
Attorney for
MCKESSON DRUG COMPANY

DONE this the 22nd of July, 2023.

ALABAMA STATE BOARD OF PHARMACY

By: _____
Robert M. Colburn, Jr., R. Ph., President

By: _____
Jennifer Muro Neumann,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
Jennifer Muro Neumann, PC
Post Office Box 381082
Birmingham, AL 35238
(205) 451-3092

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EXHIBIT A

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IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MCKESSON DRUG COMPANY	)	**BOARD OF PHARMACY**
	)	
Wholesale Distributor	)	**CASE NO: 22-L-0252**
Permit No. 192131	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: McKesson Drug Company
9501 Norwalk Boulevard
Santa Fe Springs, California 90670

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-92(12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on June 20, 2023 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate McKesson Drug Company as a Wholesale Distributor should not be subject to the discipline set out in Board Rule 680-X-2.23(h)(2)(i)(2) based upon any or all of the following, to-wit:

1. Pursuant to Board Rule 680-X-2.23(g)(3), the Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of those entities (a wholesaler) permitted for operation within the State of Alabama:

   a. Compliance with licensing requirements under previously granted licenses ((g)(3)(vi)).

   b. Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

((g)(3)(viii)).

2. It is a violation of these rules should any permitted entity operate in such a manner as to endanger the public health. (Board Rule 680-X-2.23(h)(2)(i)(1)).

3. Permitted entities shall operate in compliance with applicable state laws.

4. The Board alleges you have not complied with the licensing requirements under previously granted licenses, you have not operated consistent with public health and safety, you have operated in such a manner as to endanger the public health and/or you have not complied with applicable State law based upon the following:

(a) The entry of a Decision and Order on February 22, 2022 by the California State Board of Pharmacy attached hereto as Exhibit "A" and/or the excessive furnishing of controlled substances as set out in the First Cause for Discipline, and/or delivering drugs when not signed for or received by a pharmacist as set out in the Second and Third Cause for Discipline, those being separate and distinct violations as more particularly described in the First Amended Accusation included in Exhibit "A" hereto[1].

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

[1] This Rule was amended effective October 15, 2020 to add additional entities now regulated by the Board; however, the Rule prior to the Amendment applied to and was in full force and effect as to the permit held by the Respondent at the time of the referenced discipline.

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Dated this the 24th day of August, 2022.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

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EXHIBIT "A"

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against:

MCKESSON CORPORATION, dba
MCKESSON DRUG COMPANY,
Wholesale Permit No. WLS 3076;

and

JOHN F. BOHLINGER,
Designated Representative License No. EXC 17318,

Respondents

Agency Case No. 6850

OAH No. 2021050035

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DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 24, 2022.

It is so ORDERED on February 22, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



Seung W. Oh, Pharm.D.
Board President

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ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General
CHRISTINA THOMAS
Deputy Attorney General
State Bar No. 171168
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6297
Facsimile: (916) 731-2126
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against: **MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY** **9501 Norwalk Boulevard** **Santa Fe Springs, CA 90670** **Wholesale Permit No. WLS 3076,** **and** **JOHN F. BOHLINGER** **9501 Norwalk Blvd.** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318** Respondents.	Case No. 6850 OAH No. 2021050035 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL (AS TO MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY, ONLY)** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Christina Thomas, Deputy Attorney General.

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2. Respondent McKesson Corporation, dba McKesson Drug Company (Respondent) is represented in this proceeding by attorney Alissa Brice Castenada, whose address is: Quarles & Brady LLP One Renaissance Square Two North Central Avenue Phoenix, AZ 85004-2391

JURISDICTION

3. On or about October 2, 1995, the Board issued Wholesale Permit No. WLS 3076 to McKesson Corporation, dba McKesson Drug Company. The Wholesale Permit was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 6850 and will expire on October 1, 2022, unless renewed.

4. First Amended Accusation No. 6850 was filed before the Board of Pharmacy, Department of Consumer Affairs and is currently pending against Respondent. The First Amended Accusation and all other statutorily required documents were properly served on Respondent on January 4, 2021. Respondent timely filed its Notice of Defense contesting the First Amended Accusation. A copy of First Amended Accusation No. 6850 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 6850. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent denies the allegations in First Amended Accusation No. 6850.

9. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up its right to contest those charges.

10. Respondent agrees that its Wholesale Permit is subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified,

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supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Wholesale Permit No. WLS 3076 issued to Respondent McKesson Corporation, dba McKesson Drug Company, shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of First Amended Accusation No. 6850, attached as exhibit A.

Cost Recovery. No later than 60 days from the effective date of the Decision, Respondent shall pay $147,780.00 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew its Wholesale Permit Number until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in First Amended Accusation No. 6850, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Wholesale Permit No. WLS 3076.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Alissa Brice Castaneda. I understand the stipulation and the effect it will have on my Wholesale Permit. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

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DATED: _____

MCKESSON CORPORATION, DBA
MCKESSON DRUG COMPANY
Respondent

I have read and fully discussed with Respondent McKesson Corporation, dba McKesson Drug Company the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: _____

ALISSA BRICE CASTANEDA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

CHRISTINA THOMAS
Deputy Attorney General
Attorneys for Complainant

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DATED: 12/17/2021

MCKESSON CORPORATION, DBA
MCKESSON DRUG COMPANY
Respondent

I have read and fully discussed with Respondent McKesson Corporation, dba McKesson Drug Company the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 12/17/2021

ALISSA BRICE CASTANEDA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 12/17/21

Respectfully submitted,

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

CHRISTINA THOMAS
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 6850

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XAVIER BECERRA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General
CHRISTINA THOMAS
Deputy Attorney General
State Bar No. 171168
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6297
Facsimile: (916) 731-2126
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY** **9501 S. Norwalk** **Santa Fe Springs, CA 90670** **Wholesale Permit No. WLS 3076,** **and** **JOHN F. BOHLINGER** **9501 Norwalk Blvd.** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318** Respondents.	Case No. 6850 **FIRST AMENDED ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about October 2, 1995, the Board of Pharmacy issued Wholesale Permit Number WLS 3076 to McKesson Corporation, dba McKesson Drug Company (Respondent

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McKesson). The Wholesale Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2021, unless renewed.

3. On or about January 21, 2004, the Board of Pharmacy issued Original Certificate Number EXC 17318 to John F. Bohlinger (Respondent Bohlinger) to act as a Designated Representative. The certificate was in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2021, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Section 4300 of the Code states:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

6. Section 4307 of the Code states:

> (a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

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(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

7. Section 4301 of the Code states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(*o*) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

///

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8. California Health and Safety Code section 11153.5 states, in pertinent part:

(a) No wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, shall furnish controlled substances for other than legitimate medical purposes."

...

(c) Factors to be considered in determining whether a wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, furnished controlled substances knowing or having a conscious disregard for the fact that the controlled substances are for other than legitimate medical purposes shall include, but not be limited to, whether the use of controlled substances was for purposes of increasing athletic ability or performance, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes the product.

9. Section 4169.1 of the Code (effective January 1, 2018), states:

A wholesaler, upon discovery, shall notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the board a copy of the information that the wholesaler provides to the United States Drug Enforcement Administration. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

10. Section 4059.5, subsection (a), of the Code states:

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, or in the case of a reverse distributor a designated representative-reverse distributor, that individual shall sign for and receive the delivery.

REGULATORY PROVISIONS

11. Code of Federal Regulations, title 21, section 1301.74, subsection (b), states:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

12. California Code of Regulations, title 16, section 1783, states, in pertinent part:

(a) A manufacturer or wholesaler shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer or wholesaler shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

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(b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

(c) Dangerous drugs or devices furnished by a manufacturer or wholesaler shall be delivered only to the premises listed on the permit; provided that a manufacturer or wholesaler may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer or wholesaler if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer or wholesaler by the next business day after the delivery to the pharmacy receiving area.

COST RECOVERY

13. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

CONTROLLED SUBSTANCES / DANGEROUS DRUGS

14. Section 4021 of the Code states: "'Controlled substance' means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code."

15. Section 4022 of the Code states: "'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:

(a) Any drug that bears the legend: 'Caution: federal law prohibits dispensing without prescription,' 'Rx only,' or words of similar import.

...

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

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16. Phenergan with Codeine Syrup 6.25 mg – 10 mg / 5 ml is the brand name for promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C), a Schedule V controlled substance designated by California Health and Safety Code section 11058(c)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat coughing.

17. Xanax is the brand name for alprazolam, a Schedule IV controlled substance designated by California Health and Safety Code section 11057(d)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat anxiety.

FACTUAL ALLEGATIONS – CHILDREN'S MEDICAL CENTER PHARMACY

18. At all times relevant herein, the Children's Medical Center Pharmacy, also known as the Rady Children's Outpatient Pharmacy (Rady Pharmacy), was part of the Rady Children's Hospital of San Diego. According to its website, it is the only hospital in the San Diego area dedicated exclusively to pediatric healthcare.

19. Between May 7, 2017 and June 26, 2018, the Rady Pharmacy could not account for an inventory shortage of approximately 119 pints of P/C and 5,300 tablets of alprazolam 2mg. A pharmacy technician at the Rady Pharmacy had stolen these dangerous drugs and controlled substances for herself and her friends.

Promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C)

20. Based on Lexicomp Online, a collection of clinical database and clinical decision support tools, P/C is not recommended in pediatrics due to risk of adverse effects, such as slowed or difficult breathing, misuse, abuse, addiction, overdose, and death.

21. According to the pharmacy manager, the Rady Pharmacy did not use or dispense P/C because pediatric doctors did not prescribe P/C to children. On the rare occasion the doctor prescribed P/C, it would be during the winter season according to the pharmacy manager.

22. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, less than two 16-ounce bottles of P/C **per year** to the Rady Pharmacy between January 2014 and August 2017. Beginning in September 2017, the sales of P/C displayed an irregular pattern compared to the previous ordering pattern:

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P/C Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (16oz) of P/C Sold**
September 2017	11
October 2017	7
November 2017	7
December 2017	10
January 2018	14
February 2018	10
March 2018	15
April 2018	10
May 2018	18
June 2018	17

23. When calculating the monthly percentage change in sales, there were sales of P/C which varied from 40% to 80% more than the sale from the previous month.

24. The orders for P/C beginning in September 2017 were significantly larger and were shipped in consecutive months from September 2017 to June 2018, which totaled approximately 119 pints or 56,287 ml of P/C.

Alprazolam 2mg

25. Alprazolam is available in dosages of 0.25 mg, 0.5 mg, 1 mg, and 2mg.

26. According to Lexicomp Online, alprazolam should be titrated and used at the lowest effective dose. Lexicomp provided the following dosing information: "*Children ≥ 7 years and Adolescents < 18 years: Limited data available... Initial: 0.005 to 0.02 mg/kg/dose 3 times daily... maximum of 0.02 mg/kg/dose.*" For example, if a child is 40 kg (about 88 pounds), the dosing range is from 0.2 to 0.8 mg per dose.

27. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, one bottle of 100-count alprazolam 2mg **per year** between January 2014 and September 2017. Beginning in October 2017, the sales of alprazolam 2mg displayed an irregular pattern compared to the previous ordering pattern:

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Alprazolam 2mg Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (100-count) of alprazolam 2mg Sold**
October 2017	7
November 2017	9
December 2017	8
January 2018	4
February 2018	4
March 2018	4
April 2018	0
May 2018	15

28. When calculating the monthly percentage change in sales, there were sales of alprazolam 2mg which varied from 250% to 275% more than the sale from the previous month.

29. The orders for alprazolam 2mg beginning in October 2017 were significantly larger and were shipped in consecutive months (except April 2018) from October 2017 to May 2018, which totaled approximately 5,100 tablets of alprazolam 2 mg.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Excessive Furnishing of Controlled Substances)

30. Respondents are subject to disciplinary action under Code section 4301, subsection (e), in that Respondents clearly and excessively furnished controlled substances in violation of California Health and Safety Code section 11153.5, subsection (a), as follows:

a. Respondents furnished the Rady Pharmacy one to two pints of P/C in non-consecutive months from January 2014 to August 2017. Sales increased to seven to 18 pints ordered in consecutive months from September 2017 to June 2018.

b. Respondents furnished the Rady Pharmacy 100 to 200 tablets of alprazolam 2mg in non-consecutive months from January 2014 to September 2017. Sales increased to 400 to 1,500 tablets ordered in consecutive months from October 2017 to May 2018 (except April 2018).

c. Respondents furnished the Rady Pharmacy large quantities of controlled substances (P/C and alprazolam 2mg) that are not typically distributed to pediatric patients.

d. The P/C and alprazolam 2mg furnished by Respondents were not dispensed to patients for legitimate medical purposes but were diverted by a pharmacy technician.

Paragraphs 18 to 29 are re-alleged as if fully set forth herein.

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FACTUAL ALLEGATIONS – CARING PHARMACY

31. On January 7, 2020, a Board inspector conducted an inspection of Caring Pharmacy (Caring Pharmacy), located at 25802 Hemingway Avenue #103, Stevenson Ranch, CA 91381. K.F. is a licensed pharmacist and the owner of Caring Pharmacy. S.F. is K.F's wife and is an unlicensed individual.

32. During this inspection at approximately 9:30 a.m., the Board inspector observed Respondent McKesson's delivery driver bring a drug tote (Drug Tote) to S.F.'s car in front of Caring Pharmacy. S.F. signed for the delivery, and the delivery driver left. S.F. subsequently brought the Drug Tote into Caring Pharmacy.

33. Shortly thereafter, the Board inspector entered Caring Pharmacy, and S.F. stated that no pharmacist was present at Caring Pharmacy at that time. The invoice that accompanied the Drug Tote revealed that the Drug Tote consisted of Emgality and Repatha, both of which are dangerous drugs under California Business and Professions Code section 4022.

SECOND CAUSE FOR DISCIPLINE

(Violation of Statute Regulating Dangerous Drugs)

34. Respondents are subject to disciplinary action under Code section 4301, subsection (j), in that Respondents committed unprofessional conduct by violating California Business and Professions Code section 4059.5, subsection (a). Specifically, on or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for or received by a pharmacist. The drugs were signed for by an unlicensed individual.

THIRD CAUSE FOR DISCIPLINE

(Violation of Pharmacy Law)

35. Respondents are subject to disciplinary action under Code section 4301, subsection (o), in that Respondents committed unprofessional conduct by violating the following Pharmacy Law and regulations:

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a. California Business and Professions Code section 4059.5, subsection (a): On or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for and received by a pharmacist. The drugs were signed for by an unlicensed individual.

b. California Code of Regulations, title 16, section 1783: On or about January 7, 2020, Respondents delivered dangerous drugs to an unlicensed person at Caring Pharmacy who was not an "authorized person" under California Code of Regulations, title 16, section 1783, subsection (b).

DISCIPLINARY CONSIDERATIONS

36. On April 5, 2018, the Board issued Citation No. CI 2014 63111 to Respondent McKesson for violating California Health and Safety Code section 11153.5 [wholesaler furnishing controlled substance other than for legitimate medical purposes] and assessed a fine of $5,000.00. Respondent McKesson has paid the fine.

37. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

38. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

39. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

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40. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

OTHER MATTERS

41. Pursuant to Code section 4307, if discipline is imposed on Wholesale Permit Number WLS 3076 issued to McKesson Corporation, McKesson Corporation shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Wholesale Permit Number WLS 3076, issued to McKesson Corporation, dba McKesson Drug Company;

2. Revoking or suspending Designated Representative Number EXC 17318, issued to John F. Bohlinger;

3. Prohibiting McKesson Corporation from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if Wholesale Permit Number WLS 3076 issued to McKesson Corporation is revoked;

4. Ordering McKesson Corporation and John F. Bohlinger to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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5. Taking such other and further action as deemed necessary and proper.

DATED: 11/16/2020

Signature on File

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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BEFORE THE GEORGIA STATE BOARD OF PHARMACY
STATE OF GEORGIA

IN THE MATTER OF:	)	
	)	
MCKESSON DRUG COMPANY,	)	**DOCKET NO.**
License No. PHWH000056,	)	
	)	
Respondent.	)	

GEORGIA STATE BOARD OF PHARMACY
APR 12,2024
DOCKET NO. 2024-0056

PUBLIC CONSENT ORDER

By agreement of the Georgia State Board of Pharmacy ("Board") and McKesson Drug Company, ("Respondent"), the following disposition of this matter is entered pursuant to the provisions of O.C.G.A. T. 26, Ch. 4, and T. 43, Ch. 1.

FINDINGS OF FACT

1.

Respondent is licensed to operate as a wholesaler pharmacy in the State of Georgia. Respondent's license was issued on April 22, 1993, and expires on June 30, 2025.

2.

On or about September 16, 2022, during an inspection of Coffee Regional Medical Center by the Georgia Drugs and Narcotics Agency ("GDNA"), it was discovered that Respondent had failed to maintain prescription drugs securely. Specifically, Respondent had 1) left a delivery truck unattended at a loading dock at the rear of Coffee Regional Medical Center, with its rear roll-up door open, and totes of prescription drugs exposed, for more than 10 minutes; 2) left the truck's keys in the ignition; 3) left the truck box unlocked; and 4) did not have a lock to secure the box. Prescription drugs left unsecured in the truck included, but were not limited to, controlled substances such as diazepam, midazolam, hydrocodone, fentanyl, amphetamine, and oxycodone.

3.

Respondent waives any further findings of fact.

CONCLUSIONS OF LAW

Under O.C.G.A. T. 26, Ch. 4 and § 43-1-19, the Georgia State Board of Pharmacy is authorized to discipline Respondent's license to operate as a pharmacy for the conduct stated above. Respondent waives any further conclusions of law with respect to this matter.

ORDER

The Board, having considered the particular facts and circumstances of this case, hereby ORDERS, and Respondent hereby AGREES, that Respondent's license shall be disciplined as follows:

1.

Respondent shall submit to the Board a fine in the amount of **Ten-Thousand Dollars ($10,000.00)** for failure to maintain prescription drugs securely. Such fine shall be payable within sixty (60) days from the effective date of this Public Consent Order. Payment shall be in the form of a cashier's check or money order made payable to the Georgia State Board of Pharmacy and sent to: Georgia State Board of Pharmacy, Attention: Executive Director, 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. Respondent's failure to pay the fine by the sixtieth day shall subject Respondent's license to further disciplinary action, including revocation.

2.

Respondent shall comply with all State and Federal laws relating to drugs and otherwise regulating pharmacies. Respondent shall also comply with the Rules and Regulations of the Georgia State Board of Pharmacy. The Board hereby puts Respondent on notice that Respondent is required to maintain the integrity and security of drugs being delivered to customers. Failure to comply with all laws and rules relating to the practice of pharmacy may result in further sanction or other discipline as deemed appropriate by the Board.

3.

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Approval of this Public Consent Order by the Georgia State Board of Pharmacy shall in no way be construed as condoning Respondent's conduct, and shall not be construed as a waiver of any of the lawful rights possessed by the Board. This Public Consent Order shall not become effective until approved and docketed by the Georgia State Board of Pharmacy.

4.

Agent of Respondent, McKesson Drug Company, acknowledges that Agent has read this Public Consent Order and understands its contents. Respondent understands that Respondent has a right to a hearing in this matter, and Respondent freely, knowingly, and voluntarily waives such right by entering into this Public Consent Order. Respondent understands that this Public Consent Order will not become effective until approved and docketed by the Georgia State Board of Pharmacy. Respondent further understands and agrees that the Board shall have the authority to review the investigative file and all relevant evidence in considering this Public Consent Order. Respondent further understands that this Public Consent Order, once approved, shall constitute a public record of the Board. Respondent further understands that if this Public Consent Order is not approved, it shall not constitute an admission against interest in this proceeding or prejudice the ability of the Board to adjudicate this matter. Respondent consents to the terms and sanctions contained herein.

(signatures appear on the following page)

Approved, this 12 day of April, 2024.

GEORGIA STATE BOARD OF PHARMACY

BY: _____
CHARLES E. PAGE, R.Ph.
President



ATTEST: _____
J. CLINTON JOINER, II
Executive Director

CONSENTED TO:

DocuSigned by
Ammie McAsey
8428C2822SFB40F
AGENT
Printed Name: Ammie McAsey
ON BEHALF OF
Respondent
MCKESSON DRUG COMPANY

AS TO SIGNATURE OF AGENT ON BEHALF OF RESPONDENT MCKESSON DRUG COMPANY

Sworn to and subscribed before me
this 8th day of March, 2024.

DocuSigned by
Misti Smart
NOTARY PUBLIC
My commission expires:



-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 8/29/2024
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

BEFORE THE OHIO BOARD OF PHARMACY

In the Matter of	:	
	:	**Case No. A-2021-0363**
McKesson Corporation	:	
c/o Todd Spaulding	:	**License No. 01-0977250**
3000 Kenskill Avenue	:	
Washington Court House, OH 43160	:	
	:	
Respondent.	:	

FINAL ORDER OF THE OHIO BOARD OF PHARMACY

McKesson Corporation ("Respondent") was issued a license as a wholesale distributor of dangerous drugs by the Ohio Board of Pharmacy on November 12, 1996. The Board issued a Notice of Opportunity for Hearing ("Notice") to Respondent on September 30, 2022, via certified mail, return receipt requested. Respondent received the Notice on October 3, 2022. Pursuant to Ohio Revised Code (ORC) Section 119.07, Respondent had a right to a hearing if requested within 30 days of mailing. Respondent failed to do so. Accordingly, no hearing was held, and the matter was brought before the Board on August 5, 2024, for final adjudication pursuant to ORC 119.07, and 4729.56(D).

WHEREFORE, after review of the administrative record, the Board finds that Respondent was legally served with the Notice and informed of the allegations contained therein and the rights afforded pursuant to ORC Chapter 119.

WHEREFORE, after review of the administrative record and pursuant to ORC 4729.56(A) and Ohio Administrative Code (OAC) 4729:6-4-01(A), the Board finds and concludes that Respondent engaged in conduct set forth in ORC 4729.56, OAC 4729:6-3-04, OAC 4729:6-4-01, and all violations of law as described in the Notice. Based on the findings contained herein, the Board ORDERS as follows:

1. The Board hereby imposes a written reprimand on Respondent's terminal distributor of dangerous drugs registration no. 01-0977250.

2. The Board hereby imposes a fine in the amount of $2,750.00. This fine will be attached to the registration record and must be paid no later than 180 days from the effective date of this Agreement. To pay this fine, login to www.elicense.ohio.gov and process the items in the cart.

3. This Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which Respondent currently holds a professional license, including to the Board on renewal applications or applications for a new license or registration.

Service of this Order shall be perfected in accordance with the requirements of ORC Chapter 119.

Trina Buettner, RPh, moved for the findings and decision of the Board. Jason George, RPh, seconded the motion. Motion passed (Yes-6/No-0).
SO ORDERED.

It is hereby certified by this Board that the above language is a copy of the Order entered upon its journal in this case.

TIME AND METHOD TO PERFECT AN APPEAL

Any party desiring to appeal shall file a Notice of Appeal with the Ohio Board of Pharmacy, 77 South High Street, 17th Floor, Columbus, OH 43215, setting forth the order appealed from and stating that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The notice of appeal may, but need not, set forth the specific grounds of the party's appeal beyond the statement that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The Notice of Appeal shall also be filed by the appellant in the court of common pleas of the county in which the place of business of the licensee is located or the county in which the licensee is a resident. If the appellant is not a resident of and has no place of business in this state, the party may appeal to the court of common pleas of Franklin County. Such notices of appeal shall be filed within fifteen (15) days after the service of the Ohio Board of Pharmacy's Order as provided in Section 119.12 of the Ohio Revised Code.

BY ORDER OF THE OHIO BOARD OF PHARMACY

ORDER MAILED & EFFECTIVE: **August 29, 2024**

By: Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Director

SWS/jak/jrn

STATE OF CONNECTICUT

DEPARTMENT OF CONSUMER PROTECTION

BEFORE THE COMMISSION OF PHARMACY

In the Matter of

McKesson Corporation Case No. 2023-477

Settlement Agreement Concerning

Wholesaler of Drugs, Cosmetics and Medical Devices License of McKesson Corporation

This Settlement Agreement by and between McKesson Corporation, hereinafter referred to as "Respondent," and the duly authorized representative of the Commissioner of Consumer Protection, is entered into in accordance with Sections 4-177(c) of the Connecticut General Statutes. In accordance herewith, the parties agree that:

PARAGRAPH ONE: Respondent is the holder of Connecticut Wholesaler of Drugs, Cosmetics, & Medical Devices License No. CSW.0003956.

PARAGRAPH TWO: The Department of Consumer Protection has alleged that Respondent failed to limit entry to only authorized personnel in areas where drugs are held, in violation of Section 21a-115-32(b)(4) of the Regulations of Connecticut State Agencies.

PARAGRAPH THREE: Respondent enters into this Settlement Agreement solely for the purposes of settlement. This Settlement Agreement shall neither be considered an admission of liability or a violation of law for any purpose, nor as evidence supporting the allegations of the Department of Consumer Protection.

PARAGRAPH FOUR: Respondent shall pay, prior to the approval of this Settlement Agreement by the Commissioner, a monetary payment in the amount of One Thousand Five

Hundred Dollars ($1,500.00) into the Consumer Protection Enforcement Account, Account No. 35125.

PARAGRAPH FIVE: Respondent shall be issued a Letter of Reprimand.

PARAGRAPH SIX: Respondent waives:

a) Any right to seek judicial review or otherwise challenge or contest the validity of this Settlement Agreement;

b) Any requirement that this Settlement Agreement contain findings of fact and conclusions of law; and

c) Any right to a hearing or other procedural requirements of the Uniform Administrative Procedure Act, Connecticut General Statutes, Section 4-166 et seq.

PARAGRAPH SEVEN: This Settlement Agreement is a revocable offer of settlement that may be modified by mutual agreement or withdrawn by the Department of Consumer Protection at any time prior to its being executed and shall not become binding unless and until it is accepted and approved by the Commission of Pharmacy.

FOR RESPONDENT

Dated: July 25, 2024

By: Ammie McAsey

Name: Ammie McAsey

Title: Sr. Vice President Customer Experience

FOR THE DEPARTMENT OF CONSUMER PROTECTION

Dated: 5/28/2024 By: _____

Michael Ando, Esq.
Staff Attorney

The above Settlement Agreement concerning Respondent is accepted and approved by the Commission of Pharmacy on _____ 2023.

_____

Angela DeFazio
Chairperson, Commission of Pharmacy

STATE OF CONNECTICUT

DEPARTMENT OF CONSUMER PROTECTION

August 28, 2024

Mckesson Corporation
Mckesson Drug Company
10 Hudson Crossing Dr.
Montgomery, NY 12549

Re: LETTER OF REPRIMAND
CSW.0003956, Case No. 2023-477

To Whom It May Concern:

Pursuant to the terms of the Settlement Agreement in Case No. 2023-477 concerning your Connecticut Wholesaler of Drugs, Medical Devices and/or Cosmetics with Controlled Substances, I am issuing this Letter of Reprimand. The Commission of Pharmacy expects that in the future you will exercise extra care and diligence when performing your professional duties.

Sincerely,

Angelo DeFazio
Chairperson, Commission of Pharmacy

From: Rogers, Brian
To: McKessonLicensing
Cc: Ando, Michael
Subject: [EXTERNAL] Fully Executed Settlement Agreement - Case No. 2023-477; CSW.0003956
Date: Wednesday, September 25, 2024 9:11:36 AM
Attachments: image001.png
2023-477 Settlement Agreement (signed).pdf

CAUTION: This email was sent from an EXTERNAL source. Use caution when clicking links or opening attachments.

Good Afternoon,

Attached please find a fully executed copy of the Settlement Agreement for Case No. 2023-477. The case is now closed.

Brian Rogers
Paralegal Specialist
Connecticut Consumer Protection
Phone: 860-757-6802
brian.rogers@ct.gov

CONFIDENTIAL INFORMATION: The information contained in this e-mail is confidential and may be privileged and protected from general disclosure. The information is intended to be used solely by the recipient(s) named. If you are not an intended recipient, be aware that any review, disclosure, copying, distribution or use of this transmission or its contents is prohibited. If you have received this e-mail in error, please notify the sender immediately by replying to this message so that we can take appropriate action and thereafter immediately delete or erase this message.

STATE OF CONNECTICUT

DEPARTMENT OF CONSUMER PROTECTION

BEFORE THE COMMISSIONER OF CONSUMER PROTECTION

In the Matter of

McKesson Corporation

Case No. 2023-522

Settlement Agreement Concerning

Wholesaler of Drugs, Cosmetics and Medical Device License of McKesson Corporation

This Settlement Agreement by and between McKesson Corporation, hereinafter referred to as "Respondent," and the duly authorized representative of the Commissioner of Consumer Protection, is entered into in accordance with Sections 4-177(c) of the Connecticut General Statutes. In accordance herewith, the parties agree that:

PARAGRAPH ONE: Respondent is the holder of Connecticut Wholesaler of Drugs, Cosmetics and Medical Device License No. CSW.0003956.

PARAGRAPH TWO: The Department of Consumer Protection has alleged that Respondent failed to limit entry into areas where drugs are held to authorized personnel, in violation of Section 21a-115-32(b)(4) of the Regulations of Connecticut State Agencies.

PARAGRAPH THREE: Respondent enters into this Settlement Agreement solely for the purposes of settlement. This Settlement Agreement shall neither be considered an admission of liability nor a violation of law for any purpose, nor as evidence supporting the allegations of the Department of Consumer Protection.

PARAGRAPH FOUR: Respondent shall pay, prior to the approval of this Settlement Agreement by the Commissioner, a monetary payment in the amount of Five Thousand Dollars ($5,000.00) into the Consumer Protection Enforcement Account, Account No. 35125.

PARAGRAPH FIVE: Respondent waives:

a) Any right to seek judicial review or otherwise challenge or contest the validity of this Settlement Agreement;

b) Any requirement that this Settlement Agreement contain findings of fact and conclusions of law; and

c) Any right to a hearing or other procedural requirements of the Uniform Administrative Procedure Act, Connecticut General Statutes, Section 4-166 et seq.

PARAGRAPH SIX: This Settlement Agreement is a revocable offer of settlement that may be modified by mutual agreement or withdrawn by the Department of Consumer Protection at any time prior to its execution and shall not become binding unless and until it is accepted and approved by the Commissioner of Consumer Protection.

FOR RESPONDENT

Dated: Sept. 30, 2024

By: Ammie McAsey

Name: Ammie McAsey

Title: Sr. Vice President

FOR THE DEPARTMENT OF CONSUMER PROTECTION

Dated: 10/3/24

By: _____

Katrina Cessna, Esq.
Staff Attorney

The above Settlement Agreement concerning Respondent is accepted and approved by the Commissioner of Consumer Protection on November 14, 2024.

_____

Bryan Cafferelli
Commissioner of Consumer Protection

Please note that the disciplinary actions described below do NOT pertain to operations at the location set forth in this application.

McKesson Corporation and its wholly owned subsidiaries (hereinafter "McKesson") delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 100 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. We have limited this summary to disciplinary actions taken against these facilities during the time frame specified in the question or the last six years in accordance with McKesson Corporation's Records and Information Management (RIM) Policy. ***The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions. This statement does not include any fines that are deemed non-disciplinary by the issuing state (for example, it does not include non-disciplinary Citations and Fines issued by California). Please let us know if your state requires information regarding non-disciplinary fines.***

On January 14, 2020, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Arizona State Board of Pharmacy, regarding its Tempe, AZ distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $1,000 was imposed and paid on January 14, 2020.

On May 29, 2020, the Colorado Department of Regulatory Agencies cited **McKesson Medical-Surgical Inc.** concerning its Roseville, CA distribution center for failure to submit in a timely manner, an application to the Board detailing a change of designated representative. A fine of $1,150 was imposed and paid on July 1, 2020.

On April 20, 2021, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Ohio Board of Pharmacy, regarding its Leetsdale, PA distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $1,125 was imposed and paid on April 20, 2021.

On May 05, 2021, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Maine Board of Pharmacy, regarding its Roseville, CA distribution center, in relation to the late reporting of a disciplinary action that was imposed by the Colorado Board of Pharmacy, for failure to report a change of designated representative within the required timeframe. A $500 civil penalty/fine was paid on 5/7/2021.

On June 6, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Leetsdale, PA distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $500 was imposed and paid on June 8, 2021.

On June 15, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $3000.00 was imposed and paid on June 15, 2021.

On June 23, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $125 was imposed and paid on June 23, 2021.

On January 18, 2022, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $500 was imposed and paid on January 18, 2022.

On January 20, 2022, **McKesson Medical-Surgical Inc.** was fined by the California Board of Pharmacy related to the fact that its Middletown, PA distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now fully licensed. McKesson Medical-Surgical Inc. paid $700 fine. The fine is related to a non-disciplinary action.

On May 20, 2022, **McKesson Medical Surgical, Inc.**'s Urbancrest, Ohio facility entered into a consent order with the MI Dept of Licensing in connection with an Administrative Compliant from January 2022. The Administrative Complaint is a result of two settlement agreements with the Ohio BOP. Michigan states that these settlement agreements violated MCL 333.17768(2)(d). A $500.00 fine was imposed and paid.

On July 19, 2022, **McKesson Medical Surgical, Inc.**'s Urbancrest, Ohio facility entered into a settlement agreement with the Alabama Board of Pharmacy. The Alabama discipline was in response to discipline the facility received from the Ohio Board of Pharmacy in 2021 McKesson paid a $3,000 fine under the Alabama settlement.

On September 16, 2022, **McKesson Medical-Surgical Inc.'s** Leetsdale, PA facility entered into a consent order with the MI Dept of Licensing in connection with an Administrative Compliant from January 2022. The Administrative Complaint is a result of two settlement agreements with the Ohio BOP. Michigan states that these settlement agreements violated MCL 333.17768(2)(d). A $500.00 fine was imposed and paid.

On May 29, 2024, **McKesson Medical-Surgical Inc.**'s Jacksonville, FL facility entered into a Consent Agreement with the Georgia State Board of Pharmacy due to the facility changing ownership and updating their licensure prior to receiving board approval. Under O.C.G.A § 26-4-40, the Georgia State Board of Pharmacy is authorized to deny Applicants application for licensure due to changing ownership without Board Approval. Based on the Consent Agreement, McKesson Medical-Surgical Inc shall submit a payment of One-Thousand Seven-Hundred Dollars ($1,700) for the violation. The Board agrees to grant the ownership change and licensure update once the terms and conditions of the agreement are met.

On September 12, 2024, the Idaho Board of Pharmacy ("BOP") entered into a Stipulation and Consent Order with **McKesson Medical-Surgical Inc.** ("MMS") whereby the parties mutually agree to settle two separate matters from MMS' Chino, CA and Roseville, CA distribution centers in 2020 and 2021 involving a deficient Designated Representative application and failure to timely renew its license application, respectively. The parties agree that sufficient mitigating factors exist (including the COVID-19 pandemic and various stay-at-home orders) to warrant resolution of these matters via the Stipulation and Consent Order without an admission of guilt by MMS and whereby the Stipulation and Consent Order requires MMS to pay a fine to the BOP in the amount of $6,000 and to reimburse the BOP for investigative costs in the amount of $5,200.

On March 19th, 2025, Maryland State Board of Pharmacy ("MBOP") and **McKesson Medical-Surgical, Inc.** ("MMS") entered into a Pre-Charge Consent Order ("Consent Order") after MMS self-reported distributing prescription products into Maryland from its Distribution Center in Suwanee, GA without the required wholesale distributor permits. An MMS internal investigation revealed that approximately 400 prescription orders were distributed without the permit between September 2019 and September 2024 due to a miscoding error. MMS has since updated its product classifications and implemented additional checks. As part of the Consent Order, MMS agreed to pay a $5,000 fine to the MBOP and MBOP agreed to process MMS' pending wholesale permit application.

On April 22, 2025, the Nevada State Board of Pharmacy ("NV BOP") issued a citation and fine order to **McKesson Medical-Surgical, Inc.** ("MMS") distribution center located in Chino, CA for unprofessional conduct. MMS erroneously shipped drugs to a hospice patient's home without a legitimate request, due to a mis-pick error. This action violated NAC 639.945(1)(i) and NRS 639.210(4), posing serious risks to patient safety. The NV BOP assessed an administrative fine of $500 to MMS for the incident.

Please email mckessonlicensing@mckesson.com with any questions or requests for additional information.

ARIZONA STATE BOARD OF PHARMACY
1616 W. Adams Street
Phoenix, AZ 85007

BEFORE THE ARIZONA STATE BOARD OF PHARMACY

In the Matter of:	**Case No. 19-0304**
McKesson Medical Surgical Holder of Permit No. W000469 As a Wholesale Distributor In the State of Arizona.	**SUBPOENA DUCES TECUM**

THE STATE OF ARIZONA TO:

McKesson Medical Surgical
Attn: Michael Evans, Manager
7343 Hardy Drive, Suite 101
Tempe, AZ 85283

YOU ARE HEREBY COMMANDED by the Arizona Board of Pharmacy to provide a response to the proposed Consent Agreement offered by the Board. You may contest the Consent Agreement and request a meeting with the Board at the next Board public meeting or you may sign the Consent Agreement and return it to the Board office. A response must be delivered to the Board's office at 1616 W. Adams Street, Phoenix, AZ 85007 or by email to edodge@azpharmacy.gov, **by 5:00 p.m. on January 20, 2020.**

You have been subpoenaed by the Arizona Board of Pharmacy, whose attorney's name, address and telephone number is: Jeanne M. Galvin, Assistant Attorney General, Arizona Attorney General's Office, 2005 North Central Ave., Phoenix, Arizona 85004, (602) 542-7983.

Along with copies of the documents, you must sign, date and return a copy of this subpoena, indicating that the copies are true and correct copies of all records and materials in your possession or subject to your control that are responsive to the subpoena.

Any questions relating to this subpoena or proposed consent agreement should be directed to Dr. Kam Gandhi at 602-771-2740 or kgandhi@azpharmacy.gov.

Dated this 18th day of December, 2019

By: _____

Elizabeth Dodge, Deputy Director for
Kam Gandhi, PharmD, Executive Director
Arizona State Board of Pharmacy

Please SIGN and DATE the statement below and return it to the Board's office with copies of the subpoenaed materials.

I, Michael Evans **, certify that the attached or enclosed copies are true and correct copies of all records and materials in my possession or subject to my control that are responsive to this subpoena.**



Name

1/14/20

Date

MARK BRNOVICH
Attorney General
Firm State Bar No. 14000

JEANNE M. GALVIN
Assistant Attorney General
State Bar No. 015072
SETH T. HARGRAVES
Assistant Attorney General
State Bar No. 020176
2005 N. Central Ave., SGD/LES
Phoenix, Arizona 85004-1592
Tel: (602) 542-7983
Tel: (602) 542-7672
Fax: (602) 364-3202

Attorneys for the Arizona State Board of Pharmacy

BEFORE THE ARIZONA STATE BOARD OF PHARMACY

In the Matter of **McKESSON MEDICAL SURGICAL,** Holder of Permit No. W000469 As a Wholesale Distributor In the State of Arizona. Respondent.	Board Case No. 19-0304 **CONSENT AGREEMENT AND ORDER FOR CIVIL PENALTY**

In the interest of a prompt and judicious settlement of this case, consistent with the public interest, statutory requirements and the responsibilities of the Arizona State Board of Pharmacy ("Board") under A.R.S. § 32-1901, *et. seq.*, McKesson Medical Surgical ("Respondent"), holder of permit no. W000469 in the State of Arizona and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law and Order ("Consent Agreement") as a final disposition of this matter.

PARTIES AND JURISDICTION

1. The Board is the duly constituted authority for licensing and regulating the practice of pharmacy in the State of Arizona.

2. Respondent is the holder of permit number W000469 which allows it to operate

as a wholesale distributor in the State of Arizona.

3. The Board possesses jurisdiction over the subject matter and over Respondent pursuant to A.R.S. § 32-1901 *et seq.*

RECITALS

1. Respondent has read and understands this Consent Agreement and has had the opportunity to discuss this Consent Agreement with an attorney, or has waived the opportunity to discuss this Consent Agreement with an attorney.

2. Respondent understands that it has a right to a public administrative hearing concerning this matter at which hearing it could present evidence and cross examine witnesses. By entering into this Consent Agreement, Respondent knowingly and voluntarily relinquishes all right to such an administrative hearing, as well as rights of rehearing, review, reconsideration, appeal, judicial review or any other administrative and/or judicial action, concerning the matters set forth herein.

3. Respondent affirmatively agrees that this Consent Agreement shall be irrevocable.

4. Respondent understands that this Consent Agreement or any part of the agreement may be considered in any future disciplinary action by the Board against it.

5. Respondent understands this Consent Agreement deals with Board Complaint No. 19-0304 involving allegations of unprofessional conduct against Respondent. The investigation into these allegations against Respondent shall be concluded upon the Board's adoption of this Consent Agreement.

6. Respondent understands that this Consent Agreement does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding.

7. Respondent also understands that acceptance of this Consent Agreement does not preclude any other agency, subdivision, or officer of this State from instituting any other civil or criminal proceedings with respect to the conduct that is the subject of this Consent Agreement.

8. Respondent acknowledges and agrees that, upon signing this Consent Agreement and returning this document to the Board's Executive Director, it may not revoke its acceptance of the Consent Agreement or make any modifications to the document. Any modification to this original document is ineffective and void unless mutually agreed by the parties in writing.

9. This Consent Agreement is subject to the approval of the Board and is effective only when accepted by the Board and signed by the Executive Director. In the event that the Board does not approve this Consent Agreement, it is withdrawn and shall be of no evidentiary value and shall not be relied upon nor introduced in any action by any party, except that the parties agree that should the Board reject this Consent Agreement and this case proceeds to hearing, Respondent shall assert no claim that the Board was prejudiced by its review and discussion of this document or any records relating thereto.

10. If a court of competent jurisdiction rules that any part of this Consent Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement shall remain in full force and effect.

11. Respondent understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action of the Board and may be reported as required by law to the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.

12. Respondent understands that any violation of this Consent Agreement constitutes unprofessional conduct and may result in disciplinary action. A.R.S. §§ 32-1901.01(A)(19) and A.R.S. § - 1927.02(A)(1).

13. Respondent agrees that the Board will adopt the following Findings of Fact, Conclusions of Law and Order.

ACCEPTED AND AGREED BY RESPONDENT

Dated: 1/14/20

On behalf of McKesson Medical Surgical

FINDINGS OF FACT

1. The Board is the duly constituted authority for licensing and regulating the practice of pharmacy in the State of Arizona.

2. Respondent is the holder of certificate number Y00460, which allows it to operate as a wholesale distributor in the State of Arizona. Respondent is located at 7343 Hardy Drive, Suite 101, Tempe, AZ 85283.

3. The Board possesses jurisdiction over the subject matter and over Respondent pursuant to A.R.S. § 32-1901 *et seq.*

4. Complaint no. 19-0304 was opened after an August 14, 2019 routine compliance inspection was performed. During the inspection it was discovered that the facility was selling prescription drugs to facilities that were not permitted to receive prescription drugs. Specifically Triton Supply and Med Tech Supply which are each permitted as a CMG/DME supplier and may receive over-the-counter drugs and prescriptions only.

5. A violation for the distribution of prescription drugs was issued, along with the inspection report, on September 5, 2019.

6. Despite the violation, Respondent continued selling prescription drugs to facilities that were not permitted to receive prescription drugs.

CONCLUSIONS OF LAW

1. The Board possesses subject matter and personal jurisdiction over Respondent pursuant to A.R.S. § 32-1901 *et seq.*

2. The Board may discipline a permittee that has engaged in unprofessional conduct. A.R.S. § 32-1927.02(A)(1).

3. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(A)(18) (violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of the Pharmacy Act) as it relates to A.R.S. § 32-1983(B) (A full service wholesale permittee may furnish prescription-only drugs only to a pharmacy or medical practitioner. The full service wholesale permittee must first verify that person holds a valid license or permit.), and Arizona Administrative Code (A.A.C.) R4-23-605(G)(2)(iii) (Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance, or prescription-only drug or device, to anyone except a pharmacy, drug manufacturer, or fullservice drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32).

ORDER

Based on the Findings of Fact and Conclusions of Law and pursuant to the authority granted to the Board under A.R.S. § 32-1927.02:

1. **IT IS HEREBY ORDERED** Respondent shall pay to the Board as a civil penalty the sum of One Thousand Dollars **($1,000.00).** The civil penalty shall be paid in full to the Board within **thirty (30) days** of the effective date of this Consent Agreement and Order. The effective date of this Consent Agreement is the date it is signed by the Board's Executive Director.

2. If the Board determines that Respondent has not complied with **all** the requirements of this Consent Agreement, the Board, in its sole discretion, may institute proceedings for noncompliance with this Consent Agreement, which may result in the suspension or revocation of Respondent's license. Failing to abide by this Consent Agreement and Order is a violation of A.R.S. §32-1901.01(A)(19), which is violating a formal order, terms of probation, a consent agreement or a stipulation issued or entered into by the board it its executive director.

3. Respondent understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action.

4. If Respondent violates this Order in any way or fails to fulfill the requirements of this Order, the Board, after giving the Respondent notice and the opportunity to be heard, may revoke, suspend or take other disciplinary actions against Respondent's permit. The issue at such a hearing will be limited solely to whether this Order has been violated.

DATED this _____ day of _____, 2019.

ARIZONA STATE BOARD OF PHARMACY

By: _____
KAMLESH GANDHI, PharmD
Executive Director

ORIGINAL OF THE FOREGOING FILED
this 14 day of JAN, 2020, with:

Arizona State Board of Pharmacy
1616 W. Adams Street
Phoenix, Arizona 85007

COPY OF THE FOREGOING MAILED
BY CERTIFIED & REGULAR FIRST-CLASS MAIL
this _____ day of _____, 2019, to:

McKesson Medical Surgical
Attn: Michael Evans, Manager
7343 Hardy Drive, Suite 101
Tempe, AZ 85283

COPY OF THE FOREGOING MAILED
this _____ day of _____, 2019 to:

Jeanne M. Galvin
Seth T. Hargraves
Assistant Attorney General
2005 North Central Ave., SGD/LES
Phoenix, Arizona 85004
Attorneys for the State

Doc#8417633



(Thursday 01/16/2020)

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BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2018-8861

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE NON-RESIDENT PRESCRIPTION DRUG WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF MCKESSON MEDICAL-SURGICAL, INC., REGISTRATION NO. WHO 8346,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and McKesson Medical-Surgical ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2018-8861, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as a non-resident prescription drug wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 280, C.R.S. (2019).

2. Respondent Outlet was originally registered in the State of Colorado on or about July 11, 2018, being issued registration No. WHO 8346, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 7701 Foothills Boulevard, Roseville, California 95747.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, one hundred thirteen (113) days transpired between July 24, 2018, the date the previous designated representative ceased the position, and November 14, 2018, the date the application and fee were received.

6. On or about November 14, 2018, the Board initiated a complaint against Respondent Outlet because of the delay of one hundred thirteen (113) days in submitting an application detailing a change in designated representative and fee.

7. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

Colorado Revised Statutes

12-280-126. Unprofessional conduct - grounds for discipline. (1) The board may take disciplinary or other action as authorized in section 12-20-404, after a hearing held in accordance with the provisions of sections 12-20-403 and 12-280-127, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this article 280, including commission of an act declared unlawful in section 12-280-129, or an applicable provision of article 20 or 30 of this title 12;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drugs.

12-280-127. Disciplinary actions. (1) The board may take disciplinary or other action as authorized in section 12-20-404 when the board determines that the applicant, licensee, or registrant has engaged in activities that are grounds for discipline under section 12-280-126.

12-280-303. Wholesaler license requirements.

(2)(b) An applicant for a license shall pay any fee required by the accreditation body or the board and comply with any rules promulgated by the board.

(3)(a) An applicant for a wholesaler license shall provide to the board the following information, and any other information deemed appropriate by the board on a form provided by the board:

(VII) The name of the applicant's designated representative for the facility, the fingerprints of the designated representative, and a personal information statement for the designated representative that includes information as required by the board,

including but not limited to the information in subsection (5) of this section.

(5) The designated representative of an applicant for a wholesaler license shall:

(i) Update all of the information required in this part 3 whenever changes occur.

12-280-307. Penalty. (1) A person who engages in the wholesale distribution of prescription drugs in violation of this part 3 shall be subject to a penalty of up to fifty thousand dollars.

Pharmacy Board Rules and Regulations

15.01.11 Minimum required information for registration.

a. The following minimum information shall be required from each wholesaler as part of the registration:

(8) The name of the applicant's designated representative, who must meet the following requirements:

(a) Be at least twenty-one years of age;

(b) Have at least three years of full-time employment history with a pharmacy or a wholesaler in a capacity related to the dispensing and distribution of and the recordkeeping related to prescription drugs;

(c) Be employed by the applicant in a full-time managerial position;

(d) Be actively involved in and aware of the actual daily operation of the wholesaler;

(e) Be physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave;

(f) Serve in the capacity of a designated representative for only one applicant or wholesaler at a time, except where more than one licensed wholesaler is co-located in the same facility and the wholesalers are members of an affiliated group as defined by section 1504 of the federal "Internal Revenue code of 1986."

(g) Not have any convictions under federal, state, or local law relating to wholesale or retail prescription drug distribution or controlled substances;

(h) Not have an felony convictions pursuant to federal, state, or local law; and

(i) Undergo a background check as required by 12-280-304, C.R.S.

b. Changes in any information in section 15.01.11 shall be submitted to the Board within thirty calendar days thereof.

15.01.14 Change of name, location, or ownership, or designated representative.

c. Any change in the designated representative of a wholesaler shall be reported to the Board on a form supplied by the Board within thirty calendar days of such change. The incoming designated representative must undergo the required background check.

8. The Board finds and concludes, and Respondent Outlet agrees, that based upon Respondent Outlet's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

TERMS OF DISCIPLINE

9. **Fine with Surcharge.** Pursuant to section 12-280-127(5)(a), C.R.S., Respondent Outlet shall pay a fine of one thousand Dollars and no Cents ($1,000.00). Respondent Outlet understands and acknowledges that, pursuant to section 24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies may impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of one thousand one hundred fifty Dollars and no Cents ($1,150.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board.

10. **Compliance.** Respondent Outlet shall submit all future applications and appropriate fees to the Board detailing changes in its designated representative within the required time frame specified by Board rule or statute in effect at the time of such designated representative change.

11. **Other Requirements.** Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

b. comply fully with this Final Agency Order; and

c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

12. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges;

    c. to have a formal disciplinary hearing pursuant to sections 12-20-403, 12-280-126, and 12-280-127, C.R.S.; and

    d. to appeal this Final Agency Order.

    Respondent Outlet freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

13. **Acknowledgments.** The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

14. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under section 12-280-127(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final

Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

15. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

16. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

17. **Effective Date.** This Final Agency Order shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED BY

Respondent Outlet

Authorized Representative Dated: 06/08/2020

Rodney E. Bias / VP Compliance & Regulatory Affairs
Name/ Title

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 30 day of June, 2020.

State Board of Pharmacy

BY: _____
Dmitry Kunin
Program Director

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by electronic means or by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 30 day of June 2020, addressed as follows:

McKesson Medical-Surgical, Inc.
Attn: Designated Representative
7701 Foothills Boulevard
Roseville, California 95747
Elaine.Stutman@McKesson.com

Lana Hyatte
Agent of the Board

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2020-0459
501-2900

McKesson Medical Surgical, Inc.
c/o Shawn Litchfield
520 West Park, Suite 520
Leetsdale, PA 15056

License No. 01-2598200

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and McKesson Medical Surgical, Inc. (McKesson), for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and McKesson are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. McKesson is a licensed Wholesaler Distributor of Dangerous Drug, License No. 01-2598200, which lists Shawn Litchfield, as the Responsible Person.

FACTS

1. The Board initiated an investigation of McKesson Wholesaler Distributor of Dangerous Drugs License No. 01-2598200, related to McKesson's illegal sales of dangerous drugs to an unlicensed entity.

2. On or about March 24, 2021, the Board sent a Notice of Opportunity for Hearing to McKesson which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. McKesson neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated March 24, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. McKesson agrees to pay to the Board a monetary penalty in the amount of $1,125.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. McKesson agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. McKesson agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by McKesson of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to McKesson by the Board and will NOT discharge McKesson from any obligation under the terms of this Agreement.

6. McKesson agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. McKesson understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom McKesson will operate.

9. McKesson waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Shawn Litchfield, on behalf of)
McKesson Medical Surgical, Inc., Respondent

04.16.2021
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Jennifer M. Rudell, RPh, President,
State of Ohio Board of Pharmacy

4/20/2021
Date of Signature

Henry G. Appel, Ohio Assistant Attorney General

4/20/2021
Date of Signature

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor
Columbus, Ohio 43215-6108
Tel: (614) 466-4143
www.pharmacy.ohio.gov
4/20/2021 9:10 AM

Your payment was successful.

Order Status	Successful
Applied Payment	$1125.00
Contact	Elaine Stutman
Operator	PAULA A ECONOMUS
Process Date	4/20/2021 9:10 AM
Receipt Number	R-5455305
Payment	Credit Card
Reference Number	51289232
Card Number	XXXX XXXX XXXX0463
Amount	$1,125.00
Settlement Date	4/22/2021

Fee Payments

Licensee Name	License Number	Endorsement	Type	Amount	Amount Outstanding	Payment Amount
			PRX - Settlement Agreement (4K90)	$1,125.00	$0.00	$1,125.00

Thank you for your transaction.

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Janet T. Mills
Governor

Anne L. Head
Commissioner

May 17, 2021

Sent via email: Elaine.Stutman@McKesson.com

McKesson Medical-Surgical Inc.
Attn Stanton McComb, President, Director
12413 Willscott Place
Glen Allen, VA 23059-7620

Re: Complaint No. 2021-PHA-17216

Dear Mr. McComb:

Enclosed please find the fully executed consent agreement between you, the Maine Board of Pharmacy, and the Office of the Attorney General in the above referenced matter.

This letter also acknowledges receipt of your fine payment in the amount of $500.00. Your fine is paid in full. As all conditions of the consent agreement have been fulfilled, this complaint file is now closed.

Please feel free to contact our office at (207) 624-8651 with any questions.

Sincerely,

Jessica Gowell

Jessica Gowell, Professional Licensing Supervisor

Enclosure

cc: John Nichols, Esq., Assistant Attorney General
Andrew Black, Esq., Assistant Attorney General
Geraldine L. Betts, Board Administrator & Complainant
Thomas Avery, Board Investigator

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
MCKESSON MEDICAL-SURGICAL, INC.	)	CONSENT AGREEMENT
	)	
	)	
Case No. 2021-PHA-17216	)	

PARTIES

This document is a Consent Agreement regarding the pending application of McKesson Medical-Surgical, Inc. for the renewal of its prescription drug wholesaler license. The parties to this Consent Agreement are: McKesson Medical-Surgical, Inc. ("McKesson"), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since December 17, 2019, McKesson has been licensed in Maine as a prescription drug wholesaler with a registered location of 7701 Foothills Boulevard, Roseville, California (license number **WH70003094**).

2. On June 30, 2020, the Colorado State Board of Pharmacy imposed discipline against McKesson's Colorado registration as an out-of-state prescription drug wholesaler (Registration # WHO 8346) in Case No. 2018-8861.

3. McKesson then failed to report the Colorado disciplinary action to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

4. On December 10, 2020, McKesson submitted an application for renewal of its Maine license and reported to the Board for the first time that it had been disciplined by the Colorado State Board of Pharmacy.

5. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report a license disciplinary action to the Board within 10 days of that action.

6. At its meeting on January 7, 2021, the Board reviewed the above information and voted to preliminarily deny McKesson's application for renewal of its license to be a prescription drug wholesaler. In lieu of the denial, the Board also voted to offer McKesson this Consent Agreement. Unless McKesson either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333, by **May 17, 2021,** the preliminary denial of McKesson's application for licensure as a prescription drug wholesaler will become final.

COVENANTS

7. McKesson admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C) for failing to report disciplinary action taken in another jurisdiction against a professional license no later than 10 days after the action was taken.

8. As discipline for the violation admitted to in paragraph 7 above, McKesson agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of five hundred dollars ($500.00) payment of which shall be made payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333, and must be submitted with the signed Consent Agreement.

9. Upon receipt of the signed Consent Agreement with the enclosed payment of the civil penalty from McKesson, the Board will renew McKesson's license contingent upon it meeting all other eligibility criteria.

10. Violation of any of the terms or conditions of this Consent Agreement by McKesson shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

11. The Board and McKesson agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless McKesson fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against McKesson, and this Consent Agreement will be admitted into evidence in any future adjudicatory hearing involving McKesson. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against McKesson.

12. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

13. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

14. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

15. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

16. McKesson acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 05/05/2021

MCKESSON MEDICAL-SURGICAL, INC.

By: _____

Print Name: Rodney Bias

Title: VP Regulatory Affairs

DATED: 5/14/21

BRADLEY S. HAMILTON, R.Ph., President
MAINE BOARD OF PHARMACY

DATED: 5/17/21

JOHN NICHOLS
Assistant Attorney General

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2021-0079
I-2021-0191

McKesson Medical-Surgical, Inc.
c/o Shawn Litchfield
520 West Park, Suite 520
Leetsdale, PA 15056

License No. 01-2598200

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and McKesson Medical-Surgical, Inc. (McKesson) for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and McKesson are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. McKesson is a licensed Wholesaler Distributor of Dangerous Drug, License No. 01-2598200, which lists Shawn Litchfield, as the Responsible Person.

FACTS

1. The Board initiated an investigation of McKesson Wholesaler Distributor of Dangerous Drugs License No. 01-2598200, related to McKesson's illegal sales of dangerous drugs to an unlicensed entity.

2. On or about May 4, 2021, the Board sent a Notice of Opportunity for Hearing to McKesson which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. McKesson neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated May 4, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. McKesson agrees to pay to the Board a monetary penalty in the amount of $500.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. McKesson agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. McKesson agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by McKesson of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to McKesson by the Board and will NOT discharge McKesson from any obligation under the terms of this Agreement.

6. McKesson agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. McKesson understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom McKesson will operate.

9. McKesson waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Shawn Litchfield, on behalf of,
McKesson Medical-Surgical, Inc.,
Respondent

05.27.2021
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Jennifer M. Rudell, RPh, President,
State of Ohio Board of Pharmacy

6/4/2021
Date of Signature

Henry G. Appel, Ohio Assistant Attorney General

6/4/2021
Date of Signature

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor
Columbus, Ohio 43215-6108
Tel: (614) 466-4143
www.pharmacy.ohio.gov
6/4/2021 2:36 PM

Your payment was successful.

Order Status	Successful
Applied Payment	$500.00
Contact	Elaine Stutman
Operator	PAULA A ECONOMUS
Process Date	6/4/2021 2:35 PM
Receipt Number	R-5514652
Payment	Credit Card
Reference Number	52110295
Card Number	XXXX XXXX XXXX0463
Amount	$500.00
Settlement Date	6/8/2021

Fee Payments

Licensee Name	License Number	Endorsement	State/Province	Type	Amount	Amount Outstanding	Payment Amount
				PRX - Settlement Agreement (4K90)	$500.00	$0.00	$500.00

Thank you for your transaction.

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2020-0041

License No. 01-0828350

McKesson Medical-Surgical, Inc.
c/o Steven Robenolt
3500 Centerpoint Drive Ste. A
Urbancrest, OH 43123

June 10, 2021

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and McKesson Medical-Surgical, Inc., for the purpose of resolving all issues between the parties relating to the Board investigation of the illegal transfer of dangerous drugs. Together, the Board and McKesson Medical-Surgical, Inc. are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.

2. McKesson Medical-Surgical, Inc. is a licensed Terminal Distributor of Dangerous Drugs under license number 01-0828350.

FACTS

1. On or about October 9, 2019, the Board initiated an investigation of McKesson Medical-Surgical, Inc., Terminal Distributor of Dangerous Drugs license number 01-0828350.

2. On or about March 12, 2021, the Board sent a Notice of Opportunity for Hearing to McKesson Medical-Surgical, Inc., which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, In consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. McKesson Medical-Surgical, Inc. neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated March 12, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. McKesson Medical-Surgical, Inc. agrees to pay to the Board a monetary penalty in the amount of $3,000.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Settlement Agreement. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. McKesson Medical-Surgical, Inc. agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. McKesson Medical-Surgical, Inc. agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by McKesson Medical-Surgical, Inc. of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to McKesson Medical-Surgical, Inc. by the Board and will NOT discharge McKesson Medical-Surgical, Inc. from any obligation under the terms of this Agreement.

6. McKesson Medical-Surgical, Inc. agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. McKesson Medical-Surgical, Inc. understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom McKesson Medical-Surgical, Inc. will operate.

9. McKesson Medical-Surgical, Inc. waives its opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Steven Rosenoff
McKesson Medical-Surgical, Inc.

JUNE 15, 2021
Date of Signature

Roger N. Morris
Attorney for Respondent

6/15/21
Date of Signature

Jennifer M. Rudell, R.Ph., President
State of Ohio Board of Pharmacy

6/15/2021
Date of Signature

Henry Appel, Ohio Assistant Attorney General

6/15/2021
Date of Signature

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor
Columbus, Ohio 43215-6108
Tel: (614) 466-4143
www.pharmacy.ohio.gov
6/22/2021 10:15 AM

Your payment was successful.

Order Status	Successful
Applied Payment	$3000.00
Contact	Elaine Stutman
Operator	PAULA A ECONOMUS
Process Date	6/22/2021 10:15 AM
Receipt Number	R-5548596
Payment	Credit Card
Reference Number	52396839
Card Number	XXXX XXXX XXXX0463
Amount	$3,000.00
Settlement Date	6/24/2021

Fee Payments

Licensee Name	License Number	Endorsement	State/Province	Type	Amount	Amount Outstanding	Payment Amount
				PRX - Settlement Agreement (4K90)	$3,000.00	$0.00	$3,000.00

Thank you for your transaction.

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2020-0552
I-2020-0764

McKesson Medical-Surgical

License No. 010828350

c/o Steven Robenolt
3500-A Centerpoint Drive
Grove City, OH 43123

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and McKesson Medical-Surgical, for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and McKesson Medical-Surgical are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. McKesson Medical-Surgical, is a licensed Wholesaler Distributor of Dangerous Drug, License No. 010828350, which lists Steven Robenolt, as the Responsible Person.

FACTS

1. The Board initiated an investigation of McKesson Medical-Surgical, Wholesaler Distributor of Dangerous Drugs License No. 010828350, related to McKesson Medical-Surgical illegal sales of dangerous drugs to an unlicensed entity.

2. On or about May 4, 2021, the Board sent a Notice of Opportunity for Hearing to McKesson Medical-Surgical, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. McKesson Medical-Surgical neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated May 4, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. McKesson Medical-Surgical agrees to pay to the Board a monetary penalty in the amount of $125.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. McKesson Medical-Surgical Wholesale Distributor of Dangerous Drugs license will be issued subject to satisfactory completion of all application and inspection requirements and payment of the fine.

5. McKesson Medical-Surgical agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. McKesson Medical-Surgical agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by McKesson Medical-Surgical of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to McKesson Medical-Surgical by the Board and will NOT discharge McKesson Medical-Surgical from any obligation under the terms of this Agreement.

7. McKesson Medical-Surgical agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. McKesson Medical-Surgical understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom McKesson Medical-Surgical will operate.

10. McKesson Medical-Surgical waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

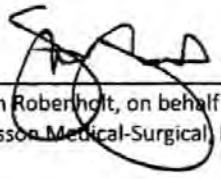
13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:



Steven Roberholt, on behalf of,
McKesson Medical-Surgical, Respondent

June 28, 2024
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Jennifer M. Rudell, RPh, President,
State of Ohio Board of Pharmacy

Date of Signature

Henry G. Appel, Ohio Assistant Attorney General

Date of Signature

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2020-0273
I-2019-1542

McKesson Medical-Surgical, Inc.
Steven Robenolt, Responsible Person
Attn: Regulatory Affairs
6651 Gate Parkway
Jacksonville, FL 32256

License No. 01-0828350

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and McKesson Medical-Surgical, Inc. for the purpose of resolving all issues between the parties relating to the Board investigation of sales of dangerous drugs while operating without a Board-issued license. Together, the Board and McKesson Medical-Surgical, Inc. are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. McKesson Medical-Surgical, Inc. is a licensed Wholesaler Distributor of Dangerous Drug, License No. 01-0828350, which lists Steven Robenolt, as the Responsible Person.

FACTS

1. The Board initiated an investigation of McKesson Medical-Surgical, Inc., Wholesaler Distributor of Dangerous Drugs License No. 01-0828350, related to McKesson Medical-Surgical, Inc.'s illegal sales of dangerous drugs without obtaining a Board-issued license.

2. On or about December 21, 2021, the Board sent a Notice of Opportunity for Hearing to McKesson Medical-Surgical, Inc., which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. McKesson Medical-Surgical, Inc. neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated December 21, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. McKesson Medical-Surgical, Inc. agrees to pay to the Board a monetary penalty in the amount of $500.00. This fine will be attached to the license record and must be paid no later than 6 months from the effective date of this Order. To pay this fine, login to www.elicense.ohio.gov and process the items in the cart.

4. McKesson Medical-Surgical, Inc. agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. McKesson Medical-Surgical, Inc. agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by McKesson Medical-Surgical, Inc. of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to McKesson Medical-Surgical, Inc. by the Board and will NOT discharge McKesson Medical-Surgical, Inc. from any obligation under the terms of this Agreement.

6. McKesson Medical-Surgical, Inc. agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. McKesson Medical-Surgical, Inc. understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom McKesson Medical-Surgical, Inc. will operate.

9. McKesson Medical-Surgical, Inc. waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Steven Robenolt, on behalf of, McKesson Medical-Surgical, Inc. Respondent	1/12/2022 Date of Signature
Attorney for Respondent (if applicable)	Date of Signature
Rich Miller, RPh, President, State of Ohio Board of Pharmacy	Date of Signature
Henry G. Appel, Ohio Assistant Attorney General	Date of Signature

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

January 20, 2022

DATED MATERIAL ENCLOSED

MCKESSON MEDICAL-SURGICAL INC
ATTN: STANTON MCCOMB, PRS
1400 AIP DR
MIDDLETOWN, PA 17057

RE: CI 2021 93765
MCKESSON MEDICAL-SURGICAL INC
OSD 7002

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- February 19, 2022: Unless the Citation is contested payment of fine(s) must be received by the Board.
- February 03, 2022: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- February 19, 2022: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Anne Sodergren
EXECUTIVE OFFICER

By:

Suelynn Yee
Citation and Fine Analyst

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **February 19, 2022.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Cashier
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than February 03, 2022 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than February 19, 2022 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have any questions regarding any documents enclosed please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2021 93765	MCKESSON MEDICAL-SURGICAL INC, OSD 7002

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775;

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4161 subd. (j)	A nonresident wholesaler or non resident third-party logistics provider shall identify and notify the board of a new designated representative in charge ceases to be the designated representative in charge	$700.00

CONDUCT:

Failure to Notify within 30 Days – Business and Professions Code section 4161(j) requires a representative-in-charge to be responsible for compliance with state and federal laws governing wholesalers. Additionally, the section requires every nonresident wholesaler to notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. Specifically, on November 4, 2021, the Board received a Change of Designated Representative-In-Charge form McKesson Medical - Surgical Inc. The form indicated that the prior Designated Representative-in-Charge (DRIC), Scott Neidig (EXC 23546), dissociated on June 15, 2021, and that Benjamin Stipe (EXC 26385) took over as the new DRIC the same day. McKesson Medical - Surgical Inc. failed to notify the Board of the change for 142 days.

CITATION ISSUED ON: January 20, 2022	TOTAL AMOUNT OF FINE(S): $700.00

PAYMENT OF FINE(S) DUE BY: February 19, 2022

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2021 93765	MCKESSON MEDICAL-SURGICAL INC, OSD 7002

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775;

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4161 subd. (j)	A nonresident wholesaler or non resident third-party logistics provider shall identify and notify the board of a new designated representative in charge ceases to be the designated representative in charge	$700.00

CONDUCT:

Failure to Notify within 30 Days – Business and Professions Code section 4161(j) requires a representative-in-charge to be responsible for compliance with state and federal laws governing wholesalers. Additionally, the section requires every nonresident wholesaler to notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. Specifically, on November 4, 2021, the Board received a Change of Designated Representative-In-Charge form McKesson Medical - Surgical Inc. The form indicated that the prior Designated Representative-in-Charge (DRIC), Scott Neidig (EXC 23546), dissociated on June 15, 2021, and that Benjamin Stipe (EXC 26385) took over as the new DRIC the same day. McKesson Medical - Surgical Inc. failed to notify the Board of the change for 142 days.

CITATION ISSUED ON: January 20, 2022	TOTAL AMOUNT OF FINE(S): $700.00

PAYMENT OF FINE(S) DUE BY: February 19, 2022

California State Board of Pharmacy
REQUEST FOR OFFICE CONFERENCE

Licensee: MCKESSON MEDICAL-SURGICAL INC

License No: OSD 7002

Citation Number : CI 2021 93765

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☐ I contest the Citation and request an Office Conference.

Check One:

☐ I contest the entire Citation or

☐ specific violations for the following reasons (list each violation with your specific reason):

_____

_____

_____

_____

_____

_____

If more space is needed attach additional sheets of paper.

Name: _____

Signature: _____ Dated: _____

Address of Service: _____

City: _____ State: _____ Zip: _____

Telephone: (Business) (___) _____ Residence: (___) _____

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: California State Board of Pharmacy
Attn: Citation and Fine Unit
2720 Gateway Oaks Drive, Suite #100
Sacramento, CA 95833
(916) 518-3100

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check ☐ I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against: MCKESSON MEDICAL-SURGICAL INC OSD 7002 Respondent	Citation Case No : CI 2021 93765 NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED _____ _____
(Respondent)

Mailing Address of Respondent:

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

_____
(Attorney's Name

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: MCKESSON MEDICAL-SURGICAL INC, OSD 7002
Citation and Fine CI 2021 93765

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On January 20, 2022, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
MCKESSON MEDICAL-SURGICAL INC ATTN: STANTON MCCOMB, PRS 1400 AIP DR MIDDLETOWN, PA 17057	7018 0360 0000 1613 3737

I declare under penalty of perjury that the forgoing is true and correct.

Executed on January 20, 2022, at Sacramento, California.

DECLARANT

Suelynn Yee

Citation and Fine Analyst

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING

In the Matter of

McKesson Medical Surgical Inc,
License Number: 53-06-002300

FILE NO.: 53-21-002501

PROOF OF SERVICE

State of Michigan

County of Ingham

I, Madison Edmunds, of Lansing, County of Ingham, State of Michigan, do hereby state that on April 21, 2022, I sent the following documents to each of the parties listed below, enclosed in an email, plainly addressed to their last known email address of record, as follows:

CONSENT ORDER AND STIPULATION dated April 20, 2022.

BY: ( ) First Class Mail
(X) Email
( ) Certified Mail, Return receipt requested
( ) Registered Mail

TO: McKesson Medical Surgical Inc
Elaine.Stutman@McKesson.com

Madison Edmunds
Compliance Section

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

April 21, 2022

McKesson Medical Surgical Inc,
Elaine.Stutman@McKesson.com

Re: File Number 53-21-002501

Dear Licensee:

As set forth in the enclosed Order issued by the Disciplinary Subcommittee of the Michigan Board of Pharmacy, at least one administrative sanction has been imposed upon your license.

Section 16241(7) of the Michigan Public Health Code requires a licensee or registrant who is reprimanded, fined, placed on probation or ordered to pay restitution, or an individual whose application for licensure or registration is denied, to notify, in writing, the licensee or registrant's employer, if any, and each hospital the licensee/registrant is admitted to practice, if any, within *ten* days of the date of the order imposing the sanction(s)

The enclosed Notice of Licensure/Registration Sanction form has been developed to assist you in complying with these provisions of law.

By May 5, 2022, you are required to:

1) Complete the front of the form;
2) Transmit a copy of the form to the individuals and/or entities described above in section 16241(7);
3) Complete the affidavit on the back of the form;
4) Have the affidavit notarized; and
5) Submit the completed original form to the Department at the address below:

Michigan Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing
Attn: Compliance Section
P.O. Box 30670
Lansing, MI 48909

Failure to comply with these provisions of the Public Health Code may result in the imposition of further administrative sanctions.

If you have any questions regarding the enclosed form, please contact the Enforcement Division at (517) 335-3114.

Enclosures

LARA/HRD-021 (11/17)

Michigan Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing – Enforcement Division
P.O. Box 30670
Lansing, MI 48909
www.michigan.gov/healthlicense Department Due Date: May 5, 2022
53-21-002501

NOTICE OF LICENSURE/REGISTRATION SANCTION

Reprimand, Restitution, Fine, Probation, Limitation

Authority: 1978 P.A. 368, as amended

This completed form serves as notification, to you, that the licensee/registrant named below has had his or her professional license/registration sanctioned for violating one or more provisions of the Michigan Public Health Code. This licensee/registrant is NOT prohibited from practicing his or her profession as long as such practice is in accordance with the sanction(s) set forth below. **This notification is required by law.**

TYPE OR PRINT IN INK ONLY

First Name	Middle Name	Last Name

Business Address (Enter street address, **NOT a P.O. Box**)			
City	State	Zip Code	Telephone Number w/Area Code

Type of License/Registration (Profession)	Michigan License/Registration Number

Type(s) of Sanction(s):

☐ REPRIMAND

☐ FINE IN THE AMOUNT OF $ _____ TO BE PAID BY _____
(Date)

☐ RESTITUTION IN THE AMOUNT OF $ _____ TO BE PAID BY _____
(Date)

☐ LIMITATION* UNTIL _____ (Date)

☐ PROBATION* UNTIL _____ (Date)

*Please describe the terms of limitation and/or probation below. Attach additional sheets if necessary.

Effective Date of Sanction	Date Transmitted to Employer(s)

Date Sent to Hospital(s)	Date Sent to the Department

Signature of Sanctioned Licensee/Registrant	Date Signed

AFFIDAVIT

I, being the undersigned, do hereby state that:

1. I have completed and reviewed the Notice of Licensure/Registration Sanction (hereafter "Notice") on the opposite side of this Affidavit for correctness.

2. I understand that the address I provided on the Notice may not be the address of record on file with the Department of Licensing and Regulatory Affairs. I further understand that all correspondence will be sent to the address of record, that this Notice does **NOT** serve as notification of a change of address of record, and that it is my responsibility to file a change of address with the Department's Licensing Section.

☐ 3. I have personally signed the completed Notice AND transmitted a copy of the signed, completed Notice to each hospital in which I am admitted to practice AND my employer within ten days after the date of the Order imposing the sanction(s);

Please check the box for either #3 or #4

OR

☐ 4. I am not employed and do not meet the criteria set forth in Sections 16241(6) and 16241(7) of the Public Health Code, as set forth in the above item #4.

I swear or affirm that the contents of this Affidavit are true and to the best of my knowledge. I understand that falsification of this affidavit may result in the imposition of further administrative sanctions against my license(s) or registration.

Print or Type Name:

Signature of Affiant:	Date Signed:

County of _____)

Signed and sworn to before me this _____ day of _____, 20 _____.

Notary Public

Date Commission Expires

_____ _____

DocuSign Envelope ID: A2A60131-7A7A-4F83-B034-709CA8C96ABA

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

MCKESSON MEDICAL SURGICAL INC
License No. 53-06-002300,

File No. 53-21-002501

Respondent.

CONSENT ORDER AND STIPULATION

CONSENT ORDER

On January 4, 2022, the Department of Licensing and Regulatory Affairs executed an Administrative Complaint charging Respondent with violating the Public Health Code, MCL 333.1101 *et seq*.

Respondent has admitted that the facts alleged in the Complaint are true and constitute a violation of the Public Health Code. The Michigan Board of Pharmacy's Disciplinary Subcommittee (DSC) has reviewed this Consent Order and Stipulation and agrees that the public interest is best served by resolution of the outstanding Complaint.

Therefore, IT IS FOUND that the facts alleged in the Complaint are true and constitute a violation of MCL 333.17768(2)(d).

Accordingly, IT IS ORDERED that for the cited violation of the Public Health Code:

Respondent is FINED $500.00 to be paid to the State of Michigan within 60 days of the effective date of this Order. Respondent shall **direct payment** to the **Department of Licensing and Regulatory Affairs, Enforcement Division, Compliance Section, P.O. Box 30189, Lansing, MI 48909**. The fine shall be paid by check or money order, made payable to the State of Michigan, and shall clearly display **File Number 53-21-002501**.

If Respondent violates any provision of this Order, the DSC may take disciplinary action pursuant to Mich Admin Code, R 338.1632 and MCL 333.16221(h).

This Order shall be effective thirty (30) days from the date signed by the Board, as set forth below.

MICHIGAN BOARD OF PHARMACY

By: _____ for
Chairperson, Disciplinary Subcommittee

Dated: April 20, 2022

STIPULATION

1. The facts alleged in the Complaint are true and constitute a violation of MCL 333.17768(2)(d).

2. Respondent understands and intends that by signing this Stipulation, Respondent is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act, MCL 24.201 *et seq*, to require the Department to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent is waving the right to appear with an attorney and such witnesses as Respondent may desire to present a defense to the charges.

3. This matter is a public record required to be published and made available to the public pursuant to the Michigan Freedom of Information Act, MCL 15.231 et seq., and this action will be reported to the National Practitioner Data Bank and any other entity as required by state or federal law.

4. This Order is approved as to form and substance by Respondent and the Department and may be entered as the final order of the DSC in this matter.

5. Factors taken into consideration in the formation of this Order are:

   a. In a written response to the Administrative Complaint, Respondent's representatives requested a settlement.

   b. Respondent wished to resolve this matter without the time and expense of an administrative hearing.

   c. Respondent proactively reported the Ohio disciplinary actions to the Department and indicated it has fully satisfied the terms of the Ohio disciplinary actions.

   d. Respondent's representatives explained that Respondent has put processes in place to prevent similar occurrences from happening.

6. A Department representative may discuss this matter with the DSC and recommend acceptance of the resolution set forth in this Order.

7. This proposal is conditioned upon acceptance by the DSC. Respondent and the Department expressly reserve the right to further proceedings without prejudice should the Order be rejected.

AGREED TO BY:

signing for

Forrest Pasanski, Director
Enforcement Division
Bureau of Professional Licensing

Dated: 3/11/2022

AGREED TO BY:

DocuSigned by:
Sunita Upadhyaya
9988F1CCF6074BE

McKesson Medical Surgical Inc
Respondent

By: Ruby Upadhyaya

Its: VP, Ops Quality & Regulatory Compliance

Dated: March 10, 2022

JP/ses

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

MCKESSON MEDICAL SURGICAL INC
License No. 53-06-002300,

File No. 53-21-002501

Respondent.

ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs by Forrest Pasanski, Enforcement Division Director, Bureau of Professional Licensing, complains against Respondent Mckesson Medical Surgical Inc as follows:

1. The Michigan Board of Pharmacy is an administrative agency established by the Public Health Code, MCL 333.1101 *et seq.* Pursuant to MCL 333.17768, the Board's Disciplinary Subcommittee is empowered to discipline licensees for violations of the Public Health Code.

2. Respondent holds a Michigan wholesaler distributor license. Respondent's facility is located in Urbancrest, Ohio.

3. On June 15, 2021, the State of Ohio Board of Pharmacy issued an Amended Notice of Opportunity for Hearing against Respondent based on information that from on or about April 29, 2016 to on or about September 9, 2019, Respondent sold drugs to Tranquility Laser Center, an Ohio business that was operating without proper Ohio licensure to obtain the drugs at the time.

4. On June 15, 2021, The State of Ohio Board of Pharmacy executed a Settlement Agreement with Respondent that resolved the above Amended Notice of Opportunity for Hearing. The Settlement Agreement fined Respondent $3,000.00.

5. A copy of the above documents, marked Exhibit A, is attached and incorporated.

6. On May 4, 2021, the State of Ohio Board of Pharmacy issued a Notice of Opportunity for Hearing against Respondent based on information that from on or about May 31, 2019 to on or about April 26, 2020, Respondent sold drugs to Harrison Pavilion, an Ohio business that was operating without proper Ohio licensure to obtain the drugs at the time.

7. On June 23, 2021, the State of Ohio Board of Pharmacy executed a Settlement Agreement with Respondent that resolved the above Notice of Opportunity for Hearing. The Settlement Agreement fined Respondent $125.00.

8. A copy of the above documents, marked Exhibit B, is attached and incorporated.

9. A review of Respondent's filings with the Department indicate that McKesson Medical Surgical Holdings Inc was the 100% stockholder of McKesson Medical Surgical Inc before and after the above disciplinary actions occurred.

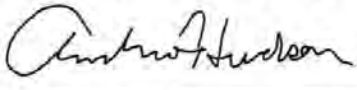
COUNT I

Respondent's stockholder maintained a financial interest in Respondent after Respondent was subject to administrative penalties in the State of Ohio, in violation of MCL 333.17768(2)(d).

RESPONDENT IS NOTIFIED that, consistent with Mich Admin Code, R 338.1607a(3), Respondent has 30 days from the date of receipt of this complaint to answer this complaint in writing and to show compliance with all lawful requirements for retention of the license. The written response shall be submitted by email to the Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing to BPL-DMS@michigan.gov. If unable to submit a response by email, Respondent may submit by regular mail to the Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing, P.O. Box 30670, Lansing, MI 48909.

MICHIGAN DEPARTMENT OF
LICENSING AND REGULATORY AFFAIRS

Dated: 1/4/2022


signing for

By: Forrest Pasanski, Director
Enforcement Division
Bureau of Professional Licensing

Attachments

JP/ses

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2020-0041

License No. 01-0828350

McKesson Medical-Surgical, Inc.
c/o Steven Robenolt
3500 Centerpoint Drive Ste. A
Urbancrest, OH 43123

June 10, 2021

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and McKesson Medical-Surgical, Inc., for the purpose of resolving all issues between the parties relating to the Board investigation of the illegal transfer of dangerous drugs. Together, the Board and McKesson Medical-Surgical, Inc. are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.

2. McKesson Medical-Surgical, Inc. is a licensed Terminal Distributor of Dangerous Drugs under license number 01-0828350.

FACTS

1. On or about October 9, 2019, the Board initiated an investigation of McKesson Medical-Surgical, Inc., Terminal Distributor of Dangerous Drugs license number 01-0828350.

2. On or about March 12, 2021, the Board sent a Notice of Opportunity for Hearing to McKesson Medical-Surgical, Inc., which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, In consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. McKesson Medical-Surgical, Inc. neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated March 12, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. McKesson Medical-Surgical, Inc. agrees to pay to the Board a monetary penalty in the amount of $3,000.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Settlement Agreement. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. McKesson Medical-Surgical, Inc. agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. McKesson Medical-Surgical, Inc. agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by McKesson Medical-Surgical, Inc. of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to McKesson Medical-Surgical, Inc. by the Board and will NOT discharge McKesson Medical-Surgical, Inc. from any obligation under the terms of this Agreement.

6. McKesson Medical-Surgical, Inc. agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. McKesson Medical-Surgical, Inc. understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom McKesson Medical-Surgical, Inc. will operate.

9. McKesson Medical-Surgical, Inc. waives its opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Steven Rosenoff McKesson Medical-Surgical, Inc.	June 15, 2021 Date of Signature
Roger N. Morris Attorney for Respondent	6/15/21 Date of Signature
Jennifer M. Rudell, R.Ph., President State of Ohio Board of Pharmacy	6/15/2021 Date of Signature
Henry Appel, Ohio Assistant Attorney General	6/15/2021 Date of Signature

STATE OF OHIO
BOARD OF PHARMACY

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 6/15/2021
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

AMENDED NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST LICENSEE

IN THE MATTER OF:

CASE No. A-2020-0041
I-2019-1157

McKesson Medical Surgical, Inc.
c/o Steven Robenolt
3500 Centerpoint Drive Ste. A
Urbancrest, OH 43123

License No. 01-0828350

June 15, 2021

Dear McKesson Medical Surgical, Inc. and Mr. Steven Robenolt:

You are hereby notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code the State of Ohio Board of Pharmacy (Board) proposes to take action against your license as a Wholesale Distributor of Dangerous Drugs under authority of Section 4729.56 of the Revised Code.

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code (ORC) and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to renew any registration certificate issued to a wholesale distributor of dangerous drugs (WDDD) pursuant to section 4729.52 of the Revised Code or may impose a monetary penalty of forfeiture not to exceed in the severity any fine designated under the Revised Code for a similar offense or $2,500 if the acts committed have not been classified as an offense by the Revised Code.

2. McKesson Medical Surgical, Inc. (McKesson) has a current WDDD license with the Board under license number 1-0828350, which lists Steven Robenolt as the Responsible Person.

ALLEGATIONS

1. From on or about April 29, 2016 to on or about September 09, 2019, McKesson, located at 3500 Centerpoint Drive Ste. A, Urbancrest, OH 43123 sold dangerous drugs, to Tranquility Laser Center, located at 1010 Woodman Drive Dayton, OH 45432, as set forth in Attachment A, attached hereto and incorporated as though fully set forth herein. Tranquility Laser Center was operating without a Board-issued Terminal Distributor of Dangerous Drugs license at this time.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(B)(1) of the ORC, as effective September 29, 2017, and March 22, 2019, no wholesale distributor shall possess for sale, sell, or distribute, at wholesale, dangerous drugs or investigational drugs or products to any person other than the following: Subject to division (D) of this section, a licensed terminal distributor of dangerous drugs, each sale being a first-degree misdemeanor, each punishable by a maximum fine of $5,000 if committed by an organization.

2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(B)(1) of the ORC, as effective April 6, 2017, no registered wholesale distributor of dangerous drugs shall possess for sale, sell, or distribute, at wholesale, dangerous drugs or investigational drugs or products, to any person other than the following: Subject to division (D) of this section, a licensed terminal distributor of dangerous drugs, each sale being a first-degree misdemeanor, each punishable by a maximum fine of $5,000 if committed by an organization.

3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(B)(1)(e) of the ORC, as effective February 1, 2016, and August 9, 2016, no registered wholesale distributor of dangerous drugs shall possess for sale, or sell, at wholesale, dangerous drugs to any person other than the following: Subject to division (B)(3) of this section, a licensed terminal distributor of dangerous drugs, each sale being a first-degree misdemeanor, each punishable by a maximum fine of $5,000 if committed by an organization.

4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(A)(1) of the ORC, as effective April 6, 2017, September 29, 2017, Before a licensee identified in division (B)(1)(a) of section 4729.52 of the Revised Code may sell or distribute dangerous drugs at wholesale to any person, except as provided in division (A)(2) of this section, the licensee shall query the roster established pursuant to section 4729.59 of the Revised Code to determine whether the purchaser is a licensed terminal distributor of dangerous drugs, each punishable by a maximum fine of $2,500 if committed by an organization.

5. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(A) of the ORC, as effective February 1, 2016, Before a registered wholesale distributor of dangerous drugs may sell dangerous drugs at wholesale to any person, other than the persons specified in divisions (B)(1) (a) to (d), (f) to (h), and (l) to (p)of section 4729.51 of the Revised Code, such wholesale distributor shall obtain from the purchaser and the purchaser shall furnish to the wholesale distributor a certificate indicating that the purchaser is a licensed terminal distributor of dangerous drugs, each punishable by a maximum fine of $2,500 if committed by an organization.

6. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Rule 4729-9-12(A)(1) of the OAC, as effective March 1, 2017, Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a terminal distributor of dangerous drugs, the wholesale distributor must obtain a copy of the current certificate of license as a terminal distributor from the purchaser pursuant to division (A) of section 4729.60 of the Revised Code or may utilize the Board's online registry to confirm licensure, each punishable by a maximum fine of $2,500 if committed by an organization.

7. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Rule 4729-9-12(A)(1) of the OAC, as effective October 5, 2015, Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a terminal distributor of dangerous drugs, the wholesale distributor must obtain a copy of the current certificate of license as a terminal distributor from the purchaser pursuant to division (A)

of section 4729.60 of the Revised Code, each punishable by a maximum fine of $2,500 if committed by an organization.

8. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Rule 4729:6-3-04 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of $2,500: Before a drug distributor may sell or distribute dangerous drugs to any person in this state, except as provided in paragraph (C) of this rule, the distributor shall conduct a documented query of a roster maintained by the Board to determine if the purchaser is licensed as either:

    a. A terminal distributor of dangerous drugs...For a limited terminal distributor of dangerous drugs license, a drug distributor shall also review a current version of the licensee's drug list to ensure the purchaser is authorized to possess the drug ordered, OAC Rule 4729:6-3-04(B)(1); and/or

    b. A distributor of dangerous drugs, OAC Rule 4729:6-3-04(B)(2).

9. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of Section 4729.56 of the ORC, effective September 29, 2017, each violation punishable by a maximum fine of $2,500 if committed by an organization:

    a. Violating any federal, state, or local drug law; any provision of chapter 4729. or Chapter 2925., 3715., or 3719. of the Revised Code; or any rule of the Board, ORC Section 4729.56(A)(2)(b); and/or

    b. Failing to satisfy the qualifications for registration under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the registration is granted or renewed, ORC Section 4729.56(A)(2)(d); and/or

    c. Any other cause for which the board may impose sanctions as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.56(A)(2)(g).

10. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of Section 4729.56 of the ORC, effective September 29, 2015, each violation punishable by a maximum fine of $2,500 if committed by an organization:

    a. Violating any federal, state, or local drug law; any provision of this chapter or Chapter 2925., 3715., or 3719. of the Revised Code; or any rule of the Board, ORC Section 4729.56(A)(2); and/or

    b. Failing to satisfy the qualifications for registration under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the registration is granted or renewed, ORC Section 4729.56(A)(4).

11. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729-9-19(A)(4) of the OAC, as effective October 5, 2015, each violation punishable by a maximum penalty of $2,500: Is not of good moral character and habits.

12. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:6-4-01 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of $2,500 if committed by an organization:

    a. Violating any rule of the Board, OAC Rule 4729:6-4-01(B)(2); and/or

b. Failing to satisfy the qualifications for licensure under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the license is granted or renewed, OAC Rule 4729:6-4-01(B)(5); and/or

c. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:6-4-01(B)(3).

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (**please note faxes will not be accepted**). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE MAILING DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a corporation, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the mailing of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY

Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Director

SWS/jak/pae

Enclosure: Attachment A

Attachment A - McKesson Corporation sales to Tranquility Laser Center

Customer	Date	Invoice	Drug	Quantity Ordered	Quantity Shipped
TRANQUILITY LASER CENTER	4/29/2016	77688687	LIDOCAINE HCL, MDV 1% 50ML (25/PK) HOSPRA	4	4
TRANQUILITY LASER CENTER	4/29/2016	77688687	AZITHROMYCIN, TAB 250MG 1X6 (6/BX) 9TEVA	4	4
TRANQUILITY LASER CENTER	5/31/2016	79386748	LIDOCAINE HCL, MDV 1% 50ML (25/PK) HOSPRA	4	4
TRANQUILITY LASER CENTER	5/31/2016	79386748	EPINEPHRINE, MDV 1MG/ML 30ML9INMED	4	4
TRANQUILITY LASER CENTER	5/31/2016	79386748	ACYCLOVIR,TAB 400MG (100/BT)9TEVA	5	5
TRANQUILITY LASER CENTER	3/24/2017	96838083	EPINEPHRINE, MDV 1MG/ML 30ML9INMED	2	2
TRANQUILITY LASER CENTER	3/30/2017	97195345	SOD CHL, IRR SOL 0.9% 1000ML (16/CS) BTL BBRAUN	1	1
TRANQUILITY LASER CENTER	3/31/2017	97255253	SOD CHL, IRR SOL BG 0.9% 1000ML (12/CS)	12	12
TRANQUILITY LASER CENTER	4/5/2017	97563265	SOD CHL, IRR SOL 0.9% 1000ML (14/CS) BAXTIV	1	1
TRANQUILITY LASER CENTER	4/13/2017	98046030	AQUAPHOR, OINT 3.5OZ9BEIRS	4	4
TRANQUILITY LASER CENTER	4/13/2017	98046030	ALOE VERA, GEL 12OZ9FRUIT	5	5
TRANQUILITY LASER CENTER	4/18/2017	1624829	EPINEPHRINE, MDV 1MG/ML 30ML9INMED	2	2
TRANQUILITY LASER CENTER	4/18/2017	1624829	SOD CHL, IVSOL PVC DEHP FREE 0.9% 500ML (24/CS) BBRAUN	1	1
TRANQUILITY LASER CENTER	4/18/2017	1624829	SODIUM CHLORIDE, FTV PF 0.9% 50ML (25/PK) HOSPRA	10	10
TRANQUILITY LASER CENTER	4/26/2017	2117934	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	2	2
TRANQUILITY LASER CENTER	4/26/2017	2117934	SOD CHL, IVSOL 0.9% 1000ML (12/CS)	2	2
TRANQUILITY LASER CENTER	5/3/2017	2595266	AQUAPHOR ORIG, OINT 14OZ9BEIRS	1	1
TRANQUILITY LASER CENTER	5/3/2017	2595266	LUBRICATING JELLY, FOIL PKT STR 3GM (144/BX 6BX/CS MGM119	1	1
TRANQUILITY LASER CENTER	5/9/2017	2946703	EPINEPHRINE, MDV 1MG/ML 30ML9INMED	1	1
TRANQUILITY LASER CENTER	5/10/2017	2973663	EPINEPHRINE, MDV 1MG/ML 30ML9INMED	2	2
TRANQUILITY LASER CENTER	5/10/2017	3033650	SOD CHL, IRR SOL 0.9% 1000ML (16/CS) BTL BBRAUN	-1	-1
TRANQUILITY LASER CENTER	5/17/2017	3391434	LAC RING, IVSOL 1000ML (14/CS)BAXTIV	1	1
TRANQUILITY LASER CENTER	5/18/2017	3486773	LAC RING, IVSOL 1000ML (14/CS)BAXTIV	6	6
TRANQUILITY LASER CENTER	6/5/2017	4483436	EPINEPHRINE, MDV 1MG/ML 30ML9INMED	2	2
TRANQUILITY LASER CENTER	7/21/2017	7323830	HYLENEX, SDV 150U/1ML 1ML (4/CT) 9HZYMI	2	2
TRANQUILITY LASER CENTER	9/11/2017	10448433	ALOE VERA, GEL CLR 20OZ9FRUIT	3	3
TRANQUILITY LASER CENTER	9/14/2017	10681225	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	1	1
TRANQUILITY LASER CENTER	9/18/2017	10880593	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	2	2
TRANQUILITY LASER CENTER	10/20/2017	13118394	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	1	1
TRANQUILITY LASER CENTER	11/6/2017	14145619	SODIUM CHLORIDE BACT, FTV MDV0.9% 30ML (25/PK) HOSPRA	10	10
TRANQUILITY LASER CENTER	11/7/2017	14216402	LIDOCAINE HCL, MDV 1% 50ML (25/PK) HOSPRA	1	1
TRANQUILITY LASER CENTER	11/10/2017	14525576	SOD CHL, IVSOL 0.9% 1000ML (12/CS)	1	1
TRANQUILITY LASER CENTER	11/20/2017	15096430	SODIUM BICARB, SYR 8.4% 1MEQ/ML 50ML (10/PK)	10	10
TRANQUILITY LASER CENTER	12/8/2017	16346232	SOD CHL, IVSOL 0.9% 1000ML (12/CS)	2	2
TRANQUILITY LASER CENTER	12/12/2017	16561978	SODIUM BICARB, SYR 8.4% 1MEQ/ML 50ML (10/PK)	-1	-1
TRANQUILITY LASER CENTER	12/12/2017	16561978	SODIUM BICARB, SYR 8.4% 1MEQ/ML 50ML (10/PK)	-9	-9
TRANQUILITY LASER CENTER	1/3/2018	17892386	LIDOCAINE HCL +EPI, FTV 1% 50ML (25/PK) HOSPRA	2	2
TRANQUILITY LASER CENTER	1/5/2018	18156327	AQUAPHOR, OINT 3.5OZ9BEIRS	4	4
TRANQUILITY LASER CENTER	2/2/2018	20140455	HYLENEX, SDV 150U/1ML 1ML (4/CT) 9HZYMI	3	3
TRANQUILITY LASER CENTER	3/7/2018	22533486	LIDOCAINE HCL, INJ SDV 1% 50MG/5ML (25/CT)	1	1
TRANQUILITY LASER CENTER	4/9/2018	24827222	HYLENEX, SDV 150U/1ML 1ML (4/CT) 9HZYMI	1	1
TRANQUILITY LASER CENTER	4/13/2018	25233928	ADRENALIN, MDV 1MG/ML 30MLRX	1	1
TRANQUILITY LASER CENTER	4/13/2018	25233928	SODIUM BICARB, FTV SDV 8.4% 1MEQ/ML 50ML (25/PK)	1	1
TRANQUILITY LASER CENTER	4/13/2018	25233928	LIDOCAINE HCL, INJ SDV 1% 50MG/5ML (25/CT)	1	1
TRANQUILITY LASER CENTER	4/13/2018	25233928	SOD CHL , IVSOL PVC DEHP FREE0.9% 500ML (10/CS)	1	1
TRANQUILITY LASER CENTER	4/13/2018	25233928	LAC RING+DEX, IVSOL 5% 1000ML(12/CS) BBRAUN	1	1
TRANQUILITY LASER CENTER	5/10/2018	27073778	ADRENALIN, MDV 1MG/ML 30MLRX	1	1
TRANQUILITY LASER CENTER	5/10/2018	27073778	SODIUM BICARB, FTV SDV 8.4% 1MEQ/ML 50ML (25/PK)	5	5
TRANQUILITY LASER CENTER	5/17/2018	27517036	SOD CHL , IVSOL PVC DEHP FREE0.9% 500ML (10/CS)	2	2
TRANQUILITY LASER CENTER	6/4/2018	28667606	SOD CHL , IVSOL PVC DEHP FREE0.9% 500ML (10/CS)	-2	-2
TRANQUILITY LASER CENTER	6/19/2018	29716705	ALOE VERA, GEL 12OZ9FRUIT	2	2
TRANQUILITY LASER CENTER	7/20/2018	31880355	HYLENEX, SDV 150U/1ML 1ML (4/CT) 9HZYMI	1	1
TRANQUILITY LASER CENTER	7/20/2018	31880342	HYLENEX, SDV 150U/1ML 1ML (4/CT) 9HZYMI	1	1
TRANQUILITY LASER CENTER	7/24/2018	32024723	HYLENEX, SDV 150U/1ML 1ML (4/CT) 9HZYMI	2	2
TRANQUILITY LASER CENTER	8/1/2018	32675299	ADRENALIN, MDV 1MG/ML 30MLRX	1	1
TRANQUILITY LASER CENTER	9/10/2018	35476153	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	2	2
TRANQUILITY LASER CENTER	9/11/2018	35575918	LIDOCAINE HCL +EPI, FTV 1% 50ML (25/PK) HOSPRA	4	4
TRANQUILITY LASER CENTER	9/21/2018	36356572	LIDOCAINE HCL +EPI, FTV 1% 50ML (25/PK) HOSPRA	10	10
TRANQUILITY LASER CENTER	12/4/2018	41785660	LIDOCAINE HCL, INJ SDV 1% 50MG/5ML (25/CT)	10	10
TRANQUILITY LASER CENTER	12/17/2018	42846310	ADRENALIN, MDV 1MG/ML 30MLRX	1	1
TRANQUILITY LASER CENTER	12/17/2018	42846310	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	1	1
TRANQUILITY LASER CENTER	12/27/2018	43492925	ALOE VERA, GEL 12OZ9FRUIT	6	6
TRANQUILITY LASER CENTER	1/29/2019	45991609	AQUAPHOR, OINT 3.5OZ9BEIRS	4	4
TRANQUILITY LASER CENTER	3/11/2019	49283207	ADRENALIN, MDV 1MG/ML 30MLRX	2	2
TRANQUILITY LASER CENTER	3/11/2019	49283207	HYLENEX, SDV 150U/1ML 1ML (4/CT) 9HZYMI	3	3
TRANQUILITY LASER CENTER	3/11/2019	49283207	AQUAPHOR, OINT 3.5OZ9BEIRS	3	3

Attachment A - McKesson Corporation sales to Tranquility Laser Center

Customer	Date	Invoice	Drug	Quantity Ordered	Quantity Shipped
TRANQUILITY LASER CENTER	4/2/2019	51018590	EPINEPHRINE, AMP PF 1MG/ML 1ML1:1000 (10/BX)	4	4
TRANQUILITY LASER CENTER	4/2/2019	51018590	XYLOCAINE, MDV 1% 50ML (25/CT)9APPPH	2	2
TRANQUILITY LASER CENTER	4/2/2019	51018590	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	4	4
TRANQUILITY LASER CENTER	6/18/2019	56982294	SOD CHL, IVSOL PVC DEHP FREE 0.9% 500ML (24/CS) BBRAUN	1	1
TRANQUILITY LASER CENTER	6/18/2019	56982294	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	1	1
TRANQUILITY LASER CENTER	8/6/2019	60772745	SODIUM CHLORIDE BACT, FTV MDV0.9% 30ML (25/PK) HOSPRA	3	3
TRANQUILITY LASER CENTER	9/6/2019	63254338	SODIUM CHLORIDE BACT, FTV MDV0.9% 30ML (25/PK) HOSPRA	5	5

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2020-0552
I-2020-0764

McKesson Medical-Surgical

License No. 010828350

c/o Steven Robenolt
3500-A Centerpoint Drive
Grove City, OH 43123

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and McKesson Medical-Surgical, for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and McKesson Medical-Surgical are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. McKesson Medical-Surgical, is a licensed Wholesaler Distributor of Dangerous Drug, License No. 010828350, which lists Steven Robenolt, as the Responsible Person.

FACTS

1. The Board initiated an investigation of McKesson Medical-Surgical, Wholesaler Distributor of Dangerous Drugs License No. 010828350, related to McKesson Medical-Surgical illegal sales of dangerous drugs to an unlicensed entity.

2. On or about May 4, 2021, the Board sent a Notice of Opportunity for Hearing to McKesson Medical-Surgical, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. McKesson Medical-Surgical neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated May 4, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. McKesson Medical-Surgical agrees to pay to the Board a monetary penalty in the amount of $125.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. McKesson Medical-Surgical Wholesale Distributor of Dangerous Drugs license will be issued subject to satisfactory completion of all application and inspection requirements and payment of the fine.

5. McKesson Medical-Surgical agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. McKesson Medical-Surgical agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by McKesson Medical-Surgical of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to McKesson Medical-Surgical by the Board and will NOT discharge McKesson Medical-Surgical from any obligation under the terms of this Agreement.

7. McKesson Medical-Surgical agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. McKesson Medical-Surgical understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom McKesson Medical-Surgical will operate.

10. McKesson Medical-Surgical waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

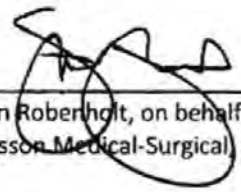
13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:



Steven Roberholt, on behalf of,
McKesson Medical-Surgical, Respondent

June 23, 2021
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Jennifer M. Rudell, RPh

6/23/2021

Jennifer M. Rudell, RPh, President,
State of Ohio Board of Pharmacy

Date of Signature



6/23/2021

Henry G. Appel, Ohio Assistant Attorney General

Date of Signature

STATE OF OHIO
BOARD OF PHARMACY

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: May 4, 2021
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST LICENSEE

IN THE MATTER OF:

CASE No. A-2020-0552
I-2020-0764

McKesson Medical-Surgical
c/o Steven Robenolt
3500-A Centerpoint Drive
Grove City, OH 43123

License No. 010828350

May 4, 2021

Dear McKesson Medical-Surgical and Mr. Steven Robenolt:

You are hereby notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code the State of Ohio Board of Pharmacy (Board) proposes to take action against your license as a Wholesale Distributor of Dangerous Drugs under authority of Section 4729.56 of the Revised Code.

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code (ORC) and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to renew any registration certificate issued to a wholesale distributor of dangerous drugs (WDDD) pursuant to section 4729.52 of the Revised Code or may impose a monetary penalty of forfeiture not to exceed in the severity any fine designated under the Revised Code for a similar offense or $2,500 if the acts committed have not been classified as an offense by the Revised Code.

2. McKesson Medical-Surgical (McKesson) has a current WDDD license with the Board under license number 010828350, which lists Steven Robenolt as the Responsible Person.

ALLEGATIONS

1. From on or about March 31, 2019 to on or about April 26th, 2020, McKesson, located at 3500-A Centerpoint Drive, Grove City, Ohio, sold dangerous drugs, to Harrison Pavilion, located at 2171 Harrison Avenue, Cincinnati, Ohio, as set forth in Attachment A, attached hereto and incorporated as though fully set forth herein. Harrison Pavilion, was operating without a Board-issued Terminal Distributor of Dangerous Drugs license at this time.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(B)(1) of the ORC, as effective March 22, 2019, no wholesale distributor shall possess for sale, sell, or distribute, at wholesale, dangerous drugs or investigational drugs or products to any person other than the following: Subject to division (D) of this section, a licensed terminal distributor of dangerous drugs, each sale being a first-degree misdemeanor, each punishable by a maximum fine of $5,000 if committed by an organization.

2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(A)(1) of the ORC, as effective September 29, 2017, Before a licensee identified in division (B)(1)(a) of section 4729.52 of the Revised Code may sell or distribute dangerous drugs at wholesale to any person, except as provided in division (A)(2) of this section, the licensee shall query the roster established pursuant to section 4729.59 of the Revised Code to determine whether the purchaser is a licensed terminal distributor of dangerous drugs, each punishable by a maximum fine of $2,500 if committed by an organization.

3. Such conduct as set forth in paragraph (1)(v) of the Allegations Section, if proven, each constitutes a violation of Rule 4729:6-3-04 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of $2,500: Before a drug distributor may sell or distribute dangerous drugs to any person in this state, except as provided in paragraph (C) of this rule, the distributor shall conduct a documented query of a roster maintained by the Board to determine if the purchaser is licensed as either:

    a. A terminal distributor of dangerous drugs...For a limited terminal distributor of dangerous drugs license, a drug distributor shall also review a current version of the licensee's drug list to ensure the purchaser is authorized to possess the drug ordered, OAC Rule 4729:6-3-04(B)(1); and/or

    b. A distributor of dangerous drugs, OAC Rule 4729:6-3-04(B)(2).

4. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of Section 4729.56 of the ORC, effective September 29, 2017, each violation punishable by a maximum fine of $2,500 if committed by an organization:

    a. Violating any federal, state, or local drug law; any provision of chapter 4729. or Chapter 2925., 3715., or 3719. of the Revised Code; or any rule of the Board, ORC Section 4729.56(A)(2)(b); and/or

    b. Failing to satisfy the qualifications for registration under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the registration is granted or renewed, ORC Section 4729.56(A)(2)(d); and/or

    c. Any other cause for which the board may impose sanctions as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.56(A)(2)(g).

5. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:6-4-01 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of $2,500 if committed by an organization:

a. Violating any rule of the Board, OAC Rule 4729:6-4-01(B)(2); and/or

b. Failing to satisfy the qualifications for licensure under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the license is granted or renewed, OAC Rule 4729:6-4-01(B)(5); and/or

c. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:6-4-01(B)(3).

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (**please note faxes will not be accepted**). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE MAILING DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a corporation, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the mailing of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY

Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Director

SWS/jak/pae

CMRRR: 7020 1810 0002 1633 8040

Enclosure: Attachment A

Attachment A - Sales made by McKesson Medical-Surgical					
Purchaser	Date	Invoice Number	Medication	Package Size	Quantity
Harrison Pavilion	10/10/2019	45038530	Fluecelvax 2019	10 does/VL	1

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MCKESSON MEDICAL-SURGICAL, INC.	)	**BOARD OF PHARMACY**
	)	
	)	
Wholesale Distributor Permit No. 195581	)	**CASE NO: 21-L-0182**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against McKesson Medical-Surgical, Inc. (hereinafter referred to as "MMS") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached collectively hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and MMS, through its counsel, engaged in negotiations and as a result, the matters at issue were resolved informally by the parties who agreed to the entry of this Consent Order which includes the following terms:

1. The Board finds that MMS violated the applicable provision of law based upon the conduct set out in all Counts of the Statement.

2. MMS shall pay to the Board an administrative fine in the amount of Three Thousand dollars ($3,000.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and MMS shall not attempt to discharge the same in any bankruptcy proceeding.

3. That MMS expressly waives its rights pursuant to the Alabama Pharmacy

Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. MMS further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, MMS hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That MMS acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against MMS's permit, including, but not limited to revocation.

6. That MMS acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. MMS acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of their attorney.

DONE this the 12th day of July, 2022.

McKesson Medical-Surgical, Inc.

By: Ruby Upadhyaya
Its: Ruby Upadhyaya/VP Ops Quality & Regulatory

Susan Brichler Trujillo, Attorney for McKesson Medical-Surgical, Inc.

DONE this the 19 day of JULY, 2022.

ALABAMA STATE BOARD OF PHARMACY

By:
Chris Phung, R.Ph., President

By:
James S. Ward
Its Attorney

WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209
(205) 871-5404

DONE this the _____day of _____, 2022.

McKesson Medical-Surgical, Inc.

By:_____
Its:_____

7/11/2022
Susan Brichler Trujillo, Attorney for McKesson Medical-Surgical, Inc.

DONE this the _____day of _____, 2022.

ALABAMA STATE BOARD OF PHARMACY

By:_____
Chris Phung, R.Ph., President

By:_____
James S. Ward
Its Attorney

WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209
(205) 871-5404

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MCKESSON MEDICAL-SURGICAL, INC.	)	**BOARD OF PHARMACY**
	)	
Wholesale Distributor Permit No. 195581	)	**CASE NO: 21-L-0182**
	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: McKesson Medical-Surgical, Inc.
3500 A Centerpoint Drive
Urbancrest, Ohio 43123

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on July 19, 2022 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate McKesson Medical-Surgical, Inc. (McKesson) as a Wholesale Distributor should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted based upon any or all of the following, to-wit:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors include:

(a) Compliance with licensing requirements under previously granted license, if any.

(b) Compliance with the requirements to maintain records required to be maintained.

(c) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

3. Board Rule 680-X-2.23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health.

4. Board Rule 680-X-2.23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation.

5. Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law.

PRIOR HISTORY

1. On September 30, 2020, a Statement of Charges and Notice of Hearing (SOC) was issued against McKesson and is attached hereto as Exhibit "A".

2. On January 11, 2021, McKesson entered into a Deferral Agreement with the Board attached hereto as Exhibit "B". The Deferral Period set out in the Deferral Agreement was from January 11, 2021 until December 31, 2021.

3. A condition of the Deferral Agreement prohibited a probable cause violation and if one occurred during the Deferral Period both the charge subject to the Deferral and the new charge would be heard.

4. The Board alleges McKesson has violated the Deferral Agreement by the entry of a Settlement Agreement with the State of Ohio Board of Pharmacy dated June 15, 2021.

5. Based on the above, the SOC attached hereto as Exhibit "A" is amended to include the following:

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(2) based upon the entry of a Settlement Agreement with the State of Ohio Board of Pharmacy dated June 15, 2021 attached hereto as Exhibit "C" and/or you selling dangerous drugs to an entity which was operating without a Board issued Terminal Distribution of Dangerous Drugs license at the time as more particularly set out in the above referenced Settlement Agreement.

COUNT THREE

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of the preceding Count.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 25th day of April, 2022.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MCKESSON MEDICAL-SURGICAL, INC.	)	**BOARD OF PHARMACY**
	)	
	)	
Wholesale Distributor Permit No. 195581	)	**CASE NO: 20-L-0094**
	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: McKesson Medical-Surgical, Inc.
3500 A Centerpoint Drive
Urbancrest, Ohio 43123

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on January 19, 2021 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate McKesson Medical-Surgical, Inc. (McKesson) as a Wholesale Distributor should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that McKesson has been guilty of the following, to-wit:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors

include:

(a) Compliance with licensing requirements under previously granted license, if any.

(b) Compliance with the requirements to maintain records required to be maintained.

(c) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

3. Board Rule 680-X-2.23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health.

4. Board Rule 680-X-2.23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation.

5. Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law.

COUNT ONE

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the public safety or endangers the public health of the citizens of this state based upon the entry of a Settlement Agreement with the State of Ohio Board of Pharmacy dated April 2, 2019 and/or you receiving and filling an order for dangerous drugs from an entity not licensed with the Ohio Board as a Terminal Distributor of Dangerous Drugs as more fully set out in the Notice of Charges included in Exhibit "A" hereto.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 30th day of September, 2020.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

EXHIBIT A

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2019-0064

McKesson Medical-Surgical
3500 Centerpoint Drive, Ste A
Urbancrest, OH 43123

WDDD License No. 01-0438700

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and McKesson Medical-Surgical, for the purpose of resolving all issues between the parties relating to the Board investigation of illegal delivery of dangerous drugs to an unlicensed site. Together, the Board and McKesson Medical-Surgical are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. McKesson Medical-Surgical is a licensed Wholesale Distributor of Dangerous Drugs under license number 01-0438700.

FACTS

1. On or about September 28, 2017 the Board initiated an investigation of McKesson Medical-Surgical, Wholesale Distributor of Dangerous Drugs license number 01-0438700, related to McKesson Medical-Surgical' s illegal delivery of dangerous drugs to an unlicensed site.

2. On or about March 1, 2019, the Board sent a Notice of Opportunity for Hearing to McKesson Medical-Surgical, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. McKesson Medical-Surgical neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated March 1, 2019; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. McKesson Medical-Surgical agrees to pay to the Board a monetary penalty the amount of $4,500.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. McKesson Medical-Surgical agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. McKesson Medical-Surgical agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by McKesson Medical-Surgical of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to McKesson Medical-Surgical by the Board and will NOT discharge McKesson Medical-Surgical from any obligation under the terms of this Agreement.

6. McKesson Medical-Surgical agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. McKesson Medical-Surgical understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom McKesson Medical-Surgical will operate.

9. McKesson Medical-Surgical waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

McKesson Medical-Surgical, Respondent — Date of Signature: 3/26/19

Attorney for Respondent (if applicable) — Date of Signature

Fred M. Weaver, RPh, President
State of Ohio Board of Pharmacy — Date of Signature: 4-2-19

Henry Appel, Ohio Assistant Attorney General — Date of Signature: 4/2/19

STATE OF OHIO
BOARD OF PHARMACY

NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION
AGAINST WHOLESALE DISTRIBUTOR OF DANGEROUS DRUG LICENSE

IN THE MATTER OF:

CASE NOS. I-2017-2411
A-2019-0064

License No. 01-0828350

McKesson Medical-Surgical, Inc.
c/o Steven Robenolt
3500-A Centerpoint Drive
Urban Crest, OH 43123

THIS IS A TRUE AND CORRECT COPY
I hereby certify that I have a true and correct copy of the original document on file with the Ohio State Board of Pharmacy
Steven Schierholt, Esq. Executive Director
DATE 3/1/19

March 1, 2018

Dear McKesson Medical-Surgical, Inc. and Mr. Stephen Robenolt:

You are hereby notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code the State of Ohio Board of Pharmacy (Board) proposes to take disciplinary action against your license as a Wholesale Distributor of Dangerous Drugs under authority of Section 4729.56 of the Revised Code.

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code (ORC) and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to renew any registration certificate issued to a wholesale distributor of dangerous drugs (WDDD) pursuant to section 4729.52 of the Revised Code or may impose a monetary penalty of forfeiture not to exceed in the severity any fine designated under the Revised Code for a similar offense or $1,000 if the acts committed have not been classified as an offense by the Revised Code.

2. McKesson Medical-Surgical, Inc., located at 3500-A Centerpoint Drive, Urban Crest, Ohio 43123, has a Category 2 Wholesale Distributor of Dangerous Drug License with the Board under license number 01-0828350 which lists Stephen Robenolt as the Responsible Person.

ALLEGATIONS

1. On or about September 21, 2017, you received an order from CrowdRx. On or about September 25, 2017, you filled the order for CrowdRx. CrowdRx was not licensed with the Board as a Terminal Distributor of Dangerous Drugs (TDDD). The order was subsequently shipped to CrowdRx at 7585 Kindle Valley Road, Thornville, Ohio. The order contained the following dangerous drugs:

a. (26) bags of 5% dextrose in lactated ringers in a cardboard box.

b. Two boxes containing (60) ipratropium bromide 0.5mg and albuterol sulfate 3mg inhalation solutions.

c. Two boxes containing (50) albuterol sulfate inhalation solutions 0.083%.

d. Five boxes of (150) ondansetron 4mg orally disintegrating tablets.

e. (4) vials of glycopyrrolate injection, 02mg/ml.

f. (10) vials of ketorolac tromethamine, 60mg/2ml.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of the section 4729.51 of the ORC, as effective April 6, 2017, no registered wholesale distributor of dangerous drugs shall...sell, or distribute, at wholesale, dangerous drugs...to any person other than...a licensed terminal distributor of dangerous drugs, a misdemeanor of the first degree, each violation punishable by a maximum penalty of $5,000 if committed by an organization, ORC Section 4729.51(B)(1).

2. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of the section 4729.51 of the ORC, as effective April 6, 2017, no person shall...sell or distribute, at retail, dangerous drugs, a felony of the fourth degree, punishable by a maximum fine of $10,000 if committed by an organization, ORC Section 4729.51(E)(1).

3. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of section 4729.60(A)(1) of the Revised Code, failing to verify the purchaser is a licensed terminal distributor of dangerous drugs, each violation punishable by a maximum fine of $1,000.

4. Such conduct, if proven, also constitutes a violation of Section 4729-9-12(A)(2) of the OAC, failure to verify a license as a terminal distributor of dangerous drugs, punishable by a maximum fine of $1,000.

5. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of the section 4729.53 of the ORC, failure to meet the registration requirements for a WDDD, each violation punishable by a maximum fine of $1,000.

    a. If the applicant has committed acts that the board finds violate any federal, state, or local law, regulation, or rule relating to drug samples, manufacturing, compounding, repackaging, wholesale or retail drug distribution, or distribution of dangerous drugs, including controlled substances, or constitute a felony, or if a federal, state, or local governmental entity has suspended or revoked any current or prior license of the applicant for the manufacture, compounding, repackaging, distribution, or sale of any dangerous drugs, including controlled substances, the applicant, to the satisfaction of the board, assures that the applicant has in place adequate safeguards to prevent the recurrence of any such violations, ORC 4729.53(A)(1); and/or

b. Personnel employed by the applicant have the appropriate education or experience, as determined by the board, to assume responsibility for positions related to compliance with this chapter and the rules adopted pursuant thereto, ORC 4729.53(A)(4); and/or

c. Adequate safeguards are assured to prevent the sale of dangerous drugs to any person other than those named in division (B) of section 4729.51 of the Revised Code, ORC 4729.53(A)(6); and/or

d. Any other requirement or qualification the board, by rule adopted in accordance with Chapter 119. of the Revised Code, considers relevant to and consistent with the public safety and health, ORC 4729.53(A)(7).

6. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of section 4729.56 of the ORC, each violation punishable by a maximum fine of $1,000:

a. Violating any federal, state, or local drug law; any provision of chapter 4729. or Chapter 2925., 3715., or 3719. of the Revised Code, or any rule of the board, ORC Section 4729.56(A)(2); and/or

b. Failing to satisfy the qualifications for registration under section 4729.53 of the Revised Code or the rules of the board or ceasing to satisfy the qualifications after the registration is granted or renewed

7. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729-9-19(A) of the OAC, each violation punishable by a maximum penalty of $1,000:

a Commission of an act that constitutes a felony in this state, regardless of the jurisdiction in which the act was committed, OAC Rule 4729-9-19(A)(2); and/or

b Is not of good moral character and habits, OAC Rule 4729-9-19(A)(4).

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (please note faxes will not be accepted) **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE MAILING DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a corporation, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the mailing of this notice, the State of Ohio Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY

Steve Schierholt, Bd Cm

Steven W. Schierholt, Esq., Executive Director

SWS/jak/kll

CMRRR: 9414 7118 9956 0039 3041 02

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EXHIBIT "B"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MCKESSON MEDICAL-SURGICAL, INC.	)	**BOARD OF PHARMACY**
	)	
	)	
Wholesale Distributor Permit No. 195581	)	**CASE NO: 20-L-0094**
	)	

DEFERRAL AGREEMENT

This Agreement is entered into by and between the Alabama State Board of Pharmacy (Board) and McKesson Medical-Surgical, Inc. (McKesson).

WHEREAS, McKesson was timely served with a Statement of Charges and Notice of Hearing (Pending Charges) alleging violations of the Alabama Pharmacy Practice Act. A copy of the Pending Charges is attached hereto as Exhibit "A".

WHEREAS, the parties have engaged in discussions concerning an informal resolution of the Pending Charges.

WHEREAS, the parties have agreed to resolve this matter pursuant to Code of Alabama (1975) 41-22-12(f) by their approval of the following terms:

IT IS THE THEREFORE UNDERSTOOD AND AGREED BY THE PARTIES AS FOLLOWS:

1. The Pending Charges against McKesson shall be deferred until December 31, 2021.

2. As a condition to the deferral described above, McKesson shall pay costs in the amount of One Thousand Dollars ($1,000.00) within thirty (30) days of the effective date of this Agreement, that being the date it is signed on behalf of the Board. Failure to pay this amount shall be considered a probable cause violation by McKesson

as defined below.

3. In the event there are no probable cause violations of the Alabama Pharmacy Practice Act involving McKesson during the deferral period set forth above, the Pending Charges shall be dismissed.

4. In the event there is a probable cause violation of the Alabama Pharmacy Practice Act involving McKesson during the deferral period set forth above, both charges in connection with the Pending Charges and any new charges shall be noticed and scheduled for a hearing.

5. Neither the Pending Charges nor this Agreement shall be reported as discipline as long as McKesson complies with the conditions of Paragraphs Two and Three of this Agreement.

6. That McKesson expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. McKesson further waives any objection to the attorney for the Board preparing, drafting or making this Deferral Agreement, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

7. By execution of this Consent Order, McKesson hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with

the matters relating to this Deferral Agreement and Statement.

8. McKesson acknowledges and agrees that it has read this Deferral Agreement and that it fully understand the terms, conditions and contents of the same. McKesson acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Deferral Agreement and is signing this Deferral Agreement on the advice of its attorney.

DONE this the 11 day of January 2021

James S. Ward
Ward & Cooper, LLC
2108 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209

Ralph E. Sorrell, R.Ph.
President, Alabama State
Board of Pharmacy

DONE this the _____ day of _____, 2020.

McKesson Medical-Surgical, Inc.

By: _____
Its: _____

Susan Brichler Trujillo, Attorney
for McKesson Medical Surgical,
Inc.

DocuSign Envelope ID: 7F222B28-2C39-48A1-9B90-DC829ACE08FF

the matters relating to this Deferral Agreement and Statement.

8. McKesson acknowledges and agrees that it has read this Deferral Agreement and that it fully understand the terms, conditions and contents of the same. McKesson acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Deferral Agreement and is signing this Deferral Agreement on the advice of its attorney.

DONE this the _____ day of _____, 2020.

_____
James S. Ward
Ward & Cooper, LLC
2100 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209

_____
Ralph E. Sorrell, R.Ph.
President, Alabama State
Board of Pharmacy

DONE this the _____ day of _____, 2020.

McKesson Medical-Surgical, Inc.

By: _____
Its: _____

Susan Brichler Trujillo, Attorney for McKesson Medical Surgical, Inc.

EXHIBIT "C"

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2020-0041

License No. 01-0828350

McKesson Medical-Surgical, Inc.
c/o Steven Robenolt
3500 Centerpoint Drive Ste. A
Urbancrest, OH 43123

June 10, 2021

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and McKesson Medical-Surgical, Inc., for the purpose of resolving all issues between the parties relating to the Board investigation of the illegal transfer of dangerous drugs. Together, the Board and McKesson Medical-Surgical, Inc. are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.

2. McKesson Medical-Surgical, Inc. is a licensed Terminal Distributor of Dangerous Drugs under license number 01-0828350.

FACTS

1. On or about October 9, 2019, the Board initiated an investigation of McKesson Medical-Surgical, Inc., Terminal Distributor of Dangerous Drugs license number 01-0828350.

2. On or about March 12, 2021, the Board sent a Notice of Opportunity for Hearing to McKesson Medical-Surgical, Inc., which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, In consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. McKesson Medical-Surgical, Inc. neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated March 12, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. McKesson Medical-Surgical, Inc. agrees to pay to the Board a monetary penalty in the amount of $3,000.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Settlement Agreement. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. McKesson Medical-Surgical, Inc. agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. McKesson Medical-Surgical, Inc. agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by McKesson Medical-Surgical, Inc. of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to McKesson Medical-Surgical, Inc. by the Board and will NOT discharge McKesson Medical-Surgical, Inc. from any obligation under the terms of this Agreement.

6. McKesson Medical-Surgical, Inc. agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. McKesson Medical-Surgical, Inc. understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom McKesson Medical-Surgical, Inc. will operate.

9. McKesson Medical-Surgical, Inc. waives its opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Steven Robenolt
McKesson Medical-Surgical, Inc.

June 15, 2021
Date of Signature

Roger W. Morris
Attorney for Respondent

6/15/21
Date of Signature

Jennifer M. Rudell, R.Ph., President
State of Ohio Board of Pharmacy

6/15/2021
Date of Signature

Henry Appel, Ohio Assistant Attorney General

6/15/2021
Date of Signature

STATE OF OHIO
BOARD OF PHARMACY

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 6/15/2021
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

AMENDED NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST LICENSEE

IN THE MATTER OF:

CASE No. A-2020-0041
I-2019-1157

McKesson Medical Surgical, Inc.
c/o Steven Robenolt
3500 Centerpoint Drive Ste. A
Urbancrest, OH 43123

License No. 01-0828350

June 15, 2021

Dear McKesson Medical Surgical, Inc. and Mr. Steven Robenolt:

You are hereby notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code the State of Ohio Board of Pharmacy (Board) proposes to take action against your license as a Wholesale Distributor of Dangerous Drugs under authority of Section 4729.56 of the Revised Code.

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code (ORC) and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to renew any registration certificate issued to a wholesale distributor of dangerous drugs (WDDD) pursuant to section 4729.52 of the Revised Code or may impose a monetary penalty of forfeiture not to exceed in the severity any fine designated under the Revised Code for a similar offense or $2,500 if the acts committed have not been classified as an offense by the Revised Code.

2. McKesson Medical Surgical, Inc. (McKesson) has a current WDDD license with the Board under license number 1-0828350, which lists Steven Robenolt as the Responsible Person.

ALLEGATIONS

1. From on or about April 29, 2016 to on or about September 09, 2019, McKesson, located at 3500 Centerpoint Drive Ste. A, Urbancrest, OH 43123 sold dangerous drugs, to Tranquility Laser Center, located at 1010 Woodman Drive Dayton, OH 45432, as set forth in Attachment A, attached hereto and incorporated as though fully set forth herein. Tranquility Laser Center was operating without a Board-issued Terminal Distributor of Dangerous Drugs license at this time.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(B)(1) of the ORC, as effective September 29, 2017, and March 22, 2019, no wholesale distributor shall possess for sale, sell, or distribute, at wholesale, dangerous drugs or investigational drugs or products to any person other than the following: Subject to division (D) of this section, a licensed terminal distributor of dangerous drugs, each sale being a first-degree misdemeanor, each punishable by a maximum fine of $5,000 if committed by an organization.

2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(B)(1) of the ORC, as effective April 6, 2017, no registered wholesale distributor of dangerous drugs shall possess for sale, sell, or distribute, at wholesale, dangerous drugs or investigational drugs or products, to any person other than the following: Subject to division (D) of this section, a licensed terminal distributor of dangerous drugs, each sale being a first-degree misdemeanor, each punishable by a maximum fine of $5,000 if committed by an organization.

3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(B)(1)(e) of the ORC, as effective February 1, 2016, and August 9, 2016, no registered wholesale distributor of dangerous drugs shall possess for sale, or sell, at wholesale, dangerous drugs to any person other than the following: Subject to division (B)(3) of this section, a licensed terminal distributor of dangerous drugs, each sale being a first-degree misdemeanor, each punishable by a maximum fine of $5,000 if committed by an organization.

4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(A)(1) of the ORC, as effective April 6, 2017, September 29, 2017, Before a licensee identified in division (B)(1)(a) of section 4729.52 of the Revised Code may sell or distribute dangerous drugs at wholesale to any person, except as provided in division (A)(2) of this section, the licensee shall query the roster established pursuant to section 4729.59 of the Revised Code to determine whether the purchaser is a licensed terminal distributor of dangerous drugs, each punishable by a maximum fine of $2,500 if committed by an organization.

5. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(A) of the ORC, as effective February 1, 2016, Before a registered wholesale distributor of dangerous drugs may sell dangerous drugs at wholesale to any person, other than the persons specified in divisions (B)(1) (a) to (d), (f) to (h), and (l) to (p)of section 4729.51 of the Revised Code, such wholesale distributor shall obtain from the purchaser and the purchaser shall furnish to the wholesale distributor a certificate indicating that the purchaser is a licensed terminal distributor of dangerous drugs, each punishable by a maximum fine of $2,500 if committed by an organization.

6. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Rule 4729-9-12(A)(1) of the OAC, as effective March 1, 2017, Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a terminal distributor of dangerous drugs, the wholesale distributor must obtain a copy of the current certificate of license as a terminal distributor from the purchaser pursuant to division (A) of section 4729.60 of the Revised Code or may utilize the Board's online registry to confirm licensure, each punishable by a maximum fine of $2,500 if committed by an organization.

7. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Rule 4729-9-12(A)(1) of the OAC, as effective October 5, 2015, Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a terminal distributor of dangerous drugs, the wholesale distributor must obtain a copy of the current certificate of license as a terminal distributor from the purchaser pursuant to division (A)

of section 4729.60 of the Revised Code, each punishable by a maximum fine of $2,500 if committed by an organization.

8. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Rule 4729:6-3-04 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of $2,500: Before a drug distributor may sell or distribute dangerous drugs to any person in this state, except as provided in paragraph (C) of this rule, the distributor shall conduct a documented query of a roster maintained by the Board to determine if the purchaser is licensed as either:

    a. A terminal distributor of dangerous drugs...For a limited terminal distributor of dangerous drugs license, a drug distributor shall also review a current version of the licensee's drug list to ensure the purchaser is authorized to possess the drug ordered, OAC Rule 4729:6-3-04(B)(1); and/or

    b. A distributor of dangerous drugs, OAC Rule 4729:6-3-04(B)(2).

9. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of Section 4729.56 of the ORC, effective September 29, 2017, each violation punishable by a maximum fine of $2,500 if committed by an organization:

    a. Violating any federal, state, or local drug law; any provision of chapter 4729. or Chapter 2925., 3715., or 3719. of the Revised Code; or any rule of the Board, ORC Section 4729.56(A)(2)(b); and/or

    b. Failing to satisfy the qualifications for registration under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the registration is granted or renewed, ORC Section 4729.56(A)(2)(d); and/or

    c. Any other cause for which the board may impose sanctions as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.56(A)(2)(g).

10. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of Section 4729.56 of the ORC, effective September 29, 2015, each violation punishable by a maximum fine of $2,500 if committed by an organization:

    a. Violating any federal, state, or local drug law; any provision of this chapter or Chapter 2925., 3715., or 3719. of the Revised Code; or any rule of the Board, ORC Section 4729.56(A)(2); and/or

    b. Failing to satisfy the qualifications for registration under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the registration is granted or renewed, ORC Section 4729.56(A)(4).

11. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729-9-19(A)(4) of the OAC, as effective October 5, 2015, each violation punishable by a maximum penalty of $2,500: Is not of good moral character and habits.

12. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:6-4-01 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of $2,500 if committed by an organization:

    a. Violating any rule of the Board, OAC Rule 4729:6-4-01(B)(2); and/or

b. Failing to satisfy the qualifications for licensure under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the license is granted or renewed, OAC Rule 4729:6-4-01(B)(5); and/or

c. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:6-4-01(B)(3).

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov **(please note faxes will not be accepted). YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE MAILING DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a corporation, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the mailing of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY

Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Director

SWS/jak/pae

Enclosure: Attachment A

Attachment A - McKesson Corporation sales to Tranquility Laser Center

Customer	Date	Invoice	Drug	Quantity Ordered	Quantity Shipped
TRANQUILITY LASER CENTER	4/29/2016	77688687	LIDOCAINE HCL, MDV 1% 50ML (25/PK) HOSPRA	4	4
TRANQUILITY LASER CENTER	4/29/2016	77688687	AZITHROMYCIN, TAB 250MG 1X6 (6/BX) 9TEVA	4	4
TRANQUILITY LASER CENTER	5/31/2016	79386748	LIDOCAINE HCL, MDV 1% 50ML (25/PK) HOSPRA	4	4
TRANQUILITY LASER CENTER	5/31/2016	79386748	EPINEPHRINE, MDV 1MG/ML 30ML9INMED	4	4
TRANQUILITY LASER CENTER	5/31/2016	79386748	ACYCLOVIR,TAB 400MG (100/BT)9TEVA	5	5
TRANQUILITY LASER CENTER	3/24/2017	96838083	EPINEPHRINE, MDV 1MG/ML 30ML9INMED	2	2
TRANQUILITY LASER CENTER	3/30/2017	97195345	SOD CHL, IRR SOL 0.9% 1000ML (16/CS) BTL BBRAUN	1	1
TRANQUILITY LASER CENTER	3/31/2017	97255253	SOD CHL, IRR SOL BG 0.9% 1000ML (12/CS)	12	12
TRANQUILITY LASER CENTER	4/5/2017	97563265	SOD CHL, IRR SOL 0.9% 1000ML (14/CS) BAXTIV	1	1
TRANQUILITY LASER CENTER	4/13/2017	98046030	AQUAPHOR, OINT 3.5OZ9BEIRS	4	4
TRANQUILITY LASER CENTER	4/13/2017	98046030	ALOE VERA, GEL 12OZ9FRUIT	5	5
TRANQUILITY LASER CENTER	4/18/2017	1624829	EPINEPHRINE, MDV 1MG/ML 30ML9INMED	2	2
TRANQUILITY LASER CENTER	4/18/2017	1624829	SOD CHL, IVSOL PVC DEHP FREE 0.9% 500ML (24/CS) BBRAUN	1	1
TRANQUILITY LASER CENTER	4/18/2017	1624829	SODIUM CHLORIDE, FTV PF 0.9% 50ML (25/PK) HOSPRA	10	10
TRANQUILITY LASER CENTER	4/26/2017	2117934	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	2	2
TRANQUILITY LASER CENTER	4/26/2017	2117934	SOD CHL, IVSOL 0.9% 1000ML (12/CS)	2	2
TRANQUILITY LASER CENTER	5/3/2017	2595266	AQUAPHOR ORIG, OINT 14OZ9BEIRS	1	1
TRANQUILITY LASER CENTER	5/3/2017	2595266	LUBRICATING JELLY, FOIL PKT STR 3GM (144/BX 6BX/CS MGM119	1	1
TRANQUILITY LASER CENTER	5/9/2017	2946703	EPINEPHRINE, MDV 1MG/ML 30ML9INMED	1	1
TRANQUILITY LASER CENTER	5/10/2017	2973663	EPINEPHRINE, MDV 1MG/ML 30ML9INMED	2	2
TRANQUILITY LASER CENTER	5/10/2017	3033650	SOD CHL, IRR SOL 0.9% 1000ML (16/CS) BTL BBRAUN	-1	-1
TRANQUILITY LASER CENTER	5/17/2017	3391434	LAC RING, IVSOL 1000ML (14/CS)BAXTIV	1	1
TRANQUILITY LASER CENTER	5/18/2017	3486773	LAC RING, IVSOL 1000ML (14/CS)BAXTIV	6	6
TRANQUILITY LASER CENTER	6/5/2017	4483436	EPINEPHRINE, MDV 1MG/ML 30ML9INMED	2	2
TRANQUILITY LASER CENTER	7/21/2017	7323830	HYLENEX, SDV 150U/1ML 1ML (4/CT) 9HZYMI	2	2
TRANQUILITY LASER CENTER	9/11/2017	10448433	ALOE VERA, GEL CLR 20OZ9FRUIT	3	3
TRANQUILITY LASER CENTER	9/14/2017	10681225	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	1	1
TRANQUILITY LASER CENTER	9/18/2017	10880593	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	2	2
TRANQUILITY LASER CENTER	10/20/2017	13118394	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	1	1
TRANQUILITY LASER CENTER	11/6/2017	14145619	SODIUM CHLORIDE BACT, FTV MDV0.9% 30ML (25/PK) HOSPRA	10	10
TRANQUILITY LASER CENTER	11/7/2017	14216402	LIDOCAINE HCL, MDV 1% 50ML (25/PK) HOSPRA	1	1
TRANQUILITY LASER CENTER	11/10/2017	14525576	SOD CHL, IVSOL 0.9% 1000ML (12/CS)	1	1
TRANQUILITY LASER CENTER	11/20/2017	15096430	SODIUM BICARB, SYR 8.4% 1MEQ/ML 50ML (10/PK)	10	10
TRANQUILITY LASER CENTER	12/8/2017	16346232	SOD CHL, IVSOL 0.9% 1000ML (12/CS)	2	2
TRANQUILITY LASER CENTER	12/12/2017	16561978	SODIUM BICARB, SYR 8.4% 1MEQ/ML 50ML (10/PK)	-1	-1
TRANQUILITY LASER CENTER	12/12/2017	16561978	SODIUM BICARB, SYR 8.4% 1MEQ/ML 50ML (10/PK)	-9	-9
TRANQUILITY LASER CENTER	1/3/2018	17892386	LIDOCAINE HCL +EPI, FTV 1% 50ML (25/PK) HOSPRA	2	2
TRANQUILITY LASER CENTER	1/5/2018	18156327	AQUAPHOR, OINT 3.5OZ9BEIRS	4	4
TRANQUILITY LASER CENTER	2/2/2018	20140455	HYLENEX, SDV 150U/1ML 1ML (4/CT) 9HZYMI	3	3
TRANQUILITY LASER CENTER	3/7/2018	22533486	LIDOCAINE HCL, INJ SDV 1% 50MG/5ML (25/CT)	1	1
TRANQUILITY LASER CENTER	4/9/2018	24827222	HYLENEX, SDV 150U/1ML 1ML (4/CT) 9HZYMI	1	1
TRANQUILITY LASER CENTER	4/13/2018	25233928	ADRENALIN, MDV 1MG/ML 30MLRX	1	1
TRANQUILITY LASER CENTER	4/13/2018	25233928	SODIUM BICARB, FTV SDV 8.4% 1MEQ/ML 50ML (25/PK)	1	1
TRANQUILITY LASER CENTER	4/13/2018	25233928	LIDOCAINE HCL, INJ SDV 1% 50MG/5ML (25/CT)	1	1
TRANQUILITY LASER CENTER	4/13/2018	25233928	SOD CHL , IVSOL PVC DEHP FREE0.9% 500ML (10/CS)	1	1
TRANQUILITY LASER CENTER	4/13/2018	25233928	LAC RING+DEX, IVSOL 5% 1000ML(12/CS) BBRAUN	1	1
TRANQUILITY LASER CENTER	5/10/2018	27073778	ADRENALIN, MDV 1MG/ML 30MLRX	1	1
TRANQUILITY LASER CENTER	5/10/2018	27073778	SODIUM BICARB, FTV SDV 8.4% 1MEQ/ML 50ML (25/PK)	5	5
TRANQUILITY LASER CENTER	5/17/2018	27517036	SOD CHL , IVSOL PVC DEHP FREE0.9% 500ML (10/CS)	2	2
TRANQUILITY LASER CENTER	6/4/2018	28667606	SOD CHL , IVSOL PVC DEHP FREE0.9% 500ML (10/CS)	-2	-2
TRANQUILITY LASER CENTER	6/19/2018	29716705	ALOE VERA, GEL 12OZ9FRUIT	2	2
TRANQUILITY LASER CENTER	7/20/2018	31880355	HYLENEX, SDV 150U/1ML 1ML (4/CT) 9HZYMI	1	1
TRANQUILITY LASER CENTER	7/20/2018	31880342	HYLENEX, SDV 150U/1ML 1ML (4/CT) 9HZYMI	1	1
TRANQUILITY LASER CENTER	7/24/2018	32024723	HYLENEX, SDV 150U/1ML 1ML (4/CT) 9HZYMI	2	2
TRANQUILITY LASER CENTER	8/1/2018	32675299	ADRENALIN, MDV 1MG/ML 30MLRX	1	1
TRANQUILITY LASER CENTER	9/10/2018	35476153	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	2	2
TRANQUILITY LASER CENTER	9/11/2018	35575918	LIDOCAINE HCL +EPI, FTV 1% 50ML (25/PK) HOSPRA	4	4
TRANQUILITY LASER CENTER	9/21/2018	36356572	LIDOCAINE HCL +EPI, FTV 1% 50ML (25/PK) HOSPRA	10	10
TRANQUILITY LASER CENTER	12/4/2018	41785660	LIDOCAINE HCL, INJ SDV 1% 50MG/5ML (25/CT)	10	10
TRANQUILITY LASER CENTER	12/17/2018	42846310	ADRENALIN, MDV 1MG/ML 30MLRX	1	1
TRANQUILITY LASER CENTER	12/17/2018	42846310	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	1	1
TRANQUILITY LASER CENTER	12/27/2018	43492925	ALOE VERA, GEL 12OZ9FRUIT	6	6
TRANQUILITY LASER CENTER	1/29/2019	45991609	AQUAPHOR, OINT 3.5OZ9BEIRS	4	4
TRANQUILITY LASER CENTER	3/11/2019	49283207	ADRENALIN, MDV 1MG/ML 30MLRX	2	2
TRANQUILITY LASER CENTER	3/11/2019	49283207	HYLENEX, SDV 150U/1ML 1ML (4/CT) 9HZYMI	3	3
TRANQUILITY LASER CENTER	3/11/2019	49283207	AQUAPHOR, OINT 3.5OZ9BEIRS	3	3

Attachment A - McKesson Corporation sales to Tranquility Laser Center

Customer	Date	Invoice	Drug	Quantity Ordered	Quantity Shipped
TRANQUILITY LASER CENTER	4/2/2019	51018590	EPINEPHRINE, AMP PF 1MG/ML 1ML:1:1000 (10/3X)	4	4
TRANQUILITY LASER CENTER	4/2/2019	51018590	XYLOCAINE, MDV 1% 50ML (25/CT)9APPPH	2	2
TRANQUILITY LASER CENTER	4/2/2019	51018590	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	4	4
TRANQUILITY LASER CENTER	6/18/2019	56982294	SOD CHL, IVSOL PVC DEHP FREE 0.9% 500ML (24/CS) BBRAUN	1	1
TRANQUILITY LASER CENTER	6/18/2019	56982294	LAC RING, IVSOL 1000ML (12/CS)BBRAUN	1	1
TRANQUILITY LASER CENTER	8/6/2019	60772745	SODIUM CHLORIDE BACT, FTV MDV0.9% 30ML (25/PK) HOSPRA	3	3
TRANQUILITY LASER CENTER	9/6/2019	63254338	SODIUM CHLORIDE BACT, FTV MOV0.9% 30ML (25/PK) HOSPRA	5	5

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

January 7, 2022

McKesson Medical-Surgical Inc
520 West Park Suite 520
Leetsdale, PA 15056

Re: File Number:53-21-002498

Dear Applicant/Licensee/Registrant:

Enclosed is an Administrative Complaint (Complaint) charging you with violation(s) of the Public Health Code. **You must respond to this Complaint IN WRITING WITHIN 30 DAYS from the date you received it.** If you fail to do so, the Complaint will be sent to your Board's Disciplinary Subcommittee (DSC) to impose a sanction.

In your written response, please provide information demonstrating your compliance with the Public Health Code or explaining your conduct. Also, please select ONE of the following three options:

- **Request a settlement**. Your written response and a copy of the Complaint will be sent to a Board member who will recommend a proposed settlement.
- **Request a compliance conference**. This is an optional, informal opportunity to meet with me to present evidence or information not contained in your written response for purposes of settlement. Use the enclosed form to request a compliance conference.
- **Request a formal administrative hearing**. At a formal administrative hearing, an administrative law judge will receive evidence, take testimony, and issue a Proposal for Decision as to whether a violation of the Public Health Code has occurred. The hearing record will then be sent to the DSC for consideration in making the final decision.
    - ALL communications should be sent via email to the assigned analyst, whose address is provided below, and BPL-DMS@michigan.gov.
    - If you are unable to communicate via email, you may respond via mail to 611 W. Ottawa St., P.O. Box 30670, Lansing, MI 48909 or fax 517-335-3560. Communication through mail or fax may experience delay.

To exercise any of these options, you must respond **IN WRITING WITHIN 30 DAYS**.

You may obtain legal representation at your expense. If you have any questions, please contact me by email or during normal business hours at the direct line listed below.

Sincerely,
Lorne Carignan
Lorne Carignan
Bureau of Professional Licensing
Email: CarignanL@michigan.gov
Fax: 517-335-3560

Department of Licensing & Regulatory Affairs
Bureau of Professional Licensing
Pharmacy & Drug Monitoring Section
P.O. Box 30670
Lansing, MI 48909-8170
BPL-DMS@michigan.gov

Enclosure

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

MCKESSON MEDICAL-SURGICAL INC,
License Number: 53-06-004689

Respondent.

File Number: 53-21-002498

ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs by Forrest Pasanski, Enforcement Division Director, Bureau of Professional Licensing, complains against Respondent as follows:

1. The Michigan Board of Pharmacy is an administrative agency established by the Public Health Code, MCL 333.1101 *et seq*. Pursuant to MCL 333.17768, the Board's Disciplinary Subcommittee is empowered to discipline licensees for violations of the Public Health Code.

2. Respondent is licensed as a pharmacy wholesaler in the state of Michigan. Respondent has an address of record with Complainant of 520 West Park, Suite 520, in Leetsdale, Pennsylvania.

3. At the time of application for licensure in 2016, Stanton J. McComb was a director and president of Respondent, and Shawn Litchfield was Respondent's facility manager.

4. Respondent's 2021 annual corporate filing with the state of Michigan listed Stanton J. McComb as a director and president of Respondent.

5. On April 20, 2021, the Ohio State Board of Pharmacy executed a Settlement Agreement against Respondent in case number A-2020-459 501-2900 that fined Respondent $1,125.00. The discipline was based on Respondent selling dangerous drugs to an unlicensed distributor in Ohio. The Settlement Agreement was signed by Shawn Litchfield on behalf of Respondent. A copy of the April 20, 2021 Ohio Board Order, marked Exhibit 1, is attached and incorporated.

6. On June 4, 2021, the Ohio State Board of Pharmacy executed a Settlement Agreement against Respondent in case number A-2021-0079 I-2021-0191 that fined Respondent $500.00. The discipline was based on Respondent selling dangerous drugs to an unlicensed distributor in Ohio. The Settlement Agreement was signed by Shawn Litchfield on behalf of Respondent. A copy of the June 4, 2021 Ohio Board Order, marked Exhibit 2, is attached and incorporated.

COUNT I

Respondent's partner, officer, or facility manager or a member of Respondent's board of directors has maintained a financial interest in a wholesale distributor

that has been subject to an administrative penalty by the state of Ohio, in violation of MCL 333.17768(2)(d).

RESPONDENT IS NOTIFIED that, pursuant to MCL 333.16231(8), Respondent has 30 days from the date of receipt of this Complaint to submit a written response to the allegations contained in it. Pursuant to MCL 333.16192(2) of the Code, Respondent is deemed to be in receipt of the complaint three days after the date of mailing listed on the attached proof of service. The written response shall be submitted by email to the Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing to **LARA-BPL-RegulationSection@michigan.gov**. If unable to submit a response by email, Respondent may respond by regular mail to the Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing, P.O. Box 30670, Lansing, MI 48909.

Respondent's failure to submit an answer within 30 days is an admission of the allegations in this Complaint. If Respondent fails to answer, the Department shall transmit this Complaint directly to the Board's Disciplinary Subcommittee to impose a sanction, pursuant to MCL 333.16231(9).

MICHIGAN DEPARTMENT OF
LICENSING AND REGULATORY AFFAIRS

Andrew Hudson signing for

DATED: 12/29/2021

Forrest Pasanski, Director
Enforcement Division,
Bureau of Professional Licensing

LLC

Exhibit 1

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2020-0459
501-2900

McKesson Medical Surgical, Inc.
c/o Shawn Litchfield
520 West Park, Suite 520
Leetsdale, PA 15056

License No. 01-2598200

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and McKesson Medical Surgical, Inc. (McKesson), for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and McKesson are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. McKesson is a licensed Wholesaler Distributor of Dangerous Drug, License No. 01-2598200, which lists Shawn Litchfield, as the Responsible Person.

FACTS

1. The Board initiated an investigation of McKesson Wholesaler Distributor of Dangerous Drugs License No. 01-2598200, related to McKesson's illegal sales of dangerous drugs to an unlicensed entity.

2. On or about March 24, 2021, the Board sent a Notice of Opportunity for Hearing to McKesson which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. McKesson neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated March 24, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. McKesson agrees to pay to the Board a monetary penalty in the amount of $1,125.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. McKesson agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. McKesson agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by McKesson of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to McKesson by the Board and will NOT discharge McKesson from any obligation under the terms of this Agreement.

6. McKesson agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. McKesson understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom McKesson will operate.

9. McKesson waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Shawn Litchfield, on behalf of
McKesson Medical Surgical, Inc., Respondent

04.16.2021
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Jennifer M. Rudell, RPh, President,
State of Ohio Board of Pharmacy

4/20/2021
Date of Signature

Henry G. Appel, Ohio Assistant Attorney General

4/20/2021
Date of Signature

STATE OF OHIO
BOARD OF PHARMACY

NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST LICENSEE

IN THE MATTER OF:

CASE No. A-2020-0459
501-2900

McKesson Medical Surgical, Inc.
c/o Shawn Litchfield
520 West Park, Suite 520
Leetsdale, PA 15056

License No. 01-2598200

March 24, 2021

Dear McKesson Medical Surgical, Inc., and Mr. Shawn Litchfield:

You are hereby notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code the State of Ohio Board of Pharmacy (Board) proposes to take action against your license as a Wholesale Distributor of Dangerous Drugs under authority of Section 4729.56 of the Revised Code.

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code (ORC) and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to renew any registration certificate issued to a wholesale distributor of dangerous drugs (WDDD) pursuant to section 4729.52 of the Revised Code or may impose a monetary penalty of forfeiture not to exceed in the severity any fine designated under the Revised Code for a similar offense or $2,500 if the acts committed have not been classified as an offense by the Revised Code.

2. McKesson Medical Surgical, Inc. (McKesson) has a current WDDD license with the Board under license number 01-2598200, which lists Shawn Litchfield as the Responsible Person.

ALLEGATIONS

1. From on or about April 1, 2019 to on or about February 25, 2020, McKesson, located at 520 West Park, Suite 520, Leetsdale, Pennsylvania, sold dangerous drugs to Advanced Health and Wellness Center of Ohio, LLC, DBA Brecksville Physical Medicine, located at 8930 Brecksville Road, Brecksville, Ohio, as set forth in Attachment A, attached hereto and incorporated as though fully set forth herein. Advanced Health and Wellness Center of Ohio, LLC, DBA Brecksville Physical Medicine, was operating without a Board-issued Terminal Distributor of Dangerous Drugs license at this time.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(B)(1) of the ORC, as effective March 22, 2019, no wholesale distributor shall possess for sale, sell, or distribute, at wholesale, dangerous drugs or investigational drugs or products to any person other than the following: Subject to division (D) of this section, a licensed terminal distributor of dangerous drugs, each sale being a first-degree misdemeanor, each punishable by a maximum fine of $5,000 if committed by an organization.

2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(A)(1) of the ORC, as effective September 29, 2017, Before a licensee identified in division (B)(1)(a) of section 4729.52 of the Revised Code may sell or distribute dangerous drugs at wholesale to any person, except as provided in division (A)(2) of this section, the licensee shall query the roster established pursuant to section 4729.59 of the Revised Code to determine whether the purchaser is a licensed terminal distributor of dangerous drugs, each punishable by a maximum fine of $2,500 if committed by an organization.

3. Such conduct as set forth in paragraph (1)(v) of the Allegations Section, if proven, each constitutes a violation of Rule 4729:6-3-04 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of $2,500: Before a drug distributor may sell or distribute dangerous drugs to any person in this state, except as provided in paragraph (C) of this rule, the distributor shall conduct a documented query of a roster maintained by the Board to determine if the purchaser is licensed as either:

    a. A terminal distributor of dangerous drugs...For a limited terminal distributor of dangerous drugs license, a drug distributor shall also review a current version of the licensee's drug list to ensure the purchaser is authorized to possess the drug ordered, OAC Rule 4729:6-3-04(B)(1); and/or

    b. A distributor of dangerous drugs, OAC Rule 4729:6-3-04(B)(2).

4. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of Section 4729.56 of the ORC, effective September 29, 2017, each violation punishable by a maximum fine of $2,500 if committed by an organization:

    a. Violating any federal, state, or local drug law; any provision of chapter 4729. or Chapter 2925., 3715., or 3719. of the Revised Code; or any rule of the Board, ORC Section 4729.56(A)(2)(b); and/or

    b. Failing to satisfy the qualifications for registration under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the registration is granted or renewed, ORC Section 4729.56(A)(2)(d); and/or

    c. Any other cause for which the board may impose sanctions as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.56(A)(2)(g).

5. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:6-4-01 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of $2,500 if committed by an organization:

    a. Violating any rule of the Board, OAC Rule 4729:6-4-01(B)(2); and/or

    b. Failing to satisfy the qualifications for licensure under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the license is granted or renewed, OAC Rule 4729:6-4-01(B)(5); and/or

    c. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:6-4-01(B)(3).

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov **(please note faxes will not be accepted)**. **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE MAILING DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a corporation, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the mailing of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY

Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Director

SWS/alg/pae

CMRRR: 7019 2970 0001 6895 7650

Enclosure: Attachment A

Attachment A - Purchases made by Advanced Health and Wellness Center of Ohio, LLC, DBA Brecksville Physical Medicine						
Wholesaler	Date	Invoice Number	Medication	Package Size	Quantity	
McKesson	4/5/2019	51303010	Triamcinolone 40mg/10ml	10ml	3	
McKesson	7/26/2019	59966228	Triamcinolone 40mg/10ml	10ml	3	
McKesson	8/19/2019	61785869	Ketorolac 60mg/2ml	25x2ml	3	
McKesson	8/19/2019	61785869	Triamcinolone 40mg/10ml	10ml	3	
McKesson	9/19/2019	64442763	Dexamethasone 4mg/ml	30ml	7	
McKesson	9/19/2019	64442763	Triamcinolone 40mg/10ml	10ml	3	
McKesson	9/19/2019	64442763	Lidocaine 2%	50ml	2	
McKesson	10/15/2019	66003719	Cyanocobalamin 1000mcg/ml	30ml	4	
McKesson	11/5/2019	68358649	Triamcinolone 40mg/10ml	10ml	3	
McKesson	12/10/2019	71280717	Triamcinolone 40mg/10ml	10ml	3	
McKesson	12/10/2019	71280717	Ketorolac 60mg/2ml	25x2ml	3	
McKesson	2/4/2020	75992188	Triamcinolone 40mg/10ml	10ml	3	

Exhibit 2

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2021-0079
I-2021-0191

McKesson Medical-Surgical, Inc.
c/o Shawn Litchfield
520 West Park, Suite 520
Leetsdale, PA 15056

License No. 01-2598200

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and McKesson Medical-Surgical, Inc. (McKesson) for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and McKesson are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. McKesson is a licensed Wholesaler Distributor of Dangerous Drug, License No. 01-2598200, which lists Shawn Litchfield, as the Responsible Person.

FACTS

1. The Board initiated an investigation of McKesson Wholesaler Distributor of Dangerous Drugs License No. 01-2598200, related to McKesson's illegal sales of dangerous drugs to an unlicensed entity.

2. On or about May 4, 2021, the Board sent a Notice of Opportunity for Hearing to McKesson which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. McKesson neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated May 4, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. McKesson agrees to pay to the Board a monetary penalty in the amount of $500.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. McKesson agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. McKesson agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by McKesson of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to McKesson by the Board and will NOT discharge McKesson from any obligation under the terms of this Agreement.

6. McKesson agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. McKesson understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom McKesson will operate.

9. McKesson waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Shawn Litchfield, on behalf of,
McKesson Medical-Surgical, Inc.,
Respondent

05.27.2021
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Jennifer M. Rudell, RPh, President,
State of Ohio Board of Pharmacy

6/4/2021
Date of Signature

Henry G. Appel, Ohio Assistant Attorney General

6/4/2021
Date of Signature

STATE OF OHIO
BOARD OF PHARMACY

NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST LICENSEE

IN THE MATTER OF:

CASE No. A-2021-0079
I-2021-0191

McKesson Medical-Surgical, Inc.
c/o Shawn Litchfield
520 West Park, Suite 520
Leetsdale, PA 15056

License No. 01-2598200

May 20, 2021

Dear McKesson Medical-Surgical, Inc. and Shawn Litchfield:

You are hereby notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code the State of Ohio Board of Pharmacy (Board) proposes to take action against your license as a Wholesale Distributor of Dangerous Drugs under authority of Section 4729.56 of the Revised Code.

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code (ORC) and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to renew any registration certificate issued to a wholesale distributor of dangerous drugs (WDDD) pursuant to section 4729.52 of the Revised Code or may impose a monetary penalty of forfeiture not to exceed in the severity any fine designated under the Revised Code for a similar offense or $2,500 if the acts committed have not been classified as an offense by the Revised Code.

2. McKesson Corporation DBA McKesson Drug Company (McKesson) has a current WDDD license with the Board under license number 01-2598200, which lists Shawn Litchfield as the Responsible Person.

ALLEGATIONS

1. From on or about September 10, 2019 to on or about October 7, 2020, McKesson, located at 520 West Park, Suite 520, Leetsdale, Pennsylvania, sold dangerous drugs to Patriot Housecall, Inc. located at 986 Tibbetts Wick Road, Girard, Ohio, as set forth in Attachment A, attached hereto and incorporated as though fully set forth herein. Patriot Housecall, Inc. was operating without a Board-Issued Terminal Distributor of Dangerous Drugs license at this time.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(B)(1) of the ORC, as effective March 22, 2019, no wholesale distributor shall possess for sale, sell, or distribute, at wholesale, dangerous drugs or investigational drugs or products to any person other than the following: Subject to division (D) of this section, a licensed terminal distributor of dangerous drugs, each sale being a first-degree misdemeanor, each punishable by a maximum fine of $5,000 if committed by an organization.

2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(A)(1) of the ORC, as effective September 29, 2017, Before a licensee identified in division (B)(1)(a) of section 4729.52 of the Revised Code may sell or distribute dangerous drugs at wholesale to any person, except as provided in division (A)(2) of this section, the licensee shall query the roster established pursuant to section 4729.59 of the Revised Code to determine whether the purchaser is a licensed terminal distributor of dangerous drugs, each punishable by a maximum fine of $2,500 if committed by an organization.

3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Rule 4729:6-3-04 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of $2,500: Before a drug distributor may sell or distribute dangerous drugs to any person in this state, except as provided in paragraph (C) of this rule, the distributor shall conduct a documented query of a roster maintained by the Board to determine if the purchaser is licensed as either:

    a. A terminal distributor of dangerous drugs...For a limited terminal distributor of dangerous drugs license, a drug distributor shall also review a current version of the licensee's drug list to ensure the purchaser is authorized to possess the drug ordered, OAC Rule 4729:6-3-04(B)(1); and/or

    b. A distributor of dangerous drugs, OAC Rule 4729:6-3-04(B)(2).

4. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of Section 4729.56 of the ORC, effective September 29, 2017, each violation punishable by a maximum fine of $2,500 if committed by an organization:

    c. Violating any federal, state, or local drug law; any provision of chapter 4729. or Chapter 2925., 3715., or 3719. of the Revised Code; or any rule of the Board, ORC Section 4729.56(A)(2)(b); and/or

    d. Failing to satisfy the qualifications for registration under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the registration is granted or renewed, ORC Section 4729.56(A)(2)(d); and/or

    e. Any other cause for which the board may impose sanctions as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.56(A)(2)(g).

5. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:6-4-01 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of $2,500 if committed by an organization:

    a. Violating any rule of the Board, OAC Rule 4729:6-4-01(B)(2); and/or

    b. Failing to satisfy the qualifications for licensure under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the license is granted or renewed, OAC Rule 4729:6-4-01(B)(5); and/or

    c. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:6-4-01(B)(3).

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov **(please note faxes will not be accepted). YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE MAILING DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a corporation, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the mailing of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY

Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Director

SWS/alg/pae

CMRRR: 7020 1810 0002 1633 8132

Enclosure: Attachment A

Attachment A - Purchases made by Patriot Housecall, Inc.					
Wholesaler	Date	Invoice Number	Medication	Package Size	Quantity
McKesson Corporation	9/10/2019	63598686	Pneumovax Syr 0.5ml	10	1
McKesson Corporation	9/18/2019	64324842	Flucelvax Quad syr 0.5ml	10	13
McKesson Corporation	10/21/2019	67071751	Flucelvax Quad syr 0.5ml	10	3
McKesson Corporation	2/13/2020	76929887	PPD Aplisol VL 5TU/	50	3
McKesson Corporation	10/6/2020	14148176	Flucelvax Quad syr 0.5ml	10	4
McKesson Corporation	10/7/2020	14211496	Flucelvax Quad syr 0.5ml	10	7

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

COMPLIANCE CONFERENCE REQUEST

Please note: If you do not desire a compliance conference in person or by telephone, completion of this form is NOT required.

Even if you complete and return this form, you still MUST submit a WRITTEN response to the Administrative Complaint.

Name: _____ File Number: _____

Address: _____

_____

Preferred Contact Number(s): _____ Best time/day to call _____

_____ _____

These days are preferable for me: (Please check all that apply)

☐M ☐T ☐W ☐Th ☐F

I prefer:

☐ AM
☐ PM

I will appear:

~~☐ In-person in Lansing~~
☐ Via Telephone

Additional comments regarding available dates:

_____

_____

Return address:

Lorne Carignan
Carignanl@michigan.gov
(Email is strongly preferred)

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing
Pharmacy & Drug Monitoring Section
P.O. Box 30670
Lansing, MI 48909-8170
Fax: (517) 335-3560

BEFORE THE GEORGIA STATE BOARD OF PHARMACY
STATE OF GEORGIA

IN THE MATTER OF:	)	
	)	
MCKESSON MEDICAL-SURGICAL, INC.,	)	**DOCKET NO.**
Applicant No. 1921064	)	
	)	
Applicant.	)	

GEORGIA STATE BOARD OF PHARMACY
MAY 29, 2024
DOCKET NO. 2024-0064

PUBLIC CONSENT AGREEMENT

By agreement of the Georgia State Board of Pharmacy ("Board") and McKesson Medical-Surgical, Inc., ("Applicant"), the following disposition of this matter is entered pursuant to the provisions of O.C.G.A. T. 26, Ch. 4, and T. 43, Ch. 1.

FINDINGS OF FACT

1.

Applicant was previously licensed under License No. PHW11004857 as a wholesaler pharmacy called Medical Specialties Distributors, LLC. Applicant's previous license was issued on May 1, 2020, and expired on June 30, 2023.

2.

On or about August 31, 2020, Applicant completed an intracompany change of ownership and change of name, before receiving approval from the Board.

3.

On or about April 22, 2021, Applicant submitted an application for a change of ownership and name to the Board.

4.

Applicant notified the Georgia Drugs and Narcotics Agency ("GDNA") that between August 31, 2020, and April 12, 2021, Applicant had made thirty-four (34) shipments of devices into the State of Georgia.

5.

Applicant admits the above findings of fact, and waives any further findings of fact with respect to the above-styled matter.

CONCLUSIONS OF LAW

Under O.C.G.A. § 26-4-40, the Georgia State Board of Pharmacy is authorized to deny Applicant's application for licensure due to changing ownership without Board approval. Applicant waives any further conclusions of law with respect to this matter.

ORDER

The Board having considered the particular facts and circumstances of this case, it is hereby ORDERED, and Applicant hereby AGREES, that Applicant's new license to operate as a pharmacy in Georgia shall be granted under the following terms and conditions:

1.

Applicant shall submit to the Board a fine in the amount of **One-Thousand Seven-Hundred Dollars ($1,700.00)** for the violation of changing ownership before receiving approval from the Board. Such fine shall be payable within sixty (60) days from the effective date of this Public Consent Agreement. Payment shall be in the form of a cashier's check or money order made payable to the Georgia State Board of Pharmacy and sent to: Georgia State Board of Pharmacy, Attention: Executive Director, 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, Georgia 30334. Applicant's failure to pay such fine by the sixtieth day shall subject Applicant to further disciplinary action, including revocation of Applicant's Retail Pharmacy license in Georgia.

2.

Approval of this Public Consent Agreement by the Georgia State Board of Pharmacy shall in no way be construed as condoning Applicant's conduct, and shall not be construed as a waiver of any of the lawful rights possessed by the Board. This Public Consent Agreement shall not become effective until approved and docketed by the Georgia State Board of Pharmacy.

3.

Agent of Applicant, McKesson Medical-Surgical, Inc., acknowledges that Agent of Applicant has read this Public Consent Agreement and understands its contents. Applicant understands that Applicant has a right to an appearance in this matter, and Applicant freely, knowingly, and voluntarily waives such right by entering into this Public Consent Agreement. Applicant understands that this Public Consent Agreement will not become effective until approved and docketed by the Georgia State Board of Pharmacy. Applicant further understands and agrees that the Board shall have the authority to review all relevant evidence in considering this Public Consent Agreement. Applicant further understands that this Public Consent Agreement once approved, shall constitute a public record of the Board. Applicant further understands that if this Public Consent Agreement is not approved, it shall not constitute an admission against interest in this proceeding or prejudice the ability of the Board to adjudicate this matter. Applicant consents to the terms and sanctions contained herein.

(signatures appear on the following page)

Approved by the Board, this 29 day of May, 2024.

GEORGIA STATE BOARD OF PHARMACY

BY: _____
CHARLES E. PAGE, R.Ph.
President

ATTEST: _____
J. CLINTON JOINER, II
Executive Director

CONSENTED TO:

_____
AGENT
Printed Name: Vicki McKee
ON BEHALF OF
Applicant
MCKESSON MEDICAL-SURGICAL, INC.

AS TO SIGNATURE OF AGENT ON BEHALF OF APPLICANT
MCKESSON MEDICAL-SURGICAL, INC.
Sworn to and subscribed before me
this 9th day of April, 2024.
_____
NOTARY PUBLIC
My commission expires: 11/30/2026

Barbara K Quevillon
Commonwealth of Virginia
Notary Public
Commission No. 8013295
My Commission Expires 11/30/2026

BEFORE THE BOARD OF PHARMACY

STATE OF IDAHO

In the Matter of the Registration of: McKESSON MEDICAL SURGICAL, INC., License/Registration Nos. W2699, W65254 Respondent.	Case Nos. BOP-21-092, BOP-22-067 **STIPULATION AND CONSENT ORDER**

The Idaho Board of Pharmacy, ("Board") has received information that constitutes sufficient grounds for the initiation of an administrative action against McKesson Medical Surgical, Inc. ("Respondent"), and the parties mutually agree to settle the matter in an expeditious manner in lieu of administrative hearings before the Board. Therefore, the parties STIPULATE AND AGREE as follows:

I.
STIPULATED FACTS AND LAW

1. The Board regulates the practice of pharmacy in the State of Idaho in accordance with Title 54, Chapter 17, of the Idaho Code, (the Idaho Pharmacy Act), the regulating provisions of Title 37, Chapter 27 (the Uniform Controlled Substances Act), and the Board's rules promulgated as IDAPA 24.36.01, *et seq.* (formerly IDAPA 27.01.01, *et seq.*).

2. Respondent operates multiple facilities that operate into Idaho and holds a registration from the Board for each of those facilities, accordingly.

3. In February 2003, the Board first issued Idaho Wholesale Distributor Registration No. W2699, ("Chino Registration") to Respondent for a facility located in Chino, California to operate as a Wholesaler and distribute prescription drugs into the State of Idaho.

4. On May 23, 2018, the Board first issued Idaho Wholesale Distributor Registration No. W48214, to Respondent for a facility located in Roseville, California to operate as a Wholesaler and distribute prescription drugs into the State of Idaho. That registration expired on December 31, 2020. After that registration expired and was canceled, the Board subsequently reinstated Respondent's registration for the Roseville facility on February 3, 2022, and issued Registration No. W65254 ("Roseville Registration").

5. Respondent's registrations are subject to the provisions of the Idaho Pharmacy Act, Uniform Controlled Substances Act, and the Board's Administrative Rules.

FACTUAL BACKGROUND

Case No. 21-092 – CHINO REGISTRATION

6. On February 14, 2020, Melissa Baca submitted a change in designated representative application and mailed her fingerprints to the Board.

7. On February 20, 2020, the Board sent a deficiency notice to Ms. Baca indicating that Ms. Baca needed to submit a residential history and business interest history to complete her application. Ms. Baca represents she did not receive this letter.

8. On March 3, 2020, Ms. Baca, again, uploaded the designated representative oath, designated representative photograph, government identification, and privacy statement.

9. On August 7, 2020, the Board sent a notice to Ms. Baca indicating that the designated representative application had expired, and that a new application would have to be submitted. Ms. Baca represents she did not receive this letter.

10. On December 7, 2020, Respondent submitted a renewal application for the Chino Registration.

11. On December 20, 2020, the Chino Registration was renewed by the Board. Respondent's information identified Melissa Baca as the designated representative on the Board's online licensing portal along with a registration number, although no expiration or issue date was noted.

12. On January 8, 2021, the Board sent a notice to Respondent at its address of record indicating that it had been operating without a designated representative and that a new designated representative application would have to be submitted. Respondent represents it did not receive this letter.

13. On April 1, 2021, the Board's investigator sent a notice to Respondent at its address of record in Chino, California, indicating that it had been operating without a designated representative and that a new designated representative application would have to be submitted and that Respondent could be subject to discipline for operating without a registered designated representative. The notice also requested a response and documentation of all shipments made by Respondent into Idaho since February 14, 2020. Respondent represents it did not receive this letter and does not deny that it did not respond.

14. On April 26, 2021, Ms. Baca asserts she received a letter through email dated May 7, 2020, from the Board informing her of deficiencies in her prior designated representative application. Ms. Baca forwarded the letter to Elaine Stutman, McKesson licensing specialist. On April 26, Ms. Stutman requested copies of any deficiency letters sent by the Board and represented Respondent had not previously received any deficiency letters.

15. On April 27, 2021, Wendy Muir, Board licensing specialist, responded to Ms. Stutman via email that Ms. Baca's designated representative application had expired and that a new application was required.

16. On May 3, 2021, Ms. Baca submitted a new application for a designated representative.

17. On May 4, 2021, the Board sent a deficiency letter to Ms. Baca indicating that Ms. Baca needed to submit fingerprints and an updated government identification as it was expired. Ms. Baca received this letter.

18. On May 18, 2021, Ms. Stutman informed the Board via email that Ms. Baca's current government identification had been uploaded to the Board licensing portal and the fingerprints would be mailed on May 19, 2021. The Board's licensing portal does not contain a record that the current identification was uploaded. The fingerprints were received by the Board on May 21, 2023.

19. On June 25, 2021, the Board's investigator followed up on the April 1, 2021 letter and emailed another representative of Respondent again requesting a list of all shipments made into Idaho from February 14, 2020, to present. On June 28, 2021, Respondent provided the requested information to the Board.

20. On September 28, 2021, Board counsel advised Respondent counsel that the Board did not receive the May 18, 2021 government identification upload.

21. On October 1, 2021, Ms. Baca's current government identification was uploaded to the Board licensing portal.

22. On October 26, 2021, the Chino Registration was renewed by the Board with Melissa Baca identified as the designated representative on the Board's online licensing portal.

23. On October 27, 2021, Respondent received notice that Ms. Baca's designated representative registration was complete and approved.

24. On December 14, 2022, the Chino Registration was renewed by the Board with Melissa Baca identified as the designated representative on the Board's online licensing portal.

25. The parties acknowledge the COVID-19 pandemic led to self-isolate and stay-at-home orders around the globe. Both Idaho and California were subject to various stay-at-home orders starting in March 2020.

26. IDAPA 24.36.01.200 states that a license or registration will only be renewed once the applicant "has satisfied the requirements of applicable statutes, and any additional criteria specified by these rules."

27. Respondent represents the Chino Registration renewals with Ms. Baca listed as designated representative on the Board licensing portal and its assertion that it did not receive deficiency letters led Respondent to understand there were no issues.

CASE #22-067 – ROSEVILLE REGISTRATION

28. On and before December 31, 2020, Respondent's contact information on file with the Board for Registration No. W48214 had the email address of gene.moody@mckesson.com.

29. On December 23, 2020, Respondent submitted a timely application to renew its registration for the Roseville facility. Respondent's renewal application indicated that Respondent had been subject to discipline by a regulatory agency relating to wholesale or retail prescription drug distribution or distribution of a controlled substance. No supporting or explanatory documentation was submitted regarding the disciplinary action.

30. On the same day, December 23, 2020, the Board sent notice that documentation was needed regarding the disciplinary action disclosed on the application. The notification stated that the renewal could not be processed or completed until that documentation had been received.

31. On December 28, 2020, the Board sent a final renewal notice. The final renewal notice stated Respondent's registration would expire after December 31, 2020. It also contained instructions about how to renew a registration, the required documentation, and how to verify the status of a registration. Respondent represents it did not receive this notice.

32. Respondent did not timely complete its renewal application by supplying the required information. Registration No. W48214 expired as of January 1, 2021.

33. On January 4, 2021, Respondent was sent an expiration notice. The expiration notice stated that Respondent was no longer registered with the State of Idaho and that it could renew its registration until January 30, 2021. It also instructed Respondent to cease and desist its activities in Idaho. Respondent represents it did not receive this notice.

34. On November 9, 2021, Respondent attempted to renew its registration and noted the expired status on the Board website. Respondent emailed the Board and was advised to submit a reinstatement application.

35. On the same day, November 9, 2021, Respondent submitted its reinstatement application.

36. On November 30, 2021, the Board sent a deficiency notice with a list of the information and fees necessary to complete the application.

37. In or around January 2022, Respondent provided the Board with the requested information to complete its reinstatement application.

38. On February 3, 2022, the Board issued Registration No. W65254 for the Roseville facility.

39. The Roseville facility was not registered in Idaho between January 1, 2021, and February 3, 2022. During that time, Respondent shipped prescriptions from that facility into Idaho.

40. On January 24, 2022, the Division of Occupational and Professional Licenses (the "Division") sent a letter to Respondent by regular and certified mail notifying it that an investigation was being conducted into whether it had engaged in the practice of pharmacy in Idaho without a registration (the "investigatory letter"). The investigatory letter requested a response to the allegation and documentation about shipments made into Idaho from January 1, 2021 to the date of the letter. The letter requested a response by February 11, 2022. The letter also notified Respondent of its obligation under the Board's administrative rules to fully cooperate with the investigation.

41. The investigatory letter was delivered to the Roseville facility on February 3, 2022. Respondent represents it did not receive this letter.

42. Respondent did not respond or provide the requested information to the Division.

43. Respondent acknowledges that the Board alleges certain violations of the following statutes and rules governing the practice of pharmacy in Idaho:

a. **Failure to provide information for a designated representative:** Idaho Code § 54-1753(g),(h) (2020) (a wholesaler must provide to the Board the name of its designated representative for the facility together with the person's residential history, date and place of birth, employment history, administrative disciplinary history, civil injunctive history, business interests in pharmaceutical-related businesses, felony criminal history, and a photograph.)[1];

[1] On July 1, 2021, the Idaho Pharmacy Act was amended and the qualifications for the designated representative were changed to the person being physically present and actively

b. **Operating without a registration**: Idaho Code § 54-1732(1) (no drug outlet shall be operated until a certificate of registration has been issued to said facility by the Board); IDAPA 24.36.01.230 (a certificate of registration is required for drug outlets prior to doing business in or into Idaho); and

c. **Failure to fully cooperate with an investigation:** IDAPA 24.36.01.503.05 (licensees must fully cooperate with Board investigations).

44. If proven, violations of these laws and rules would constitute grounds for disciplinary action against Respondent's registration to practice pharmacy in Idaho. I.C.§§ 54-1726(1)(f); 54-1728(1)(f).

45. The Board and Respondent acknowledge sufficient mitigating factors exist to warrant resolution via this Stipulation and Consent Order.

II.
WAIVER OF PROCEDURAL RIGHTS

In entering into this Stipulation and Consent Order ("Stipulation"), Respondent or Respondent's legally authorized representative acknowledges the following:

46. The parties mutually agree to resolve this matter in an expeditious manner to avoid the delay, uncertainty, inconvenience and expense of litigation and agree to voluntarily enter into this Stipulation for the purpose of responding to and addressing these allegations.

designated representative were changed to the person being physically present and actively involved in the daily operations of the wholesaler and passing a criminal history check. The requirements to submit government identification, fingerprints, an oath, photograph and privacy statement were all removed. Idaho Code § 54-1729A(2),(3) (2021).

47. Respondent's representative has read the above Stipulation fully and has had the opportunity to discuss it with legal counsel. Respondent understands and acknowledges that by its terms, Respondent is waiving certain rights provided under Idaho law.

48. Respondent understands that Respondent has the right to a full and complete hearing; the right to confront and cross-examine witnesses; the right to testify, present evidence, and call witnesses; the right to reconsideration of the Board's orders; the right to judicial review of the Board's orders; and all rights accorded by the Administrative Procedure Act of the State of Idaho and the laws and rules governing the practice of pharmacy in the State of Idaho. Respondent hereby freely and voluntarily waives these rights in order to enter into this Stipulation as a resolution of the pending allegations.

49. Respondent understands that in signing this Stipulation, Respondent is enabling the Board to impose the terms set forth in this Stipulation upon Respondent's registrations without further process. Moreover, the Board and its agents, without further notice or action otherwise required by Idaho law or administrative rules, is authorized to enforce all terms of this Stipulation.

III.
STIPULATED TERMS

50. Respondent acknowledges and agrees that the following terms imposed for the allegations set forth herein are reasonable under the circumstances.

51. Respondent shall reimburse investigative costs of the Board in the amount of $5,200.00 within sixty (60) days after the Board approves and enters the Order incorporating this Stipulation.

52. Respondent shall pay a fine in the amount of $6,000.00. This fine becomes due within sixty (60) days after the Board approves and enters the Order incorporating this Stipulation.

53. Respondent's violation of any of the terms of this Stipulation may warrant further Board action. The Board, therefore, retains jurisdiction over this proceeding until all matters set forth in this Stipulation are resolved.

54. This Stipulation is the informal resolution of a contested case and is a public record.

55. The terms and conditions agreed upon by the parties set forth in this Stipulation will be completed upon the date that payment in full is received by the Board.

56. This Stipulation does not constitute an admission by Respondent.

57. A faxed or scanned executed copy of this Stipulation shall be sufficient and the same as the original signed document.

58. This Stipulation contains the entire agreement between the parties, and Respondent is not relying on any other agreement or representations of any kind, verbal or otherwise.

IV.
PRESENTATION OF STIPULATION TO BOARD

59. The Board's prosecutor or another Board agent shall present this Stipulation to the Board with a recommendation for approval so it may consider whether to approve or reject it.

60. The Board may accept, modify with Respondent's approval, or reject this Stipulation. If the Board rejects this Stipulation, a formal Complaint may be filed against Respondent with the Board. In the event this Stipulation is rejected and a formal Complaint is

filed, Respondent waives any potential right to challenge the Board's impartiality to hear the allegations in the Complaint based on the Board's consideration and rejection of this Stipulation. Respondent does not waive any other rights regarding challenges to Board members.

61. If the Board rejects this Stipulation, with the exception of Respondent's waiver set forth in the preceding paragraph, this Stipulation shall be regarded as null and void, and admissions in this Stipulation and negotiations preceding the signing of this Stipulation will not be admissible at any subsequent disciplinary hearing. Additionally, and with the exception of Respondent's waiver set forth in the preceding paragraph, this Stipulation shall not become effective until it has been approved by a majority of the Board and a Board member signs the attached Order.

VI.
ACKNOWLEDGMENT

I have read, understood, and voluntarily enter into the attached Stipulation in its entirety and have had the opportunity to discuss it with legal counsel prior to execution this Stipulation. I have the authority to execute this Stipulation and bind the licensee with regard to the Stipulation. I hereby declare and represent that I relied wholly upon my own judgment, belief and knowledge of the matters set forth herein and/or the advice of my counsel, if any, and execute this document without any reliance upon any statement or representation of the Board or its members, representatives, or employees. I understand that, by its terms, I am waiving certain rights accorded me under Idaho law. I understand that the Board will issue an Order on this Stipulation according to the aforementioned terms, and I hereby agree to the above Stipulation for settlement.

DATED this 18 day of August, 2024.

Sunita Upadhyaya

on behalf of
McKesson Medical Surgical, Inc.

ORDER

Pursuant to Idaho Code § 54-1728, the Idaho Board of Pharmacy hereby accepts the terms and conditions of the foregoing Stipulation and Consent Order and incorporates them into this Order; and it is hereby ORDERED that Respondent comply with such terms and conditions.

DATED this 12th day of September, 2024.

Board Chair

CERTIFICATE OF SERVICE

I hereby certify that on the 12th day of September, 2024, I caused to be served, by the method(s) indicated, a true and correct copy of the foregoing upon:

Brenda M. Shafer Quarles & Brady LLP	___ ___ X	U.S. Mail Certified Mail, Return Receipt Requested Email: brenda.shafer@quarles.com Fax Transmission
Joan E. Callahan Naylor & Hales, P.C. 950 W. Bannock St., Ste. 610 Boise, ID 83702	___ ___ X ___	U.S. Mail Hand Delivered Email: joan@naylorhales.com Fax Transmission: 208-383-9516

Division of Occupational and Professional Licenses

IN THE MATTER OF	*	**BEFORE THE**
McKESSON MEDICAL-SURGICAL, INC.	*	**MARYLAND STATE**
	*	**BOARD OF PHARMACY**
Wholesale Distributor Applicant	*	**Case No. 25-033**

* * * * * * * * * * *

PRE-CHARGE CONSENT ORDER

Background

The Maryland State Board of Pharmacy (the "Board") received a self-report from McKesson Medical-Surgical, Inc., (the "McKesson") on July 29, 2024, disclosing that McKesson had distributed four (4) prescription products into Maryland without an appropriate permit. The Board subsequently opened an investigation and received documents indicating that McKesson had distributed approximately 400 prescription orders into Maryland without a Maryland wholesale distributor's permit. The Board is currently processing an application submitted by McKesson for a wholesale distributor's permit.

In lieu of instituting formal proceedings against McKesson in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 *et seq.*, the Board and McKesson have agreed to resolve this matter as set forth in this Pre-Charge Consent Order.

FINDINGS OF FACT

1. McKesson Medical-Surgical, Inc., is a wholesale distributor located and licensed in Suwanee, Georgia.
2. On or about July 29, 2024, McKesson self-reported to the Board that is distributed four (4) prescription products into Maryland without a wholesale distributor's

permit. McKesson discovered the error with respect to the four (4) prescription products while it was undergoing an inspection conducted by the National Association of Boards of Pharmacy (NABP).

3. The Board subsequently opened an investigation and obtained information from McKesson indicating that it had distributed approximately 400 prescription products into Maryland between September 2019 and September 2024 without a Maryland wholesale distributor's permit.
4. McKesson asserts that the prescription products at issue were miscoded as non-prescription in McKesson's system and thus inadvertently shipped. McKesson further asserts that product classifications have been updated and additional checks have been implemented to ensure accuracy of product information.
5. A wholesale distributor located outside of Maryland must hold a wholesale distributor permit issued by the Board before it may distribute any prescription drugs or prescription devices into Maryland.
6. McKesson has submitted to the Board an application for a wholesale distributor permit, which is pending the resolution of the matter herein.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that McKesson Medical-Surgical, Inc., is subject to discipline in accordance with Md. Code Ann., Health Occ. §§ 12-601, 12-6C-03 and 12-6C-11.

ORDER

Based upon an affirmative vote of the Board under the authority of Md. Code Ann., Health Occ. § 12-101, *et seq.*, it this 19th day of March, 2025, hereby,

ORDERED that McKesson shall pay a FINE in the amount of FIVE THOUSAND DOLLARS ($5,000.00), payable to the Maryland Board of Pharmacy within thirty (30) days of the date of this Order, and mailed to:

Wells Fargo Bank
Attn: State of MD - Board of Pharmacy
Lockbox 2051
401 Market Street
Philadelphia, PA 19106

NOTE: Please include the case number, 25-033, on your check or money order in order to ensure proper assignment to this case; and be it further,

ORDERED that upon payment of the fine assessed above, the Board shall process the application submitted by McKesson for a wholesale distributor's permit and shall issue such permit provided that all application requirements are otherwise satisfied; and be it further,

ORDERED that in the event that McKesson violates any of the terms above, the Board, after notice and an opportunity for a hearing, and a determination of a violation, may impose any sanction it deems appropriate, including the imposition of further fines in accordance with Health Occ. §§ 12-601 and 12-6C-11; and be it further,

ORDERED that this is a formal order and as such is a public document pursuant to the Maryland Public Information Act, Md. Code Ann., General Provisions Art. § 4-101, *et seq.*

3-19-25
Date

Deena Speights-Napata, M.A.
Executive Director for:

Kristopher Rusinko, Pharm.D.,
Board President

CONSENT

1. McKesson Medical-Surgical, Inc., acknowledges the validity of this Pre-Charge Consent Order as if it were made after a hearing in which it would have had the right to counsel, to confront witnesses, and to all other substantial procedural protections provided by law.

2. McKesson Medical-Surgical, Inc., acknowledges that, by entering into this Pre-Charge Consent Order, it is waiving its right to appeal any adverse ruling of the Board that might have followed such an evidentiary hearing.

3. McKesson Medical-Surgical, Inc., acknowledges the legal authority and jurisdiction of the Board to enter and enforce this Pre-Charge Consent Order.

4. McKesson Medical-Surgical, Inc., signs this Pre-Charge Consent Order freely and voluntarily, after having had the opportunity to consult with counsel. McKesson Medical-Surgical, Inc., fully understands the language, meaning, and effect of this Pre-Charge Consent Order.

5. By signing this Consent, McKesson Medical-Surgical, Inc., makes no admission to the facts but submits to the foregoing Pre-Charge Consent Order as a resolution of this matter in lieu of formal charges, and agrees to be bound by its terms and conditions.

3/17/2025
Date

Name: Kevin DeBorde, Esq.
Title: Asst. General Counsel, MMS

STATE OF Virginia,
COUNTY/CITY OF Henrico:

I hereby certify that on this 17th day of March, 2025, before me, a Notary Public of the State and County/City aforesaid, personally appeared Kevin DeBorde, and made an oath in due form that the foregoing Consent was his/her voluntary act and deed on behalf of McKesson Medical-Surgical, Inc.

Notary Public
My commission expires: 11/30/2026

Barbara K Quevillon
Commonwealth of Virginia
Notary Public
Commission No. 8013295
My Commission Expires 11/30/2026

Barbara K Quevillon
Commonwealth of Virginia
Notary Public
Commission No. 8018295
My Commission Expires 11/30/2026

ORIGIN ID:CCRA
BEATRIX ERDEI
[redacted]

WALNUT CREEK, CA
UNITED STATES US
[redacted]

SHIP DATE: 09MAY25
ACTWGT: 1.00 LB
CAD: 10086482/INET4535

BILL SENDER

TO **NEVADA BOARD OF PHARMACY**
NEVADA BOARD OF PHARMACY
985 DAMONTE RANCH PKWY
SUITE 206
RENO NV 89521
(775) 850-1440
INV:
PO:
REF: 275 - DR CHANGE
DEPT:

58C/3/630D/C8C4

FedEx Express

/2520250408Guv

MON - 12 MAY 5:00P
STANDARD OVERNIGHT

TRK# 0201 **8811 5393 2583**

WQ RNOA

89521
NV-US RNO

After printing this label:
CONSIGNEE COPY - PLEASE PLACE IN FRONT OF POUCH
1. Fold the printed page along the horizontal line.
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Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of $100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of $100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is $1,000, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.

McKESSON

May 9, 2025

State Of Nevada Board of Pharmacy
Attn: Gregory Zunino
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

RE: Case No.: 24-395-WH-O
McKesson Medical Surgical Inc.
Registration Number: WH01100

Mr. Zunino:

Enclosed with this letter please find payment of $500 (cashier's check number: 140186) to **24-395-WH-O** and the copy of the Citation-and-Fine Order as requested.

Please contact me at your earliest convenience if you have further questions about this matter.

Sincerely,

Beatrix Erdei
Sr. Manager, Licensing, Enterprise Quality Management
t 925.322.9713
beatrix.erdei@mckesson.com

Confidentiality Notice: This document, including any attachments, is for the sole use of its intended recipients and may contain confidential, proprietary and/or privileged information of McKesson Corporation or its affiliates. Any unauthorized review, use, disclosure or distribution is prohibited.

0688

McKESSON & HEALTHCARE PROVIDERS
FEDERAL CREDIT UNION

1785 Arnold Drive
Martinez, CA 94553
(925) 524-5000

CASHIER'S CHECK

90-7198/3211

140186

VOID AFTER 90 DAYS

Memo: RE:MCKESSON INV 202050428

05/07/2025 $********500.00

PAY FIVE HUNDRED & 00/100 **********

TO THE ORDER OF NEVADA BOARD OF PHARMACY

Authorized Signature

Security features. Details on back.

[redacted]

JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA
BOARD OF PHARMACY
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

April 22, 2025

Via Certified/Standard U.S. Mail and Email
McKesson Medical-Surgical, Inc
Attn: Bill Wilson
License No. WH01100
16043 El Prado Ave.
Chino, CA 91708
mckessonlicensing@mckesson.com

9489 0178 9820 3042 2557 16

CITATION-AND-FINE ORDER: McKesson Medical, Case No. 24-395-WH-O, Unprofessional Conduct

Dear Mr. Wilson:

The Nevada State Board of Pharmacy ("Board") has determined that McKesson Medical ("McKesson") engaged in unprofessional conduct in its role as a wholesaler of pharmaceutical products in Nevada. Specifically, McKesson was found to have shipped Propofol Injectable Emulsion to a patient's home without a legitimate request for the medication, in error, and without proper oversight in the fulfillment process.

Specifically, McKesson shipped 100 vials of 20ml Propofol Injectable Emulsion to the home of a hospice patient receiving care through ProCare Hospice of Nevada. The medication had not been requested by the provider, and the excessive quantity of Propofol—an anesthetic typically used in surgical settings—raised serious concerns about patient safety. According to McKesson's Distribution Center in Chino, California, the shipment error resulted from a mis-pick: a package intended to include a case of Ensure and hydrocellular foam dressings was mistakenly filled with Propofol instead.

Pursuant to NAC 639.945(1)(i), performing duties in an incompetent, unskillful, or negligent manner constitutes unprofessional conduct. The shipment of a dangerous medication to an unintended recipient, without appropriate verification, poses serious risks to patient safety and public health. In this instance, had the family not been present, the Propofol could have been left at the patient's home, creating potential for accidental administration or misuse.

While McKesson acknowledged the error and coordinated with ProCare for the

destruction of the Propofol at the patient's home, the initial mistake was a failure in the shipping and inventory management processes. As a result, the Board has determined that McKesson's actions failed to meet the standard of competency and compliance required for licensed wholesalers serving Nevada patients. Pursuant to NRS 639.210(4), a licensee or registrant is subject to discipline for unprofessional conduct. Accordingly, the Board has assessed an administrative fine against McKesson in the amount of **Five Hundred and 00/100 Dollars ($500)** for unprofessional conduct.

If you do not intend to contest the above fine, please pay the fine within 30 days of receipt of this citation or otherwise contact Board staff to request an extension for good cause shown. Payment must be made by *certified check, cashier's check,* or *money order* payable to "**State of Nevada, Office of the Treasurer**," and it must be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

You may appeal this citation by submitting a notice of appeal requesting a public hearing before the Board. You must submit any such notice of appeal not later than 30 days after receipt of this citation. NRS 639.2895(2). Please mail or personally deliver any notice of appeal to the Reno address listed on the letterhead. If you have any questions, please contact the Board's Senior General Counsel, Gregory Zunino, at 775-850-1440, ext. 124, or *via* email at zunino@pharmacy.nv.gov.

Sincerely,

The Nevada State Board of Pharmacy

40

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Langham Logistics, Inc.

Physical Address: 4995 Perry Worth Road

City: Whitestown State: IN Zip: 46075

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 855-214-2844 Website: www.elangham.com

Name of Designated Representative (DR): Charles Shuff

Licensing Company Email: LL@iqvia.com DR Email: charlesshuff@elangham.com

Entities the Wholesaler will Serve (✔ all applicable)	Products to be Handled or Wholesaled (✔ all applicable)	Type of Wholesaling (✔ all applicable)
☐ Pharmacies	☑ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☑ Others:	☐ Warehouse
☐ Veterinarians	Bulk API, Injectables	☐ Retail pharmacy wholesale distributor
☑ Others: Manufacturers		☑ Others: Third Party Logistics

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

→ Original Signature (electronic, copies or stamps not accepted)

10/31/2025

→ Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: McKesson
Address: 8313 Polk Lane City: Olive Branch State: MS Zip: 38654
Name: Cardinal Health
Address: 5995 Commerce Center Drive City: Groveport State: OH Zip: 43199
Name: Eli Lilly Plainfield Distribution Center
Address: 2222 Stanley Road City: Plainfield State: IN Zip: 46168
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: IN
Parent Company (if any):
Corporation/Organization Name: Langham Logistics, Inc.
Mailing Address: 4995 Perry Worth Road
City: Whitestown State: IN Zip: 46075
Telephone: 815-214-2844 Email: info@elangham.com
Contact Person Name: Kevin Charlebois

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✔	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Langham Logistics, Inc.

Facility Name

Kevin Charlebois

Print Name of Authorized Person Submitting Application

Kevin Charlebois

→ Original signature of Authorized Person (copies or stamps not accepted)

10/31/2025

→ Date

Board Use Only	Date Received: 11/7/25	Amount: $1000 ck 663997

Accredited Drug Distributors

Find an Accredited Drug Distributor

Hanzo Logistics Inc dba Hanzo Logistics	4334 Plainfield Rd Plainfield, IN 46168	02/20/26
Henry Schein, Inc	5315 W 74th St Indianapolis, IN 46268	07/27/24
Henry Schein, Inc	5445 Guion Rd Indianapolis, IN 46254	08/12/23
Indiana University Health, Inc dba Indiana University Health Integrated Service Center	390 Airtech Pkwy Plainfield, IN 46168	11/16/25
J Knipper and Company, Inc	1250 Patrol Rd Ste 200 Charlestown, IN 47111	04/12/25
Kremers Urban Pharmaceuticals Inc	1101 C Avenue W Seymour, IN 47274	09/30/25
Kroger Limited Partnership II dba Peyton's Northern	1111 S Adams St Bluffton, IN 46714	11/30/24
LAAD Pharmaceuticals, LLC dba LAAD Pharmaceuticals	2502 Beech St, Ste 50 Valparaiso, IN 46383	12/30/25
Langham Logistics, Inc	319 Warrior Trail, Ste 100 Whiteland, IN 46184	11/20/25
Langham Logistics, Inc	4995 Perry Worth Rd Whitestown, IN 46075	11/20/25

<<Previous 1 2 3 4 5 6 7 Next >>

Copyright © 2023 National Association of Boards of Pharmacy® (NABP®).

Contact

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NABP ACCREDITED

DRUG DISTRIBUTOR

Langham Logistics, Inc.

located at

4995 Perry Worth Rd, Whitestown, IN, 46075

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

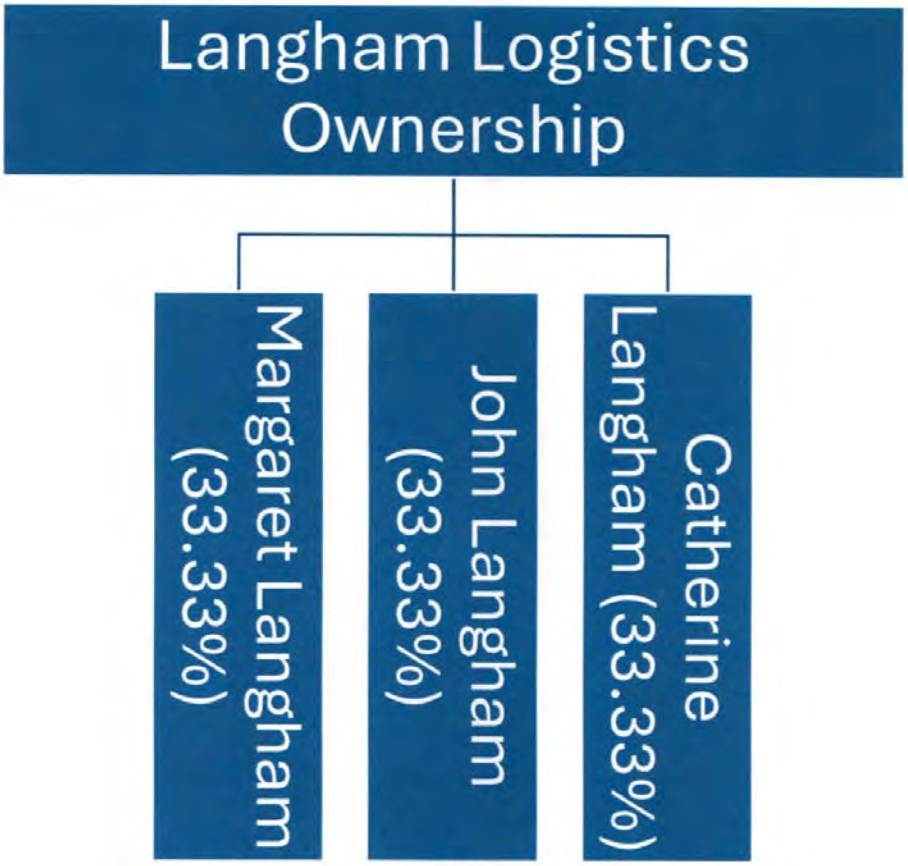
0698

Langham Logistics is a licensed third-party logistics (3PL) provider specializing in the distribution, storage, and transportation of prescription drugs and life-science products. Our scope of services includes temperature-controlled warehousing, order fulfillment, inbound/outbound distribution, and value-added supply chain support to pharmaceutical and biotech manufacturers. Langham does not purchase or resell products; we operate strictly as a logistics and distribution partner on behalf of our clients. Products in scope include finished prescription drugs and over-the-counter pharmaceuticals

Langham Logistics, Inc.
5335 West 74th Street
Indianapolis, IN 46268

FEIN: 35-1745665
State of Incorporation: Indiana

Officer Name	Title	Address
Catherine Langham	Founder, Owner, and CEO	5335 W. 74th Street, Indianapolis, IN 46268
Kevin Charlebois	President, Chief Operations Officer	5335 W. 74th Street, Indianapolis, IN 46268
Brian Landrum	President, Chief Revenue Officer	5335 W. 74th Street, Indianapolis, IN 46268
Tracy Jaisle	Chief Financial Officer	5335 W. 74th Street, Indianapolis, IN 46268


Langham Logistics Ownership
Catherine Langham (33.33%)
John Langham (33.33%)
Margaret Langham (33.33%)

State of Indiana
Office of the Secretary of State

CERTIFICATE OF EXISTENCE

To Whom These Presents Come, Greeting:

I, DIEGO MORALES, Secretary of State of Indiana, do hereby certify that I am, by virtue of the laws of the State of Indiana, the custodian of the corporate records and the proper official to execute this certificate.

I further certify that records of this office disclose that

LANGHAM LOGISTICS INC.

duly filed the requisite documents to commence business activities under the laws of the State of Indiana on June 06, 1988, and was in existence or authorized to transact business in the State of Indiana on March 25, 2026.

I further certify this Domestic For-Profit Corporation has filed its most recent report required by Indiana law with the Secretary of State, or is not yet required to file such report, and that no notice of withdrawal, dissolution, or expiration has been filed or taken place. All fees, taxes, interest, and penalties owed to Indiana by the domestic or foreign entity and collected by the Secretary of State have been paid.

In Witness Whereof, I have caused to be affixed my signature and the seal of the State of Indiana, at the City of Indianapolis, March 25, 2026

Diego Morales

DIEGO MORALES
SECRETARY OF STATE

1988060230 / 20264979073

All certificates should be validated here: https://bsd.sos.in.gov/ValidateCertificate

Expires on April 24, 2026.

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

Third Party Logistics Provider

Registration Number	Expire Date
94000232A	09/30/2026

Langham Logistics, Inc.
4995 Perry Worth Rd
Whitestown IN 46075

Mike Braun
Governor
State of Indiana

Lindsay M. Hyer
Executive Director
Indiana Professional Licensing Agency

Indiana Professional Licensing Agency
402 W. Washington Street, W072
Indianapolis, IN 46204

Third Party Logistics Provider

Registration Number	Expire Date
94000232A	**09/30/2026**

Langham Logistics, Inc.

Signature

State of Indiana

DEMOGRAPHIC INFORMATION

Name: Langham Logistics, Inc.

ADDRESS INFORMATION

Line 1: 4995 Perry Worth Rd
Line 2:
City/State/Zip: Whitestown IN 46075
County: Boone

LICENSE INFORMATION

Lic #:	94000232A	Profession:	Pharmacy Board	Type:	Third Party Logistics Provider	Secondary:	
Status:	Active	Issued:	8/17/2022	Expiration:	9/30/2026	Renewed:	12/13/2024
Method:	Application						

DISCIPLINE INFORMATION

-

RELATED LICENSES

No Related Licenses

LANGLOG-CL AMILLER

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 3/17/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Gregory & Appel Insurance
433 N Capitol Ave Suite 400
Indianapolis, IN 46204

CONTACT NAME: Lori Young
PHONE (A/C, No, Ext): (317) 686-6452 FAX (A/C, No):
E-MAIL ADDRESS: lyoung@gregoryappel.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Old Republic Insurance Co	24147
INSURER B : Third Coast Insurance Company	10713
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Langham Logistics Inc
5335 W. 74th Street
Indianapolis, IN 46268

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$	2,000,000
	CLAIMS-MADE X OCCUR			MWZY318074	2/1/2026	2/1/2027	DAMAGE TO RENTED PREMISES (Ea occurrence)	$	500,000
	X Agg per Project						MED EXP (Any one person)	$	5,000
							PERSONAL & ADV INJURY	$	2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	4,000,000
	POLICY PRO-JECT X LOC						PRODUCTS - COMP/OP AGG	$	4,000,000
	OTHER:							$	
A	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$	5,000,000
	X ANY AUTO			MWTB318645	2/1/2026	2/1/2027	BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
B	X UMBRELLA LIAB X OCCUR						EACH OCCURRENCE	$	5,000,000
	EXCESS LIAB CLAIMS-MADE			GXL0001810	2/1/2026	2/1/2027	AGGREGATE	$	5,000,000
	DED X RETENTION $ 0							$	
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						X PER STATUTE OTH-ER		
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N/A	N/A		MWC318073	2/1/2026	2/1/2027	E.L. EACH ACCIDENT	$	1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
The following locations are included in coverage:
Whitestown Location: 4995 S Perry Worth Rd, Whitestown, IN 46075
Whiteland Location: 319 Warrior Trail, Whiteland, IN 46184
Plainfield Location: 4334 Plainfield Road, Plainfield, IN 46168

CERTIFICATE HOLDER

For Informational Purposes
Proof of Insurance Only

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Shawn Bruhnke

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TRAVELERS

License No. _____

RIDER

To be attached to and form part of Bond No. 107989882.

Issued on behalf of **Langham Logistics Inc.** as Principal, and in favor of State of Nevada and to the Nevada State Board of Pharmacy as Obligee.

It is agreed that:

☐ 1. The Surety hereby gives its consent to change the Name:

from: _____

to: _____

☐ 2. The Surety hereby gives its consent to change the Address:

from: _____

to: _____

☒ 3. The Surety hereby gives its consent to change the locations covered:

from: **319 Warrior Trail, Whiteland, IN 46184, 4995 S Perry Worth Rd., Whitestown, IN 46075**

to: **319 Warrior Trail, Whiteland, IN 46184, 4995 S Perry Worth Rd., Whitestown, IN 46075,** 4334 Plainfield Road Plainfield, IN 46168

This rider shall become effective as of **February 2, 2026**

PROVIDED, however, that the liability of the Surety under the attached bond as changed by this rider shall not be cumulative.

Signed, sealed and dated **February 2, 2026**.

Travelers Casualty and Surety Company of America

By: _____

Andrew S Appel
Attorney-in-Fact

Accepted: State of Nevada and to the Nevada State Board of Pharmacy
Obligee

or **Langham Logistics Inc.**
Principal

By: _____

By: _____

S-4111 (8/66)

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Kathleen T. DeVito** of **INDIANAPOLIS**, **Indiana**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April, 2021**.

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **21st** day of **April, 2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 2nd day of February, 2026.

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107989882

Application/License No. _____

Langham Logistics Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
5335 W. 74th St., Indianapolis, IN 46268, as
(Address of Applicant/Principal)
PRINCIPAL, and Travelers Casualty and Surety Company of America, a
(Surety Company)
corporation organized under the laws of the state of CT
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
280 East 96th Street, Suite 300, Indianapolis, IN 46240 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 24, 2025.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 24th day of February, 20 25.

APPLICANT/PRINCIPAL

COMPANY Langham Logistics Inc.

Authorized Representative

SURETY

Travelers Casualty and Surety Company of America

Surety Company's Representative

Andrew S Appel, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Kathleen T. DeVito

Witness Robin L. Young

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **ANDREW S APPEL** of **INDIANAPOLIS**, **Indiana**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April**, **2021**.

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **21st** day of **April**, **2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June**, **2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this **24th** day of **February**, **2025**

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Langham Logistics, Inc.

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 4995 Perry Worth Road

City Whitestown State IN Zip 46075

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855-214-2844 Website www.elangham.com

Licensing Company Email LL@iqvia.com

Section 2: Personal Information

First Charles Middle Timothy Last Shuff

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 4995 Perry Worth Road

City Whitestown State IN Zip 46075

Telephone 765-335-1075 Email charlesshuff@elangham.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Garrett High School		08/95 - 05/99	
Address	City	State	Zip
804 Houston Street	Garrett	IN	46738
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
		___/___ - ___/___	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/24 - 10/25	[redacted]	Thorntown	IN	[redacted]
07/22 - 09/24		Whitestown	IN	
07/15 - 07/22		Webster	FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Langham Logistics, Inc.			4/25 - present	
Business Address		**City**	**State**	**Zip**
4995 Perry Worth Road		Whitestown	IN	46075
Phone	**Title**		**Number of Employed Hours**	
317-509-3456	General Manager		1000+	

Description of Duties

-Lead operations at a licensed pharmaceutical 3PL site specializing in prescription drug stoarge and distribution (ambient, refrigerated, and frozen) -Oversee 45 employees across operations, quality and customer service teams -Ensure full compliance with FDA, DEA, and IN Board of Pharmacy regulations -Manage facility audits, quality events, and CAPA closures under GDP and QMS standards -parter with Quality and Compliance teams to maintain licensing and readiness for NABP inspections -Spearhead continuous improvement initiatives to drive safety, service, and profibility

Business Name			From - To (MM/YY – MM/YY)	
Exel Inc. dba DHL Supply Chain (USA)			3/22 - 4/25	
Business Address		**City**	**State**	**Zip**
4435 500 E		Whitestown	IN	46075
Phone	**Title**		**Number of Employed Hours**	
765-336-1003	General Manager		6000+	

Description of Duties

-direct a site with 75 full-time headcount -Manage volume through parcel, LTL, and export formats (Ambient, Cold Chain, and Frozen SKUs) -Increased safety ownership (earned 3 consecutive Presidential Safety Awards for no recordables -Led full site turnaround: 24 months of green KPIs and full performance recovery -Implemented LMS, OMS and Picker Accuracy Standards -Improved QMS from High Risk to Low Risk through closure of 52 CAPAs -Full P&L accountability

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Charles Shuff, **certify that as the designated representative for**

Langham Logistics, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CTS I am at least 21 years of age;
3. CTS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CTS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CTS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CTS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Charles Shuff

Print Name (First, Last)

→ Original Signature (electronic, copies or stamps not accepted)

11-4-2025

→ Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Charles Shuff

Print Name (First, Last)

→ Original Signature (electronic, copies or stamps not accepted)

11-4-2025

→ Date

Please have this section completed in the presence of a Notary Public.

State of INDIANA, ss. County of MARION

I, Charles Shuff, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

→ **Original Signature**

11-4-2025

→ **Date**

Subscribed and Sworn to before me this 4th day of Nov.

→ **Notary Public Signature**

My commission Expires
03-14-2026

GERALD FIELDS
Commission Expires
03-14-2026
NOTARY PUBLIC
NOTARY SEAL
Comm #711476
Hamilton County
STATE OF INDIANA

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Langham Logistics, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 5335 W 74th Street

City: Indianapolis State: IN Zip: 46268

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 855-214-2844 Website: elangham.com

Licensing Company Email: LL@iqvia.com

Section 2: Personal Information

First: Catherine Middle: Ann Last: Langham

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: 5335 W 74th Street

City: Indianapolis State: IN Zip: 46268

Telephone: 855-214-2844 Email: cathylangham@elangham.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
North Central HS		1973-1976	
Address	**City**	**State**	**Zip**
1801 E 86th Street	Indianapolis	IN	46240
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Indiana University		1977-1980	
Address	**City**	**State**	**Zip**
107 S Indiana Ave	Bloomington	IN	47405
Diploma/Degree obtained, if any			
BS Marketing			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10+yrs	[redacted]	Carmel	IN	[redacted]
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Langham Logistics, Inc.			1988 - Current
Business Address	**City**	**State**	**Zip**
5335 West 74th St.	Indianapolis	IN	46268
Phone	**Title**		
855-214-2844	Founder, CEO		

Description of Duties

Business Leader and Public Board member with extensive experience in business growth, strategic advancement, and team development. Found/CEO of Langham Logistics, Inc. and successfully led the company to become a $100+ million global transportation and warehousing enterprise.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____, Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

→ Catherine Langham
Original Signature (electronic, copies or stamps not accepted)

→ 2/17/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Catherine Langham

Print Name (First, Last)

→ Catherine Langham — 2/17/2026

Original Signature (electronic, copies or stamps not accepted) → Date

---

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Hamilton

I, Catherine Langham, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

→ Catherine Langham — 2/17/2026

Original Signature → **Date**

Subscribed and Sworn to before me this 27 day of February.

→ Notary Public Signature



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Langham Logistics, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 5335 West 74th Street

City: Indianapolis State: IN Zip: 46268

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 855-214-2844 Website: elangham.com

Licensing Company Email: LL@iqvia.com

Section 2: Personal Information

First: John Middle: Henry Last: Langham

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 5335 W 74th Street

City: Indianapolis State: IN Zip: 46268

Telephone: 317-506-5132 Email: johnlangham@elangham.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Northwestern University			1989	
Address		City	State	Zip
633 Clark St		Evanston	IL	60208
Diploma/Degree obtained, if any				
Masters Degree				

School Name			From - To (MM/YY – MM/YY)	
Indiana University			1978	
Address		City	State	Zip
107 S Indiana Ave		Bloomington	IN	4745
Diploma/Degree obtained, if any				
Bachelors of Science				

School Name			From - To (MM/YY – MM/YY)	
North Central High School			1974	
Address		City	State	Zip
1801 E 86th St		Indianapolis	IN	46240
Diploma/Degree obtained, if any				
HS Diploma				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2019-Present	[redacted]	Carmel	IN	[redacted]
1996-2019		Carmel	IN	

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Langham Logistics Inc.			1990 - Present
Business Address	**City**	**State**	**Zip**
5335 West 74th Street	Indianapolis	IN	46268
Phone	**Title**		
1-855-214-2844	Owner/VP		

Description of Duties

Developed, managed and served on Board of Langham Logistics, Inc. for 35+ years. Oversaw revenue growth to $120M. Implemented strategic growth plans, advanced operational automation, effective team management and innovative customer service plans. Extensive management in areas such as accounting, finance, warehouse operations, freight operations, quality, human resources, new customer on boarding and information technology.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

→ Original Signature (electronic, copies or stamps not accepted)

→ Date 3/18/26

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Langham

Print Name (First, Last)

→ Original Signature (electronic, copies or stamps not accepted)

→ Date 2/18/26

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Hamilton

I, John Langham, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

→ **Original Signature**

→ **Date** 2/18/26

Subscribed and Sworn to before me this 27 day of February.

→ **Notary Public Signature**



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Langham Logistics, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 5335 W 74th Street

City: Indianapolis State: IN Zip: 46268

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 855-214-2844 Website: elangham.com

Licensing Company Email: LL@iqvia.com

Section 2: Personal Information

First: Margaret Middle: Last: Langham

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: 5335 W 74th Street

City: Indianapolis State: IN Zip: 46268

Telephone: [redacted] Email: margaretlangham@eLangham.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
IUPUI		09/79 – 06/83	
Address	City	State	Zip
755 W Michigan St	Indianapolis	IN	46202
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
North Central		09/76 – 06/79	
Address	City	State	Zip
1801 E. 86th St	Indianapolis	IN	46240
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2013 - Current	[redacted]	Carmel	IN	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Langham Logistics Inc.			07/88 - Present
Business Address	**City**	**State**	**Zip**
5335 W 74th St	Indianapolis	IN	46268
Phone	**Title**		
317-471-5122	Vice President		
Description of Duties			
OWNER BOARD MEMBER			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

→ _____ Original Signature (electronic, copies or stamps not accepted)

→ 26FEB2026 Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Margaret Langham

Print Name (First, Last)

→ Original Signature (electronic, copies or stamps not accepted)

→ Date 26 FEB 2026

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Hamilton

I, Margaret Langham, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

→ **Original Signature**

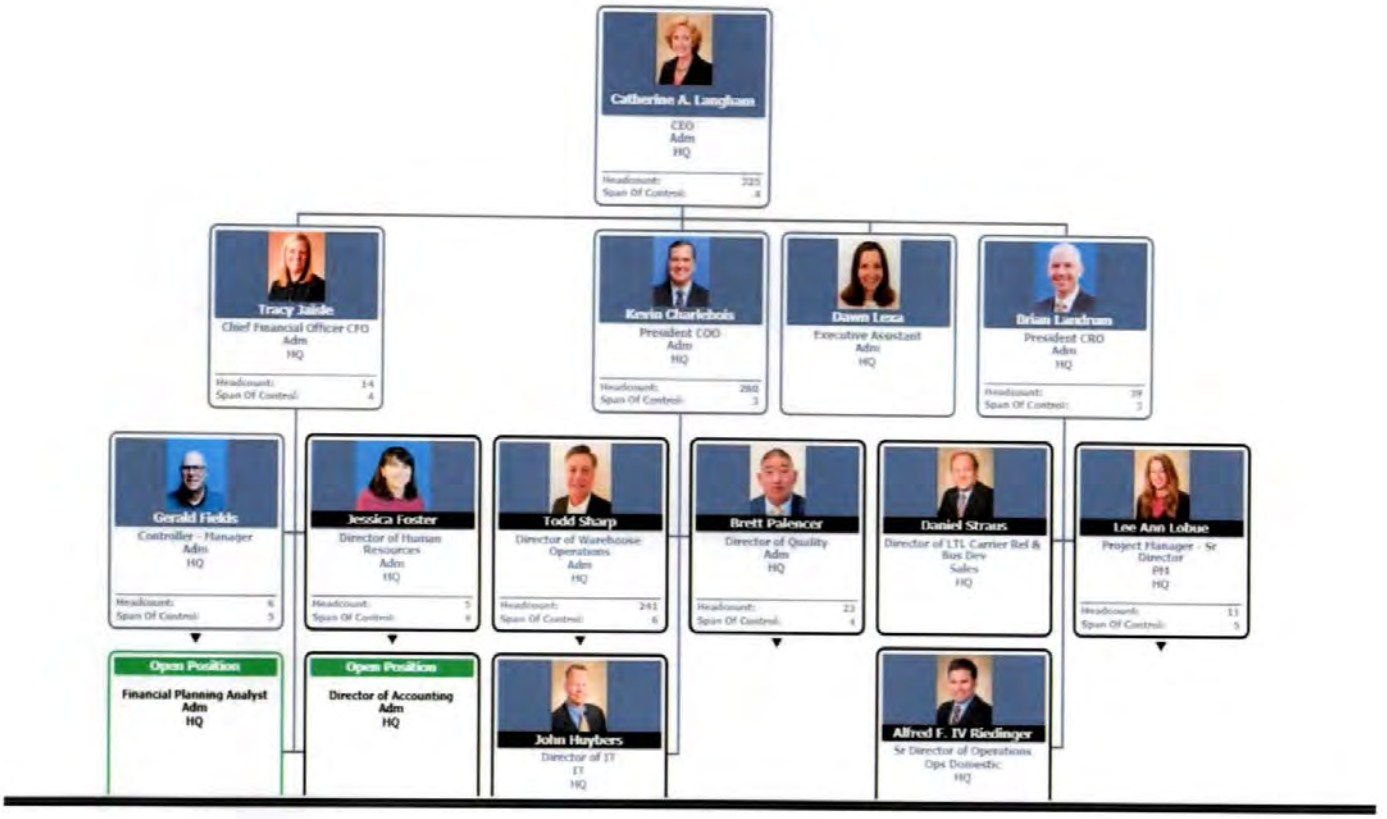
→ **Date** 26 FEB 2026

Subscribed and Sworn to before me this 26 day of February 2026

→ **Notary Public Signature**

MARY C BULLARD
Notary Public
Hamilton County - State of Indiana
Commission Number NP0759828
My Commission Expires Nov 6, 2032

(Seal)


Catherine A. Langham
CEO
Adm
HQ
Headcount: 335
Span Of Control: 4
Tracy Jaide
Chief Financial Officer CFO
Adm
HQ
Headcount: 14
Span Of Control: 4
Kevin Charlebois
President COO
Adm
HQ
Headcount: 280
Span Of Control: 3
Dawn Leza
Executive Assistant
Adm
HQ
Brian Landrum
President CRO
Adm
HQ
Headcount: 39
Span Of Control: 3
Gerald Fields
Controller - Manager
Adm
HQ
Headcount: 6
Span Of Control: 5
Jessica Foster
Director of Human Resources
Adm
HQ
Headcount: 5
Span Of Control: 4
Todd Sharp
Director of Warehouse Operations
Adm
HQ
Headcount: 241
Span Of Control: 6
Brett Palencer
Director of Quality
Adm
HQ
Headcount: 23
Span Of Control: 4
Daniel Straus
Director of LTL Carrier Rel & Bus Dev
Sales
HQ
Lee Ann Lobue
Project Manager - Sr Director
PM
HQ
Headcount: 11
Span Of Control: 5
Open Position
Financial Planning Analyst
Adm
HQ
Open Position
Director of Accounting
Adm
HQ
John Huybers
Director of IT
IT
HQ
Alfred F. IV Riedinger
Se Director of Operations
Ops Domestic
HQ

4P

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Langham Logistics, Inc

Physical Address: 319 Warrior Trail, Suite 100

City: Whiteland State: IN Zip: 46184

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 815-214-2844 Website: elangham.com

Name of Designated Representative (DR): Connor O'Neal

Licensing Company Email: LL@iqvia.com/daniella.fancher@IQVIA.com DR Email: connoroneal@elangham.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☑ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☑ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Manufacturers		☑ Others: Third Party Logistics

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Tom Chambers

→ Original Signature (electronic, copies or stamps not accepted)

10/31/25

→ Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: McKesson
Address: 8313 Polk Lane City: Olive Branch State: MS Zip: 38654
Name: Cardinal Health
Address: 5995 Commerce Center Drive City: Groveport State: OH Zip: 43199
Name: Eli Lilly Plainfield Distribution Center
Address: 2222 Stanley Road City: Plainfield State: IN Zip: 46168
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: IN
Parent Company (if any):
Corporation/Organization Name: Langham Logistics, Inc.
Mailing Address: 319 Warrior Trail suite 100
City: Whiteland State: IN Zip: 46184
Telephone: 815-214-2844 Email: info@elangham.com
Contact Person Name: Kevin Charlebois

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✔	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✔" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✔	✔		
• **List the top four corporation shareholders and their percent ownership.**	✔			
• **List of all corporation shareholders and their percent ownership.**		✔		
• **List of all partners and their percent ownership.**			✔	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✔	✔	✔	✔
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✔	✔	✔
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✔	✔	✔
• **Copy of DEA certificate if handling controlled substances**	✔	✔	✔	✔
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✔			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✔	✔	✔	✔
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✔	✔	✔	✔
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✔	✔	✔	✔
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✔	✔	✔	✔
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✔	✔	✔
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✔	✔	✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Langham Logistics, Inc.

Facility Name

Kevin Charlebois

Print Name of Authorized Person Submitting Application

Kevin Charlebois

→ Original signature of Authorized Person (copies or stamps not accepted)

10/31/20

→ Date

Board Use Only	Date Received: _____	Amount: _____

Accredited Drug Distributors

Find an Accredited Drug Distributor

Hanzo Logistics Inc dba Hanzo Logistics	4334 Plainfield Rd Plainfield, IN 46168	02/20/26
Henry Schein, Inc	5315 W 74th St Indianapolis, IN 46268	07/27/24
Henry Schein, Inc	5445 Guion Rd Indianapolis, IN 46254	08/12/23
Indiana University Health, Inc dba Indiana University Health Integrated Service Center	390 Airtech Pkwy Plainfield, IN 46168	11/16/25
J Knipper and Company, Inc	1250 Patrol Rd Ste 200 Charlestown, IN 47111	04/12/25
Kremers Urban Pharmaceuticals Inc	1101 C Avenue W Seymour, IN 47274	09/30/25
Kroger Limited Partnership II dba Peyton's Northern	1111 S Adams St Bluffton, IN 46714	11/30/24
LAAD Pharmaceuticals, LLC dba LAAD Pharmaceuticals	2502 Beech St, Ste 50 Valparaiso, IN 46383	12/30/25
Langham Logistics, Inc	319 Warrior Trail, Ste 100 Whiteland, IN 46184	11/20/25
Langham Logistics, Inc.	4995 Perry Worth Rd Whitestown, IN 46075	11/20/25

<<Previous 1 2 3 4 5 6 7 Next >>

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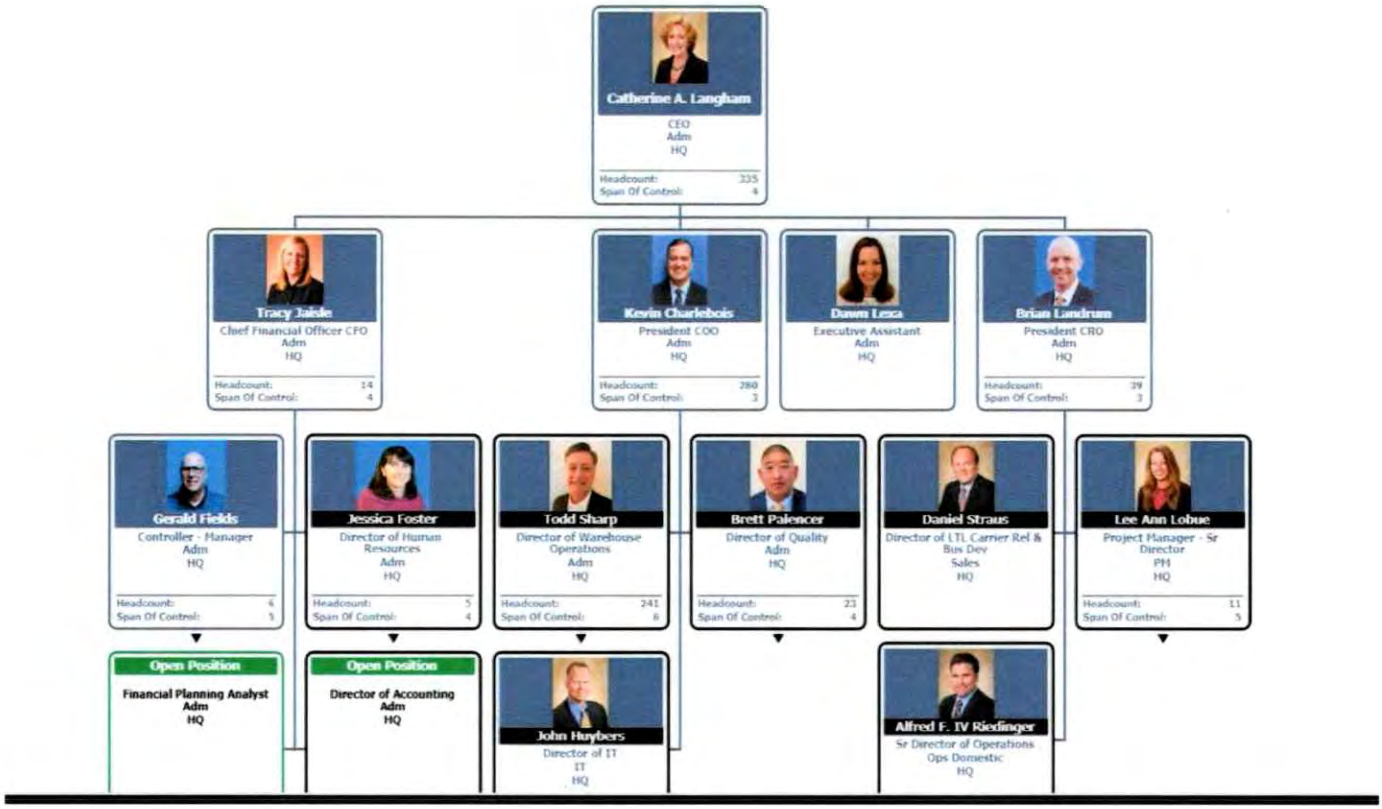
Verified MH 12/30/25

Langham Logistics, Inc.
5335 West 74th Street
Indianapolis, IN 46268

FEIN: 35-1745665
State of Incorporation: Indiana

Officer Name	Title	Address
Catherine Langham	Founder, Owner, and CEO	5335 W. 74th Street, Indianapolis, IN 46268
Kevin Charlebois	President, Chief Operations Officer	5335 W. 74th Street, Indianapolis, IN 46268
Brian Landrum	President, Chief Revenue Officer	5335 W. 74th Street, Indianapolis, IN 46268
Tracy Jaisle	Chief Financial Officer	5335 W. 74th Street, Indianapolis, IN 46268

Langham Logistics Ownership
Margaret Langham (33.33%)
John Langham (33.33%)
Catherine Langham (33.33%)


Catherine A. Langham
CEO
Adm
HQ
Headcount: 335
Span Of Control: 4
Tracy Jaisle
Chief Financial Officer CFO
Adm
HQ
Headcount: 14
Span Of Control: 4
Kevin Charlebois
President COO
Adm
HQ
Headcount: 280
Span Of Control: 3
Dawn Lesa
Executive Assistant
Adm
HQ
Brian Lindrum
President CRO
Adm
HQ
Headcount: 39
Span Of Control: 3
Gerald Fields
Controller - Manager
Adm
HQ
Headcount: 6
Span Of Control: 5
Jessica Foster
Director of Human Resources
Adm
HQ
Headcount: 5
Span Of Control: 4
Todd Sharp
Director of Warehouse Operations
Adm
HQ
Headcount: 241
Span Of Control: 6
Brett Palencer
Director of Quality
Adm
HQ
Headcount: 23
Span Of Control: 4
Daniel Straus
Director of LTL Carrier Rel & Bus Dev
Sales
HQ
Lee Ann Lobue
Project Manager - Sr Director
PM
HQ
Headcount: 11
Span Of Control: 5
Open Position
Financial Planning Analyst
Adm
HQ
Open Position
Director of Accounting
Adm
HQ
John Huybers
Director of IT
IT
HQ
Alfred F. IV Riedinger
Sr Director of Operations
Ops Domestic
HQ

Langham Logistics is a licensed third-party logistics (3PL) provider specializing in the distribution, storage, and transportation of prescription drugs and life-science products. Our scope of services includes temperature-controlled warehousing, order fulfillment, inbound/outbound distribution, and value-added supply chain support to pharmaceutical and biotech manufacturers. Langham does not purchase or resell products; we operate strictly as a logistics and distribution partner on behalf of our clients. Products in scope include finished prescription drugs and over-the-counter pharmaceuticals

State of Indiana
Office of the Secretary of State

CERTIFICATE OF EXISTENCE

To Whom These Presents Come, Greeting:

I, DIEGO MORALES, Secretary of State of Indiana, do hereby certify that I am, by virtue of the laws of the State of Indiana, the custodian of the corporate records and the proper official to execute this certificate.

I further certify that records of this office disclose that

LANGHAM LOGISTICS INC.

duly filed the requisite documents to commence business activities under the laws of the State of Indiana on June 06, 1988, and was in existence or authorized to transact business in the State of Indiana on October 05, 2025.

I further certify this Domestic For-Profit Corporation has filed its most recent report required by Indiana law with the Secretary of State, or is not yet required to file such report, and that no notice of withdrawal, dissolution, or expiration has been filed or taken place. All fees, taxes, interest, and penalties owed to Indiana by the domestic or foreign entity and collected by the Secretary of State have been paid.

In Witness Whereof, I have caused to be affixed my signature and the seal of the State of Indiana, at the City of Indianapolis, October 05, 2025

Diego Morales

DIEGO MORALES
SECRETARY OF STATE

1988060230 / 20254661226

All certificates should be validated here: https://bsd.sos.in.gov/ValidateCertificate

Expires on November 04, 2025.

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

Third Party Logistics Provider

Registration Number	Expire Date
94000262A	09/30/2026

Langham Logistics, Inc.
319 Warrior Trail
Whiteland IN 46184

Mike Braun
Governor
State of Indiana

Lindsay M. Hyer
Executive Director
Indiana Professional Licensing Agency

Indiana Professional Licensing Agency
402 W. Washington Street, W072
Indianapolis, IN 46204

Third Party Logistics Provider

Registration Number	Expire Date
94000262A	**09/30/2026**

Langham Logistics, Inc.

Signature

State of Indiana

DEMOGRAPHIC INFORMATION

Name: Langham Logistics, Inc.

ADDRESS INFORMATION

Line 1: 319 Warrior Trail
Line 2:
City/State/Zip: Whiteland IN 46184
County: Johnson

LICENSE INFORMATION

Lic #:	94000262A	Profession:	Pharmacy Board	Type:	Third Party Logistics Provider	Secondary:	
Status:	Active	Issued:	6/13/2023	Expiration:	9/30/2026	Renewed:	12/13/2024
Method:	Application						

DISCIPLINE INFORMATION

-

RELATED LICENSES

No Related Licenses

LANGLOG-CL AMILLER

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 3/17/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Lori Young	
Gregory & Appel Insurance 433 N Capitol Ave Suite 400 Indianapolis, IN 46204	PHONE (A/C, No, Ext): (317) 686-6452	FAX (A/C, No):
	E-MAIL ADDRESS: lyoung@gregoryappel.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Old Republic Insurance Co	24147
INSURED	INSURER B : Third Coast Insurance Company	10713
Langham Logistics Inc 5335 W. 74th Street Indianapolis, IN 46268	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY318074	2/1/2026	2/1/2027	EACH OCCURRENCE	$ 2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 500,000
	X Agg per Project						MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 4,000,000
	POLICY PRO-JECT X LOC						PRODUCTS - COMP/OP AGG	$ 4,000,000
	OTHER:							$
A	AUTOMOBILE LIABILITY			MWTB318645	2/1/2026	2/1/2027	COMBINED SINGLE LIMIT (Ea accident)	$ 5,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
B	X UMBRELLA LIAB X OCCUR			GXL0001810	2/1/2026	2/1/2027	EACH OCCURRENCE	$ 5,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$ 5,000,000
	DED X RETENTION $ 0							$
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			MWC318073	2/1/2026	2/1/2027	X PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

The following locations are included in coverage:
Whitestown Location: 4995 S Perry Worth Rd, Whitestown, IN 46075
Whiteland Location: 319 Warrior Trail, Whiteland, IN 46184
Plainfield Location: 4334 Plainfield Road, Plainfield, IN 46168

CERTIFICATE HOLDER

For Informational Purposes
Proof of Insurance Only

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Shawn Bruhnke

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TRAVELERS

License No. _____

RIDER

To be attached to and form part of Bond No. 107989882.

Issued on behalf of **Langham Logistics Inc.** as Principal, and in favor of State of Nevada and to the Nevada State Board of Pharmacy as Obligee.

It is agreed that:

☐ 1. The Surety hereby gives its consent to change the Name:

from: _____

to: _____

☐ 2. The Surety hereby gives its consent to change the Address:

from: _____

to: _____

☒ 3. The Surety hereby gives its consent to change the locations covered:

from: **319 Warrior Trail, Whiteland, IN 46184, 4995 S Perry Worth Rd., Whitestown, IN 46075**

to: **319 Warrior Trail, Whiteland, IN 46184, 4995 S Perry Worth Rd., Whitestown, IN 46075, 4334 Plainfield Road Plainfield, IN 46168**

This rider shall become effective as of **February 2, 2026**

PROVIDED, however, that the liability of the Surety under the attached bond as changed by this rider shall not be cumulative.

Signed, sealed and dated **February 2, 2026**.

Travelers Casualty and Surety Company of America

By: _____

Andrew S Appel
Attorney-in-Fact

Accepted: State of Nevada and to the Nevada State Board of Pharmacy
Obligee

By: _____

or **Langham Logistics Inc.**
Principal

By: _____

S-4111 (8/66)

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Kathleen T. DeVito** of **INDIANAPOLIS**, **Indiana**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April, 2021.**

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **21st** day of **April, 2021,** before me personally appeared **Robert L. Raney,** who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes,** the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 2nd day of February, 2026.

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-In-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107989882

Application/License No. _____

Langham Logistics Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5335 W. 74th St., Indianapolis, IN 46268 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 280 East 96th Street, Suite 300, Indianapolis, IN 46240 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 24, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 24th day of February, 2025.

APPLICANT/PRINCIPAL

COMPANY Langham Logistics Inc.

Authorized Representative

SURETY

Travelers Casualty and Surety Company of America

Surety Company's Representative

Andrew S Appel, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Kathleen T. DeVito

Witness Robin L. Young

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **ANDREW S APPEL** of **INDIANAPOLIS**, **Indiana**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April**, **2021**.

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **21st** day of **April**, **2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June**, **2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this **24th** day of **February**, **2025**

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Langham Logistics, Inc MDEG License # (if applicable) _____

Physical Address 319 Warrior Trail suite 100

City Whiteland State IN Zip 46184

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855-214-2844 Website elangham.com

Licensing Company Email LL@iqvia.com

Section 2: Personal Information

First Connor Middle Evan Last O'Neal

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 317 Warrior Trail, Suite 100

City Whiteland State IN Zip 46184

Telephone [redacted] Email connoroneal@elangham.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Ball State University		08/2010-12/2014	
Address	**City**	**State**	**Zip**
2000 W. University Avenue	Muncie	IN	47306
Diploma/Degree obtained, if any			
College Degree - International Business			

School Name		From - To (MM/YY – MM/YY)	
Carmel High School		08/2006-05/2010	
Address	**City**	**State**	**Zip**
520 East Main Street	Carmel	IN	46032
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2023-Present	[redacted]	Indianaplis	IN	[redacted]
2020-2023		Indianapolis	IN	
2015-2020		Carmel	IN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Langham Logistics, Inc.			05/23 - Present	
Business Address	**City**		**State**	**Zip**
319 Warrior Trail, Suite 100	Whiteland		IN	46184
Phone	**Title**		**Number of Employed Hours**	
317-503-5854	Senior Operations Manager		5100+	
Description of Duties				
-oversight of a 500k square foot cold chain DC, managing compliant storage and distribution of pharmaceutical products - Manage/Develop a team of 10 salaried leaders and 120+ associates, fostering engagement, safety, and productivity - Lead Go-Live validations and training for 4 various temperature storage environments, Drive continuous improvement initiatives and launch development programs to cultivate internal talent				

Business Name			From - To (MM/YY – MM/YY)	
Geodis			10/21 - 05/23	
Business Address	**City**		**State**	**Zip**
281 Airtech Parkway, Suite 191	Plainfield		IN	46168
Phone	**Title**		**Number of Employed Hours**	
317-517-7496	Assistant Operations Manager		3400+	
Description of Duties				
-Manage the H&M Inbound Operation with over 90 teammates across 5 departments - Set record-breaking 2022 receiving volumes by processing over 68k cases per week - Leading 6-month Digital Returns Go-Live consisting of two-story mezzanine constructions - Coordinate international inventory movements of 7k cases per week - Maintain 22% contribution margin for Inbound Operations daily				

Business Name			From - To (MM/YY – MM/YY)	
MD Logistics			01/20 - 10/21	
Business Address	**City**		**State**	**Zip**
2150 Stanley Rd	Plainfield		IN	46168
Phone	**Title**		**Number of Employed Hours**	
317-838-8900	Operations Supervisor		4000+	
Description of Duties				
Oversaw life science operations for Merck Co & CSL Behring. Led 6-month Go-Live project introducing small parcel operations to the Plainfield facility.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: **Personal and Professional History**	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
2010 & 2011		IN	Carmel	Hamilton
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Hamilton County Sherriff's Office/Carmel Police Department		
Reason/Charge				
Illegal Consumption of Alcohol & Possession of Paraphernalia				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				

Provide explanation below:

I was cited for illegal consumption of alcohol & possession of paraphernalia in February of 2010 at a residential party during my High School years.

In May of 2011, I was cited for illegal consumption of alcohol. This was also at a residential party that I attended during summer time of my college years. I was under the age of 21 during both charges stated above.

After completing diversion program, all charges from both arrests were dismissed. - Connor O'Neal

→ Original Signature (electronic, copies or stamps not accepted)

10-31-2025

→ Date

I, Connor O'Neal, **certify that as the MDEG Administrator for**

Langham Logistics, Inc,

that I (initial that you have read and meet the following requirements):

1. CEO Have a high school diploma or its equivalent;
2. CEO Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CEO Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CEO Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Connor O'Neal

Print Name (First, Last)



→ Original Signature (electronic, copies or stamps not accepted)

10-31-2025

→ Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Y

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Langham Logistics, Inc.

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 317 Warrior Trail, Suite 100

City Whiteland State IN Zip 46184

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855-214-2844 Website www.elangham.com

Licensing Company Email LL@iqvia.com

Section 2: Personal Information

First Connor Middle Evan Last O'Neal

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 317 Warrior Trail, Suite 100

City Whiteland State IN Zip 46184

Telephone [redacted] Email connoroneal@elangham.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Ball State University		08/2010-12/2014	
Address	**City**	**State**	**Zip**
2000 W. University Avenue	Muncie	IN	47306
Diploma/Degree obtained, if any			
College Degree - International Business			

School Name		From - To (MM/YY – MM/YY)	
Carmel High School		08/2006-05/2010	
Address	**City**	**State**	**Zip**
520 East Main Street	Carmel	IN	46032
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2023-Present	[redacted]	Indianaplis	IN	[redacted]
2020-2023		Indianapolis	IN	
2015-2020		Carmel	IN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Langham Logistics, Inc.			05/23 - Present	
Business Address	**City**		**State**	**Zip**
319 Warrior Trail, Suite 100	Whiteland		IN	46184
Phone	**Title**		**Number of Employed Hours**	
317-503-5854	Senior Operations Manager		5100+	

Description of Duties

-oversight of a 500k square foot cold chain DC, managing compliant storage and distribution of pharmaceutical products - Manage/Develop a team of 10 salaried leaders and 120+ associates, fostering engagement, safety, and productivity - Lead Go-Live validations and training for 4 various temperature storage environments, Drive continuous improvement initiatives and launch development programs to cultivate internal talent

Business Name			From - To (MM/YY – MM/YY)	
Geodis			10/21 - 05/23	
Business Address	**City**		**State**	**Zip**
281 Airtech Parkway, Suite 191	Plainfield		IN	46168
Phone	**Title**		**Number of Employed Hours**	
317-517-7496	Assistant Operations Manager		3400+	

Description of Duties

-Manage the H&M Inbound Operation with over 90 teammates across 5 departments - Set record-breaking 2022 receiving volumes by processing over 68k cases per week - Leading 6-month Digital Returns Go-Live consisting of two-story mezzanine constructions - Coordinate international inventory movements of 7k cases per week - Maintain 22% contribution margin for Inbound Operations daily

Business Name			From - To (MM/YY – MM/YY)	
MD Logistics			01/20 - 10/21	
Business Address	**City**		**State**	**Zip**
2150 Stanley Rd	Plainfield		IN	46168
Phone	**Title**		**Number of Employed Hours**	
317-838-8900	Operations Supervisor		4000+	

Description of Duties

Oversaw life science operations for Merck Co & CSL Behring. Led 6-month Go-Live project introducing small parcel operations to the Plainfield facility.

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✔	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	✔	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2010 + 2011		IN	Carmel	Hamilton
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Hamilton County Sheriff's Office / Carmel PD		
Reason/Charge				
Illegal Consumption of Alcohol + Possession of Paraphernalia				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

I was cited for illegal consumption of alcohol + possession of paraphernalia in February of 2010 at a residential party during my High School years.

In May of 2011, I was cited for Illegal Consumption of alcohol. This was also at a residential party that I attended in the summer time of my college years. I was under the age of 21 during both scenarios stated above.

After completing diversion program, all charges from both arrests were dismissed. - Connor O'Neal

→ Original Signature (electronic, copies or stamps not accepted)

10-31-2025
→ Date

To Whom It May Concern:

My first infraction occurred on February 12th, 2010 when I was breathalyzed after a high school residential party and registered a BAC under the legal limit of 0.08%. I was not yet 21 years old (19 at the time) and was cited for Illegal Consumption of an Alcoholic Beverage. In the same moment, the Officer asked me about another smell. I admitted to him that I was carrying a smoking vaporizer, which he collected and added Possession of Paraphernalia to my citation. I completed a diversion program shortly after and all charges were dismissed.

My second infraction also occurred during a residential party during my college years on May 26th, 2011. The police arrived and I was breathalyzed and cited for a charge of Illegal Consumption of Alcohol as I was 20 years old at the time. This charge was also dismissed.

To my knowledge, the above misdemeanors are the only citations on my record, and I hope this does not impact any decisions made for my license application. If there are any further questions, please contact me and I'm happy to discuss.

Sincerely,

Connor O'Neal



State of Indiana v. Connor O'Neal

05/26/2011

29H01-1105-CM-000522

Court	Carmel City Court
Case Type	CM - Criminal Misdemeanor
Filed	05/26/2011
Status	12/19/2011, Decided
Charges	7.1-5-7-7(a)(2)/MC: Illegal Consumption of an Alcoholic Beverage
Parties	State of Indiana, O'Neal
Attorneys	Freeman, Crum

State of Indiana v. Connor O'Neal

02/12/2010

29D05-1002-CM-000830

Court	Hamilton Superior Court 5
Case Type	CM - Criminal Misdemeanor
Filed	02/12/2010
Status	05/06/2011, Decided
Charges	35-48-4-8.3(a)(1)/MA: Possession of Paraphernalia, 7.1-5-7-7(a)(2)/MC: Illegal Consumption of an Alcoholic Beverage
Parties	State of Indiana, O'Neal
Attorneys	Wissel

I, Connor O'Neal **, certify that as the designated representative for**

Langham Logistics, Inc.

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CEO I am at least 21 years of age;
3. CEO I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CEO I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CEO I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CEO I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CEO I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Connor O'Neal

Print Name (First, Last)

→ Original Signature (electronic, copies or stamps not accepted)

10-31-2025

→ Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Connor O'Neal

Print Name (First, Last)

→ Original Signature (electronic, copies or stamps not accepted)

10-31-2025

→ Date

Please have this section completed in the presence of a Notary Public.

State of IN, ss. County of Johnson

I, Connor O'Neal, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

→ **Original Signature**

10-31-2025

→ **Date**

Subscribed and Sworn to before me this 31st day of October, 2025.

Renessa Troyer

→ **Notary Public Signature**

RENESSA TROYER
Notary Public - Seal
Johnson County - State of Indiana
Commission Number NP0749697
My Commission Expires Jun 20, 2031

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Langham Logistics, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 5335 W 74th Street

City Indianapolis State IN Zip 46268

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855-214-2844 Website elangham.com

Licensing Company Email LL@iqvia.com

Section 2: Personal Information

First Catherine Middle Ann Last Langham

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 5335 W 74th Street

City Indianapolis State IN Zip 46268

Telephone 855-214-2844 Email cathylangham@elangham.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
North Central HS		1973-1976	
Address	**City**	**State**	**Zip**
1801 E 86th Street	Indianapolis	IN	46240
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Indiana University		1977-1980	
Address	**City**	**State**	**Zip**
107 S Indiana Ave	Bloomington	IN	47405
Diploma/Degree obtained, if any			
BS Marketing			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10+yrs	[redacted]	Carmel	IN	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Langham Logistics, Inc.			1988 - Current	
Business Address		**City**	**State**	**Zip**
5335 West 74th St.		Indianapolis	IN	46268
Phone	**Title**			
855-214-2844	Founder, CEO			
Description of Duties				
Business Leader and Public Board member with extensive experience in business growth, strategic advancement, and team development. Found/CEO of Langham Logistics, Inc. and successfully led the company to become a $100+ million global transportation and warehousing enterprise.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

→ Catherine Langham
Original Signature (electronic, copies or stamps not accepted)

→ 2/17/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Catherine Langham

Print Name (First, Last)

→ Catherine Langham — 2/17/2026

Original Signature (electronic, copies or stamps not accepted) → Date

---

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Hamilton

I, Catherine Langham, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

→ Catherine Langham — 2/17/2026

Original Signature → **Date**

Subscribed and Sworn to before me this 27 day of February.

→ **Notary Public Signature**



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Langham Logistics, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 5335 West 74th Street

City Indianapolis State IN Zip 46268

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855-214-2844 Website elangham.com

Licensing Company Email LL@iqvia.com

Section 2: Personal Information

First John Middle Henry Last Langham

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 5335 W 74th Street

City Indianapolis State IN Zip 46268

Telephone [redacted] Email johnlangham@elangham.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northwestern University		1989	
Address	**City**	**State**	**Zip**
633 Clark St	Evanston	IL	60208
Diploma/Degree obtained, if any			
Masters Degree			

School Name		From - To (MM/YY – MM/YY)	
Indiana University		1978	
Address	**City**	**State**	**Zip**
107 S Indiana Ave	Bloomington	IN	4745
Diploma/Degree obtained, if any			
Bachelors of Science			

School Name		From - To (MM/YY – MM/YY)	
North Central High School		1974	
Address	**City**	**State**	**Zip**
1801 E 86th St	Indianapolis	IN	46240
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2019-Present	[redacted]	Carmel	IN	[redacted]
1996-2019		Carmel	IN	

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Langham Logistics Inc.			1990 - Present
Business Address	**City**	**State**	**Zip**
5335 West 74th Street	Indianapolis	IN	46268
Phone	**Title**		
1-855-214-2844	Owner/VP		

Description of Duties

Developed, managed and served on Board of Langham Logistics, Inc. for 35+ years. Oversaw revenue growth to $120M. Implemented strategic growth plans, advanced operational automation, effective team management and innovative customer service plans. Extensive management in areas such as accounting, finance, warehouse operations, freight operations, quality, human resources, new customer on boarding and information technology.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

→ Original Signature (electronic, copies or stamps not accepted)

→ Date 2/18/26

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Langham

Print Name (First, Last)

→ Original Signature (electronic, copies or stamps not accepted)

→ Date 2/18/26

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Hamilton

I, John Langham, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

→ **Original Signature**

→ **Date** 2/18/26

Subscribed and Sworn to before me this 27 day of February.

→ **Notary Public Signature**



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Langham Logistics, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 5335 W 74th Street

City Indianapolis State IN Zip 46268

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855-214-2844 Website elangham.com

Licensing Company Email LL@iqvia.com

Section 2: Personal Information

First Margaret Middle _____ Last Langham

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 5335 W 74th Street

City Indianapolis State IN Zip 46268

Telephone [redacted] Email margaretlangham@eLangham.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
IUPUI		09/79 – 06/83	
Address	City	State	Zip
755 W MICHIGAN ST	INDIANAPOLIS	IN	46202
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
NORTH CENTRAL		09/76 – 06/79	
Address	City	State	Zip
1801 E. 86TH ST	INDIANAPOLIS	IN	46240
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2013 - Current	[redacted]	Carmel	IN	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Langham Logistics Inc.			07/88 - Present
Business Address	**City**	**State**	**Zip**
5335 W 74th St	Indianapolis	IN	46268
Phone	**Title**		
317-471-5122	Vice President		
Description of Duties			
OWNER BOARD MEMBER			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

→ _____ Original Signature (electronic, copies or stamps not accepted)

→ 26FEB2026 Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Margaret Langham

Print Name (First, Last)

→ Original Signature (electronic, copies or stamps not accepted)

→ Date: 26 FEB 2026

Please have this section completed in the presence of a Notary Public:

State of Indiana, ss. County of Hamilton

I, Margaret Langham, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

→ **Original Signature**

→ **Date**: 26 FEB 2026

Subscribed and Sworn to before me this 26 day of February 2026

→ **Notary Public Signature**

MARY C BULLARD
Notary Public
Hamilton County - State of Indiana
Commission Number NP0759828
My Commission Expires Nov 6, 2032

(Seal)

4Q

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03321	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: On Target Laboratories, Inc.

Physical Address: 1281 Win Hentschel Blvd Suite 2542

City: West Lafayette State: IN Zip: 47906

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 765-588-4547 Website: https://ontargetlabs.com/

Name of Designated Representative (DR): Pravin Gagare

Licensing Company Email: afornicola@ontargetlabs.com DR Email: pgagare@ontargetlabs.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies ■ Practitioners ■ Hospitals ☐ Wholesalers ☐ Veterinarians ☐ Others:	■ Dangerous Drugs ☐ Controlled Substances ☐ [a]Medical devices, equipment, supplies, gases ☐ Others:	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ■ Retail pharmacy wholesale distributor ☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: RxCrossroads 3PL LLC
Address: 5101 Jeff Commerce Dr City: Louisville State: KY Zip: 40219
Name: Fisher Clinical Services Inc.
Address: 7554 Schantz Rd. City: Allentown State: PA Zip: 18100
Name: Grand River Aseptic Manufacturing
Address: 140 Front Ave SW City: Grand Rapids State: MI Zip: 49506
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): N/A
Corporation/Organization Name: On Target Laboratories, Inc.
Mailing Address: 1281 Win Hentschel Blvd., Suite 2542
City: West Lafayette State: IN Zip: 47906-4357
Telephone: 765-588-4547 Email: cbrisson@ontargetlabs.com
Contact Person Name: Catherine Brisson

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration Virtual Manufacturer; Labeler Code: 81052; NDA: 214907 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

On Target Laboratories, Inc.

Facility Name

Roderick McLeod

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

12/19/25

Date

Board Use Only	Date Received: 3/9/26	Amount: $1000-EK 1000001520

NABP ACCREDITED
DRUG DISTRIBUTOR

On Target Laboratories, Inc.

located at

1281 Win Hentschel Blvd, Ste 2542 West Lafayette, IN, 47906

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

0796

Accredited Drug Distributors

Find an Accredited Drug Distributor

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

<<Previous 1 2 3 4 5 6 7 Next >>

Name	Address	Accreditation Date
LifeScience Logistics, LLC	2128 Gateway Point Clayton, IN 46188	12/08/25
LifeScience Logistics, LLC dba LifeScience Logistics	1105 E Northfield Dr Brownsburg, IN 46112	01/11/25
MD Logistics LLC	1301 Perry Rd Plainfield, IN 46168	04/26/25
MD Logistics, LLC	2150 Stanley Rd, Ste 100 Plainfield, IN 46168	03/31/25
Medline Industries, LP	251 Hilton Drive Jeffersonville, IN 47130	04/15/25
Midwest Veterinary Supply, Inc	6251 Innovation Blvd Fort Wayne, IN 46818	01/11/26
MWI Veterinary Supply Co dba MWI Animal Health	5025 State Route 267 Lebanon, IN 46052	09/14/23
Northwind Health Company, LLC	4838 Fletcher Ave, Ste 1000 Indianapolis, IN 46203	07/06/23
On Target Laboratories, Inc.	1281 Win Hentschel Blvd, Ste 2542 West Lafayette , IN 47906-4357	08/17/25
Patterson Dental Supply, Inc	6110 Technology Center Dr Ste 100 Indianapolis, IN 46278	09/28/24

<<Previous 1 2 3 4 5 6 7 Next >>

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Contact

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Live Chat

On Target Laboratories, Inc.			
Ownership Prior to 10/1/25 (OLD)			
Name	**Title**	**Address**	**Percent Owned**
On Target Investments, LLC (Hurvis)	Owner	160 Paloma Dr, Coral Gables, FL, 33143-6545	38.98%
Pension Fund of the Christian Church	Owner	1099 N Meridian St #720, Indianapolis, IN 46204	13.92%
Purdue / Cook Fund	Owner	1281 Win Hentschel Blvd., West Lafayette, IN 47906	0.49%
Foundry Investment Fund, LLC	Owner	1281 Win Hentschel Blvd., West Lafayette, IN 47906	
J&J Innovation, JJDC	Owner	255 Main St, Cambridge, MA 02142	21.13%
3B Future Health Fund S.A. SICAR	Owner	Boulevard de la Foire L-1526 Luxembourg, Grand Duchy of Lu	2.23%
Elevate Ventures	Owner	50 E 91st St #213, Indianapolis, IN 46240	2.98%
HIG	Owner	500 Boylston Street, 20th Floor, Boston, MA 02116	11.15%
PSL Investments, LLC	Founder	5840 Farm Ridge Road, West Lafayette, IN 47906	7.60%
On Target Laboratories, Inc. Employees			1.52%
			100.00%

* Less than 3% of entity ownership consists of individually owned non-voting profit interests

On Target Laboratories, Inc.			
Ownership Effective 10/1/2025 (CURRENT)			
Name	**Title**	**Address**	**Percent Owned**
On Target Investments, LLC (Hurvis)	Owner	160 Paloma Dr, Coral Gables, FL, 33143-6545	34.75%
Pension Fund of the Christian Church	Owner	1099 N Meridian St #720, Indianapolis, IN 46204	12.24%
Foundry Investment Fund, LLC	Owner	1281 Win Hentschel Blvd., West Lafayette, IN 47906	0.32%
J&J Innovation, JJDC	Owner	255 Main St, Cambridge, MA 02142	18.48%
3B Future Health Fund S.A. SICAR	Owner	Boulevard de la Foire L-1526 Luxembourg, Grand Duchy of Lu	1.95%
Elevate Ventures 21st Century Fund	Owner	50 E 91st St #213, Indianapolis, IN 46240	1.60%
HIG	Owner	500 Boylston Street, 20th Floor, Boston, MA 02116	9.80%
PSL Investments, LLC	Founder	5840 Farm Ridge Road, West Lafayette, IN 47906	0.58%
On Target Laboratories, Inc. Employees	Owner		18.33%
Olympus Innovation Ventures, LLC	Owner	800 West Park Drive, Westborough, MA 01581	1.20%
Indiana Angel Network Fund, LLC	Owner	1 Virginia Ave, Suite 200, Indianapolis, IN 46204	0.75%
			100.00%

** The two new owners have been highlighted in green.

Name	Title	DOB	Business Address	Email
Stanley William (Bill) Peters	President & CEO	[redacted]	1281 Win Hentschel Blvd. Suite 2542 West Lafayette, IN 47906-4357	bpeters@ontargetlabs.com
Rodney MacLeod	CFO	[redacted]	1281 Win Hentschel Blvd. Suite 2542 West Lafayette, IN 47906-4357	rmacleod@ontargetlabs.com

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ON TARGET LABORATORIES, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF APRIL, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "ON TARGET LABORATORIES, INC." WAS INCORPORATED ON THE TENTH DAY OF FEBRUARY, A.D. 2014.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5479545 8300

SR# 20251521336

Authentication: 203417070

Date: 04-11-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. NV5967188

Application/License No. _____

On Target Laboratories, Inc (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1281 Win Hentschel Blvd, Suite 2542 West Lafayette, IN 47906 (Address of Applicant/Principal), as PRINCIPAL, and Merchants Bonding Company (Mutual) (Surety Company), a corporation organized under the laws of the state of Iowa (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 6700 Westown Parkway, West Des Moines, IA 50266 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 14, 2022 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 14th day of July, 20 22.

APPLICANT/PRINCIPAL COMPANY

On Target Laboratories, Inc

Authorized Representative

SURETY

Merchants Bonding Company (Mutual)

Surety Company's Representative

Kerri Hatton-Rudnik, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Rita Carlson

Witness Tracy Chehoski

Countersigned by:

Nevada Resident Agent Countersignature Law Repealed

LP 2079 NV (5/21)

Posted February 20, 2020

MERCHANTS
BONDING COMPANY.

POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

Kerri Hatton-Rudnik

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the following By-Laws adopted by the Board of Directors of Merchants Bonding Company (Mutual) on April 23, 2011 and amended August 14, 2015 and adopted by the Board of Directors of Merchants National Bonding, Inc., on October 16, 2015.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner-Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 14th day of July , 2022

MERCHANTS NATIONAL BONDING, INC. -o- INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.

By Larry Taylor
President

STATE OF IOWA
COUNTY OF DALLAS ss.
On this 14th day of July 2022 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC.; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL IOWA
POLLY MASON
Commission Number 750576
My Commission Expires
January 07, 2023

Polly Mason
Notary Public

(Expiration of notary's commission does not invalidate this instrument)

I, William Warner, Jr., Secretary of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 14th day of July , 2022

MERCHANTS NATIONAL BONDING, INC. -o- INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

William Warner Jr.
Secretary

POA 0018 (1/20) For bond verification contact verify@merchantsbonding.com

MERCHANTS BONDING COMPANY (MUTUAL)
P.O. BOX 14498, DES MOINES, IOWA 50306-3498
PHONE: (800) 678-8171 FAX: (515) 243-3854

COMMERCIAL BOND APPLICATION

Bond No. NV5967188

Applicant (Exactly as it will appear on bond) On Target Laboratories, Inc					
Home Address					Single ☐ Married ☐ Legal Domestic Partner ☐
City	State	Zip	Phone	FEIN/Social Security #	
Home E-mail		Business E-mail			
Business Address 1281 Win Hentschel Blvd, Suite 2542		City West Lafayette	State Indiana	Zip 47906	
Type of Business or Individual's Occupation		Type of Organization Individual ☐ Partnership ☐ LLC ☐ Corporation ☐		How long in business?	
Name & Address of Owner or Co-Applicant or Indemnitor			Social Security #	% of Ownership	
Name & Address of Owner or Co-Applicant or Indemnitor			Social Security #	% of Ownership	
Obligee Name & Address State of Nevada and Nevada State Board of Pharmacy	Type of Bond	Amount of Bond $ $100,000.00	Effective Date July 14, 2022		
Previous Surety ☐ Yes ☐ No If Yes, give name and reason for change:		Other Surety Bonds in force? ☐ Yes ☐ No If Yes, provide name of Surety:			

Has the applicant had any bankruptcies, liens, or judgments or compromises with any creditors in the past 5 years? ☐ Yes ☐ No If Yes, submit for underwriting.

NOTICE: The undersigned individual(s) hereby gives consent to MERCHANTS BONDING COMPANY (MUTUAL), and it subsidiaries, to obtain a consumer credit report about the individual in connection with this application for insurance. This authorization extends to subsequent consumer credit reports obtained for the purpose of reviewing, increasing the amount of, or any other legitimate purpose associated with the bond.

INDEMNITY AGREEMENT

This Agreement entered into by and between the undersigned applicant or applicants and/or indemnitors, hereinafter called the undersigned, and Merchants Bonding Company (Mutual), hereinafter called the Company, witnesseth:

The undersigned certifies that the foregoing statements and declarations are true and, in consideration of the Company executing as surety the herein bond applied for, does hereby promise and agree to pay an annual premium to the Company until such time as the undersigned shall furnish the Company with evidence satisfactory to it of the complete termination of its liability on said bond.

The undersigned further agrees to indemnify and save harmless the said Company, in connection with any bond executed on behalf of the person or entity named as applicant, for, from and against any and all losses, costs, damages and expenses of any nature whatsoever, including counsel fees and expenses, and reimburse said Company for loss adjusting expenses and compensation at the rate of $100.00 per day for officers and $50.00 per day for all other personnel, which may accrue to the said Company by reason of the said Company having become surety on said bonds.

The undersigned hereby further agrees that the vouchers or other evidence of payments made by the said Company under its obligation of suretyship shall be conclusive evidence against the undersigned of the fact and extent of the undersigned's liability to the said Company under said obligation of the undersigned, whether said payments were made to discharge a penalty thereunder, incurred in the investigation of a claim made thereon or adjusting a loss or claim in connection therewith, or in completing the work covered thereby, and whether voluntarily made or paid after suit and judgment against said Company.

If the Company shall set up a reserve to cover any claim, suit or judgment under any such bonds, the undersigned will, immediately upon demand, deposit with the Company a sum of money equal to such reserve, such sum to be held by the Company as collateral security on such bonds, and such sum and any other money or property which shall have been, or shall hereafter be, pledged as collateral security on any such bond shall, unless otherwise agreed in writing by the Company, be available, in the discretion of the Company, as collateral security on any other bonds coming within the scope of this Agreement.

This Agreement shall constitute a Security Agreement to the Company and also a Financing Statement, both in accordance with the provisions of the Uniform Commercial Code of every jurisdiction wherein such Code is in effect. This Agreement shall, if recorded, constitute a consensual lien upon any and all real estate owned by the undersigned at the time of such recording. However, the filing or recording of this Agreement shall be solely at the option of the Company, and the failure to do so shall not release or impair any of the obligations of the undersigned under this Agreement or otherwise arising, nor shall such failure be in any manner in derogation of the rights of the Company under this Agreement or otherwise. The use of this Agreement as a Security Agreement, Financing Statement or consensual lien shall in no way abrogate, restrict or limit the rights of the Company under this Agreement or at law or in equity. The undersigned waive all right to claim any property, including homestead, as exempt from levy, execution, sale or other legal process.

It is further agreed that the terms and conditions of this application shall also apply to increases and/or decreases in the amount of any and all bonds, and shall also apply to all renewals whether the bond is continuous, renewed by Continuation Certificate or by the filing of a new bond.

The Company shall have the right, and is hereby authorized, but not required to fill up any blanks left herein, and to correct any errors in the description of any of said bonds, or in said premium or premiums, or in any name or names, it being agreed that such insertion or corrections, when so made, shall be prima facie correct. This application shall be liberally construed so as to fully protect and indemnify the Company, its successors, assigns and reinsurers. The undersigned appoints any officer of the Company as the attorney-in-fact of the undersigned with full right to execute on behalf of the undersigned any document necessary to carry into effect the intent and purposes of this Agreement.

A facsimile copy of this document or the signature(s) thereon, shall be deemed to be an original and/or original signature(s) for all purposes.

Dated the 14th day of July 2022 **Sign Application Twice - as Applicant and Indemnitor**

Witness _____ Applicant's Signature _____

In consideration of the MERCHANTS BONDING COMPANY (Mutual) executing the bond herein applied for, I (we) jointly and severally join in the above indemnity agreement.

Witness _____ Indemnitor _____

Witness _____ Indemnitor _____

Witness _____ Indemnitor _____

Witness _____ Indemnitor _____

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: On Target Laboratories, Inc.
Pharmacy/Wholesaler License # (if applicable): 03321
Physical Address: 1281 Win Hentschel Blvd., Suite 2542
City: West Lafayette State: IN Zip: 47906
Mailing Address (if different from physical address): Same as above
City: State: Zip:
Telephone: 765-588-4547 Website: ontargetlabs.com
Licensing Company Email: afornicola@ontargetlabs.com

Section 2: Personal Information

First: Pravin Middle: Dattatraya Last: Gagare
Alias(es, nicknames, name changes, etc.):
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X
Mailing Address: [redacted]
City: West Lafayette State: IN Zip: [redacted]
Telephone: [redacted] Email: pgagare@ontargetlabs.com
Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Purdue University		2005 - 2010	
Address	**City**	**State**	**Zip**
610 Purdue Mall	West Lafayette	IN	47907
Diploma/Degree obtained, if any			
Ph.D in Chemistry and M.S. in Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Ahmednager College		1997 - 1999	
Address	**City**	**State**	**Zip**
Station Rd, Chandni Chowk, Maharashtra	Ahilyanagar	India	414001
Diploma/Degree obtained, if any			
M.S. Drug Chemistry, Post Graduate School for Biological Studies			

School Name		From - To (MM/YY – MM/YY)	
Rahuri College		1993 - 1997	
Address	**City**	**State**	**Zip**
Tal. Rahuri, Dist. Ahmednagar	Rahuri	India	413 722
Diploma/Degree obtained, if any			
B.S. in Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/17 - present	[redacted]	West Lafayette	IN	[redacted]
From - To (MM/YY – MM/YY)		City	State	
06/15 - 01/17		West Lafayette	IN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
On Target Laboratories, Inc.			01/18 - present	
Business Address		**City**	**State**	**Zip**
1281 Win Hentschel Blvd., Suite 2542		West Lafayette	IN	47908
Phone	**Title**		**Number of Employed Hours**	
765-588-4547	Director		15000+	

Description of Duties

Member of multidisciplinary teams, contributing: project strategy, research activities, analyzing & interpreting data, reviewing documentation. Support CMOs, Support DS/DP related activities, technology transfer & process execution

Business Name			From - To (MM/YY – MM/YY)	
On Target Laboratories, Inc.			06/13 - 12/17	
Business Address		**City**	**State**	**Zip**
1281 Win Hentschel Blvd., Suite 2542		West Lafayette	IN	47908
Phone	**Title**		**Number of Employed Hours**	
765-588-4547	Scientist		9000+	

Description of Duties

Develop targeted near-infrared fluorescence probes for cancer guided surgery; synthesis & biological evaluation of fluorescent imaging agents for prostate-specific membrane antigen. Develop targeted-photodynamic therapeutic agent.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

02/12/2026
Date

I, Pravin Gagare, **certify that as the designated representative for**

On Target Laboratories, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PG I am at least 21 years of age;
3. PG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Pravin Gagare

Print Name (First, Last)

P Gagare

Original Signature (electronic, copies or stamps not accepted)

02/12/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Pravin Gagare

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/12/2026

Date

Please have this section completed in the presence of a Notary Public.

State of INDIANA, ss. County of TIPPECANOE

I, PRAVIN GAGARE, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02/12/2026

Date

Subscribed and Sworn to before me this 12TH day of FEBRUARY 2026

Notary Public Signature

Dan A Lavengood
Notary Public Seal State of Indiana
Tippecanoe County
My Commission Number NP0734623
My Commission Expires 07/05/2029

(Seal)

Officers and Employees
On Target Laboratories, Inc

Officers

Peters, Stanley W,	CEO - Chief Executive Officer
MacLeod, Roderick H,	CFO - Chief Financial Officer

Executive Leadership

Biro, Timothy G,	Head of Product Development
Brisson, Mary C	VP, Regulatory and Quality
Lee, Tommy D	EVP, Clinical Operations
Tillinghast, William C	VP, Sales
Fornicola, Anne J	VP, CMC
Todd, Jessica W	VP, Marketing
Macdonald, Philip A	VP, Market Access, Reimbursement,

Employees

Atchison, Jeremy R
Barrett, Tina S
Blackwell, Brady J
Brohee, Eugene A
Burton, Andrew S
Cirino, Angelo A
Cox, Ashley O
Crosslin, Alison P
Datta Roy, Priyanshu
Desimone, Pamela A
Ecton, Kristina F
Gagare, Pravin D
Hall, Julie M
Hall, Thais S
Hegglin, Troy J
Hutchinson, Justin C
LaScola-Parks, Sarah M
Laswell, Christopher Ian
Lavengood, Dan A
Lee, Crystal
Low, Philip S
Maglaque, Alan M
Mahoney, Madeline E
McCormick, Andrew T
Mooney, Allison D
Munir, Hira
Needham, Keith A
Nelson, Deanna M
Osborn, Alicia L
Precure, Patrick W
Rice, Jeffrey P
Ripp, Kathleen
Schultz, David J

4R

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Patterson Veterinary Supply, Inc.

Physical Address: 1031 Mendota Heights Road, Suite 100

City: Saint Paul State: MN Zip: 55120

Mailing Address (if different from physical address): 1031 Mendota Heights Road, Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 651-686-1600 Website: https://www.pattersonvet.com/

Name of Designated Representative (DR): Ernest Pasillas III

Licensing Company Email: facilitylicensing@pattersoncompanies. DR Email: ernest.pasillas@pattersoncompanies.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Medical Class I & II Devices	☐ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Universities & Research Facilities		■ Others: Virtual Wholesaler

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
Please see attached	

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/5/2025
Date

PATTERSON VETERINARY

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.225.7911

AFFIRMATIVE RESPONSE TO DISCIPLINARY QUESTION(S)

NEVADA

Drug Distribution Agent Application
Patterson Veterinary Supply, Inc.
1031 Mendota Heights Road, Suite 100
Saint Paul, MN 55120

QUESTION: Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?

RESPONSE: Yes.

*The following disciplinary actions are unrelated to this facility and should not be construed as reflective of its operations or personnel.

A. On February 1, 2005, the Kentucky Board of Pharmacy cited Webster Veterinary Supply, Inc., Lexington, KY (license #W01683) for failure to timely notify the board of an ownership change from Milburn Distributors to Webster Veterinary Supply, Inc. Agreement was reached, a fine was paid, and the license was unencumbered.

B. On June 24, 2005, the Florida Department of Health cited Webster Veterinary Supply, Inc. in Ocala, FL (license #22:1462), for operating without a valid permit during the transition from Milburn Distributions (and, consequently, inaccurate pedigree and audit trail information because ownership changed) and for purchasing prescription drugs from an establishment not permitted under the Florida Drug and Cosmetic Act. A civil fine was paid for the violations (case #05-06932). Florida approved Webster Veterinary Supply's application for registration based on the change of ownership.

C. On December 19, 2007, Webster Veterinary Supply, Inc. and Patterson Logistics Services, Inc., Alachua, FL, received notice from the Florida Department of Health Drugs, Devices, and Cosmetics Program of the agency's intent to deny the facility's permit application. The agency alleged that the facility distributed prescription drugs after its permit expired on July 31, 2007, and distributed prescription drugs without providing a complete and accurate pedigree. The audit trail was incomplete as it did not provide the license number of the sources of the drugs distributed from the establishment. An agreement was reached with Patterson Logistics Services, Inc., neither admitting nor denying the allegations, and a fine was imposed. Webster Veterinary Supply, Inc., has since closed.

D. On June 6, 2013, the Maine Board of Pharmacy cited Webster Veterinary Supply, Inc., Devens, MA (license #WH70001724) for violating a Board Rule concerning a 2005 renewal application that failed to convey the 2005 Kentucky discipline referred to above. A consent agreement was

reached, a reprimand and civil penalty were imposed, and the license was issued.

E. On December 21, 2017, the Florida Department of Business & Professional Regulation cited Patterson Veterinary Supply, Inc. (license #221462) for alleged violations of Chapter 499, failure to maintain proper records, and distribution to persons not authorized to receive prescription drugs. PVSI neither admitted nor denied the allegations but entered into a settlement and paid a civil fine of $24,500.

F. On January 6, 2022, the Ohio Board of Pharmacy cited Patterson Veterinary Supply, Inc (PVSI), Grove City, OH (license #01-2037250, - closed October 29, 2021) for sales of dangerous drugs, including controlled substances, to entities that did not possess an active Ohio Terminal Distributor of Dangerous Drugs license at the time of the sales, the statutes and regulations in Ohio require prescriber practices, such as veterinary and dental clinics, to obtain a Terminal Distributor of Dangerous Drugs (TDDD) license to purchase prescription drugs as a business. This contrasts with most states, where prescription drugs are obtained by an individual with a practitioner license issued by that state. At the time of sale, the practitioners practicing at these locations had active licenses in Ohio. Patterson updated their systems to ensure that expiration dates for the TDDD licenses and practitioners' licenses were validated. In addition, the Board alleged that PVSI failed to enter a change of its responsible person in the Ohio Board of Pharmacy's online system in a timely manner. Patterson Veterinary Supply, Inc. received a written reprimand and paid a civil monetary penalty of $3,125 on January 7, 2022. The Grove City, Ohio, location has since ceased operations for reasons unrelated to these allegations and has surrendered all licenses.

G. On January 6, 2022, the Ohio Board of Pharmacy cited Patterson Veterinary Supply, Inc., Phoenix, AZ (license # 01-1988450) for sales of dangerous drugs, including controlled substances, to entities that did not possess an active Ohio Terminal Distributor of Dangerous Drugs license at the time of the sales, the statutes and regulations in Ohio require prescriber practices, such as veterinary and dental clinics, to obtain a Terminal Distributor of Dangerous Drugs (TDDD) license to purchase prescription drugs as a business. This contrasts with most states, where prescription drugs are obtained by an individual with a practitioner license issued by that state. At the time of these sales, the practitioners practicing at these locations had active licenses in Ohio. Patterson updated their systems to ensure that expiration dates for the TDDD licenses and practitioners' licenses were validated. Patterson Veterinary Services. On January 7, 2022, Patterson Veterinary Supply, Inc. received a written reprimand and paid a civil monetary penalty of $6,500.

H. On June 23, 2022, the Utah Division of Occupational and Professional Licensing cited Patterson Veterinary Supply, Inc., Denver, CO (license# 11651073-1710) for failing to notify the board of a change of designated representative in a timely manner. Patterson Veterinary Supply, Inc. received a written reprimand and paid a $1250 fine on July 11, 2022.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: American Regent, Inc.
Address: 26 Precision Dr. City: Shirley State: NY Zip: 11967

Name: Clipper Distributing Company LLC
Address: 1302 S. 59th St. City: St. Joseph State: MO Zip: 64507

Name: Elanco US Inc.
Address: 2500 Innovation Way City: Greenfield State: IN Zip: 46140

Name: Merial Limited (Boehringer Ingelheim Animal Health USA Inc)
Address: 5701 Providence Hill Dr. City: St. Joseph State: MO Zip: 64503

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota
Parent Company (if any): Patterson Companies, Inc.
Corporation/Organization Name: Patterson Veterinary Supply, Inc.
Mailing Address: 1031 Mendota Heights Road
City: Saint Paul State: MN Zip: 55120
Telephone: 651-686-1600 Email: facilitylicensing@pattersoncompanies.com
Contact Person Name: Kelley Karau

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Patterson Veterinary Supply, Inc.

Facility Name

George L. Henriques

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/5/2025

Date

Board Use Only	Date Received: 11/10/25	Amount: $1000.00

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 04-0115

IN RE: WHOLESALER PERMIT NO. W01683 HELD BY WEBSTER VETERINARY SUPPLY

Agreed Order

Come the parties, the Kentucky Board of Pharmacy ("the Board") and Webster Veterinary Supply ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Pursuant to Chapter 315 of the Kentucky Revised Statutes, the Board is authorized to regulate and control all matters related to pharmacists and pharmacies not delegated to another agency of the Commonwealth.

(2) Respondent is a wholesaler in the Commonwealth of Kentucky, having been assigned pharmacy permit no. W01683.

(3) (a) On or about December 3, 2004, the Board received an *Application for Drug Wholesaler* wherein the Respondent indicated an new wholesaler. However, respondent had purchased Millburn Distributors located at same address on or about October 15, 2004.

(b) Since permits are issued only for the premises and persons named in the application and are not transferable under 201 KAR 2:050 Section 1(13), and Respondent operated a wholesaler effective October 15, 2004, but did not notify of a ownership change until December 3, 2004, Respondent operated a wholesaler without having first obtained a permit, in violation of KRS 315.036(1).

(c) The above facts subject Respondent to discipline pursuant to KRS 315.121(1)(h).

(4) The Board and the Respondent have agreed to address this matter by entering into this Agreed Order, in lieu of the filing of a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) The Respondent is FINED $500 payable on or before March 2, 2005. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, 23 Millcreek Park, Frankfort, Kentucky 40601.

(B) By entering into this Agreed Order, the Respondent expressly acknowledges that it was fully and completely informed of its right to due process, that it fully understands those rights, and that it knowingly, voluntarily, and willingly agrees to waive those rights and to enter this Agreed Order.

(C) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Mark Edwards, President
Kentucky Board of Pharmacy

2/9/05
Date

Webster Veterinary Supply
Respondent

2/14/05
Date

Webster Veterinary Supply, Inc.
86 Leominster Road, Sterling, Massachusetts 01564 • Phone: (978) 422-8211 • Fax: (978) 422-8959

AGREEMENT
Case No: 05-06932
Current Permit No: 22:01462

Milburn Distribution, Inc., by and through its president / chief executive officer, Jeffrey H. Webster, hereby agree to pay a fine of Four Thousand Dollars ($4,000) and submit corrective action documentation. By signing this Agreement, Milburn Distribution, Inc., agrees to waive its right to a hearing under Chapter 120, Florida Statutes related to this Notice of Violation Letter.

I am fully authorized to bind Milburn Distribution, Inc., to the terms of this Agreement. I hereby affirm the violations cited in this letter have been corrected and that I, Milburn Distribution, Inc., will comply with all provisions of the Florida Drug and Cosmetic Act, Chapter 499, F.S., and the rules adopted thereunder.

Corporate Seal:

by: _____ 7/25/05
President / CEO — Date

attested by: _____ 7/27/05
Corporate Secretary — Date

From: Tom Burke Operations Manager Millburn Distributions, Inc.
To: Mary Mayleben, Pharm. D. Regional Drug Agent
Re: Inspection of Millburn Distributions, Inc. Ocala, Fl.
4-28-05

Ms. Mayleben,

I would like to preface my response by saying that Millburn Distributions, Inc. will do whatever is necessary to correct any problems areas that you discovered on your inspection of our Ocala, Florida warehouse. In the past 4 years of our doing business in the State of Florida and past inspections that were done, I hope that you have seen we have always been above reprue. I will respond to each remark you listed on the inspection to the best of my ability. Please let me know if there is any further action required.

We take these matters very seriously and are correcting them hopefully to your satisfaction. No intent was made to violate the laws of the State of Florida. These are matters that can be corrected immediately.

1) *Name change was verified by me to you on 4-19-05*
2) *A work order to Sunbelt Computers was initiated on 4-22-05 to change the name on all Purchase Orders and Invoices to reflect the Ocala, Florida warehouse address. I will fax a copy of this work order to you. Notice on the work order that it will take 2-3 weeks for the change to happen. You had told me that it would be alright to put Ocala address labels over the Arizona address until that took place. If that is still o.k. let me know and that will be done immediately. The address change will also include our permit number for the State of Florida. We complied with a request to include the veterinarian's license number shortly after we started doing business there almost 4 years ago.*
3) *We are a veterinary wholesale distributor*
4) *Customer base is the veterinarian*
5) *Area of coverage is correct with what you have written down*
6) *Barb Champion is our designated rep. There*
7) *Our RX audit trail will be corrected with the correction of our address on the invoice and also with our purchasing department verifying that each vendor that we but prescription drugs from whether human or veterinary is licensed in the State of Florida via your state's website.*
8) *We sell to licensed veterinary doctors and are proactive in making sure the licenses are checked monthly.*
9) *In the case of Truxton with the Ampicillin product, I verified with Bob Smith of Truxton that they are in the process of becoming licensed in Florida. We voluntarily transferred the product out of the Florida warehouse to one of our other warehouses. We will not carry the Truxton product until they are compliant and licensed in Florida.*
10) *We will make sure that all vendors are licensed with the State of Florida and that if we purchase from a wholesaler that they are listed as an ADR of the vendor to also insure compliance.*

04/22/2005 14:05 FAX 928 928 8821 MILLBURN DISTRIBUTIONS + FL 002/002

11) *The Pliva manufacturer problem was handled by making a* call to Jim Miller who is the purchasing agent for Phoenix Pharmaceutical in St. Joseph, Missouri. Pliva is listed in the State of Florida and Bloodworth is an ADR for Pliva, but Phoenix Pharmaceutical is not on the list. Phoenix Pharmaceutical will ask for pedigree papers until they get listed under Bloodworth and Pliva.

12) *I will also fax to you the correction to our Policy and Procedure manual for the Ocala, Florida warehouse. I hope it meets with your approval.*

Respectfully,

Jan Rabi

1. RECEIPT
   A. All vendors that we purchase from are long-standing, established companies that abide by every state's drug laws.
   B. DEA labeled prescription drugs will be accepted and received by one of two people: Rene Hunter or Patty Navarro. Other inventory items will be accepted and received by Renee Hunter, Patty Navarro or Chris Brouelette. A visual inspection of incoming merchandise will ensure that the product is acceptable to put in our stock for sale. We will rely upon vendors to inform us of any potential problem with their products.
   C. Packing slips or invoices from our vendors with the correct purchase order number on them will be matched with our purchase order. We list product code numbers, description, unit size and any other information necessary for the accurate receipt of every item. If items are lot tracked, we make provisions for that. Expiration dates are recorded at time of receipt for dating purposes. Inventory is placed on the shelf and rotated by expiration date. We maintain these records indefinitely.
   D. Pedigree papers will be required for any and all human or veterinary prescription drugs. All vendors will be checked against the Florida Department of Health website to verify that they are licensed in the state of Florida. Any vendor not on the list will not be stocked or offered for sale. This will be accomplished through our purchasing department's vigilant effort to make sure we are compliant.

2. STORAGE
   A. Our warehouse is air-conditioned and therefore all doors remain closed unless we are receiving merchandise. All extra waste shall be removed on a daily basis. Waste consists of cardboard and general trash. Our warehouse floor is sealed so as to block any concrete dust from coming to the surface. We have sweeping mops and brooms that will be used along with sweeping compound to keep the floors free of dust. The facility staff to maintain a proper appearance and cleanliness will perform all housekeeping duties.
   B. We have contracted with a pest control company that will establish inside and outside controls to keep us pest free. Being a wholesaler, we do not manufacture, nor do we open any sealed containers and expose product to outside sources.
   C. DEA controlled prescription drugs will have their own security cage that they will remain locked in. All other product will be stored in the warehouse on regular inventory shelves. We have a security system that is activated at night and weekends when the facility is closed. It is monitored 24 hours a day, 7 days a week. All outside warehouse doors will remain locked unless we need to open them to receive merchandise. We will rely on the honesty and integrity of our facility manager and our employees to ensure these steps are adhered to.
   D. DEA labeled prescription drugs will be locked up in their own security cage and will only be put in the cage or taken out by Rene Hunter or Patty Navarro. Patty Navarro or Chris Brouelette will access the remaining inventory. The above named employees are the only authorized persons to handle the inventory. Any visitors to the facility will be escorted by one of these individuals.
   E. All temperature requirements are closely monitored for each item. Any product that needs to be stored at 46° or lower goes into our cooler. Our cooler has a temperature gauge built into the wall of the cooler. We also have a secondary gauge which monitors the inside cooler temperature, outside cooler temperature, and humidity. Any product that needs to go in the cooler clearly states a temperature range on the product label. The balance of remaining product consistently has a temperature range not to exceed

PATTERSON COMPANIES, INC.

Patterson Companies, Inc.
1031 Mendota Heights Road
St. Paul, MN 55120
651 / 686-1600

[redacted]

Vendor # 34628 Vendor Name: DRUGS, DEVICES AND COSMETICS T Check Date: 07/15/05

Invoice No.	Date	Description	P.O. No.	Gross Amount	Discount Amount	Net Amount
[redacted]	07/11/05	VIOLATION NOTICE	* 820	$ 4,000.00		$ 4,000.00

Final Order No. DOH-09-1234-S-MQA
FILED DATE - 6.30.09
Department of Health
By: Rachel Bh
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

Patterson Logistics Services, Inc., and Webster Veterinary Supply, Inc.,
Petitioners,
vs.
Department of Health; Drugs, Devices, & Cosmetics Program;
Respondent.
_____/

DOH case no.: 2007-11284
DOAH case no.: 08-0840
Permit type: 2322

FINAL ORDER

This proceeding was initiated by a petition of January 9, 2008, requesting a formal administrative hearing to challenge the Department of Health's intent to deny an application for a permit to operate a prescription drug wholesaler establishment pursuant to the ***Florida Drug and Cosmetic Act***, Part I, Chapter 499, Florida Statutes. The Petitioners were notified of the Department's denial decision by letter dated December 19, 2007; which is identified as exhibit I and incorporated by reference.

Subsequently, the parties resolved this matter in a settlement agreement as amended, identified as exhibits II and III, respectively, and incorporated by reference. The parties request that this proceeding be closed based on their settlement agreement as amended. Also, closed and made public based on the settlement agreement as amended is investigative case number 2007-11284.

Based on the foregoing, the settlement agreement as amended is accepted, and the parties are directed to comply with it.

DONE and ORDERED this 16 day of June 2009 in Tallahassee, Florida.

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General

By: Jean L. Kline
Jean L. Kline, R.N., B.S.N., M.P.H.
Deputy Secretary for Health

Copy furnished to each of the following:

Shannon B. Hartsfield, Esquire
Holland & Knight, LLP
Post Office Drawer 810
Tallahassee, Florida 32302-0810

Gary L. Asbell, Esquire
Department of Health
4052 Bald Cypress Way, bin A-02
Tallahassee, Florida 32399-1703

Rebecca R. Poston
Department of Health
Drugs, Devices, & Cosmetics Program
4052 Bald Cypress Way, bin C-19
Tallahassee, Florida 32399-1739

CERTIFICATE OF SERVICE

I CERTIFY that a copy of the foregoing Final Order has been served by ordinary mail via the United States Postal Service, hand delivery, or by inter-office mail to each of the above named persons this 10 day of June 2009.

Deputy Agency Clerk
Department of Health
4052 Bald Cypress Way, bin C-01
Tallahassee, Florida 32399-3251
phone: (850)245-4121

STATE OF FLORIDA
DEPARTMENT OF HEALTH

PATTERSON LOGISTICS SERVICES, INC.,
and WEBSTER VETERINARY SUPPLY, INC.,

Petitioners,

vs. DOH CASE NO.:

DEPARTMENT OF HEALTH,

Respondent.
_____/

SETTLEMENT AGREEMENT FOR FINAL ORDER

IT IS AGREED and STIPULATED by and between Patterson Logistics Services, Inc., (referred to as "Petitioner" or "PLSI") and Webster Veterinary Supply, Inc. (referred to as "Petitioner" or "Webster") and the State of Florida, Department of Health, through its Drugs, Devices and Cosmetics Program (referred to as "Respondent"), collectively referred to as the Parties that:

1. The Department of Health, through its Division of Medical Quality Assurance, Board of Pharmacy/Drugs, Devices and Cosmetics Program ("DDC"), formerly the Bureau of Statewide Pharmaceutical Services, 4052 Bald Cypress Way, Bin C-04, Tallahassee, Florida 32399 is responsible for, among other duties under the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes (the "Act") and the rules adopted thereunder, Fla. Admin. Code Rule 64F-12, the regulation and permitting of prescription drug wholesaling and distributing in and into Florida.

2. On or about July 31, 2007, PLSI submitted an application to Respondent for renewal of a Prescription Drug Wholesaler permit (hereinafter "Application for Permit") to

EXHIBIT
TL

operate under the name Patterson Logistics Services, Inc., at 13510 Martin Luther King Highway, Alachua, Florida 32615 (hereinafter referred to as the "Establishment").

3. On or about December 19, 2007, Respondent notified PLSI that it intended to deny PLSI's Application for Permit (hereinafter referred to as "Notice of Intent"). Petitioners disputed one or more of the Respondent's allegations contained in the Notice and requested an administrative hearing pursuant to Section 120.57(1), Florida Statutes, by timely filing a Petition for Formal Administrative Hearing. The decision concerning transmittal of that Petition has been abated through mutual agreement of the parties, pending settlement of the matters described below.

4. Furthermore, Respondent has one investigation pending against Petitioners identified and assigned Case Number 2007-11284, arising out of Respondent's inspection of Petitioners' customer on or about December 8, 2006.

5. By execution of the Settlement Agreement for Final Order and by the filing of the subsequent Final Order in this cause, the Parties intend to and do resolve all issues pertaining to the pending administrative proceeding and all matters referred to in paragraphs 3 and 4 of this Settlement Agreement for Final Order.

6. PLSI neither admits nor denies the allegations of violations contained in the Respondent's Notice of Intent, or contained in any inspection report generated as a result of any on-site inspection conducted prior to the effective date of this Agreement, or contained in the inspections and reports generated by Respondent's agents in Case Number 2007-11284.

7. Upon entry of the Final Order adopting the Settlement Agreement, Respondent will not seek or attempt to seek further disciplinary action against Webster or PLSI based on any of the alleged violations contained in any inspection report generated as a result of any on-site

inspection conducted prior to the effective date of this Agreement, or contained in the inspections and reports generated by Respondent's agents in Case Number 2007-11284, or deny an Application for Permit at the Establishment based on any of the grounds enumerated in Respondent's Notice of Intent and any and all pending matters between the Department and Patterson.

8. Petitioners voluntarily enter into this Settlement Agreement for Final Order. Petitioners waive the right to a hearing in this matter and all further and other proceedings to which either may be entitled by law or administrative rules. Petitioners hereby knowingly and voluntarily waive all rights to challenge or to contest this Settlement Agreement or the Final Order issued by Respondent in any forum now or in the future available to them, including the right to any administrative proceeding, circuit or federal court action, or any appeal.

9. None of the parties will appeal this Settlement Agreement for Final Order, or the Final Order to be issued in this matter, and the parties specifically waive notice of the right to appeal as required by Section 120.569(1), Florida Statutes.

10. This document is a public record and contains information that is routinely published by the Respondent. Upon the filing of this Settlement Agreement and entry of a Final Order by Respondent, the existence of Case Number 2007-11284 and all matters therein are no longer confidential and exempt from public disclosure.

11. Each party to this proceeding shall bear its own costs and attorney fees.

12. This Settlement Agreement is a legal and binding document and is fully enforceable in any court of competent jurisdiction. The signatories hereto represent that they have read this Settlement Agreement and are authorized to execute it on behalf of their respective principals and, as duly designated representatives, to fully bind such principals, as

well as the Parties' successors and assigns. The terms of this Agreement are effective on the date of the last signature below. The Parties shall sign two originals of this Agreement so that each party will have custody of a fully executed original Agreement.

13. This Settlement Agreement is subject to the approval of the State Surgeon General or her designee. Upon her approval, and without further notice, the State Surgeon General or her designee may issue a Final Order providing for the following:

a. Incorporation by reference of all the terms and conditions of this Settlement Agreement for Final Order.

b. The Application for Permit shall be amended by either PLSI or Webster (the applicant shall be referred to in Sections 13 and 14 as "Applicant") by submitting to Respondent a revised application form appropriate for the Applicant's intended activities, showing the Applicant's correct establishment name, including the correct d/b/a name, and the proposed physical address to be located at 13510 Martin Luther King Highway, Alachua, Florida 32615, within 180 calendar days of the effective date of this Settlement Agreement.

c. Petitioners agree that the Applicant shall be required to pass an inspection conducted by Respondent at the Establishment, demonstrating compliance with Chapter 499 Part I, Florida Statutes, and the rules promulgated thereunder applicable to the permit for which they have applied.

d. Respondent agrees to accept and process the renewal applications submitted by PLSI for Prescription Drug Wholesaler and Out-of-State Prescription Drug Wholesaler permits in Jacksonville, Florida and Boone, Iowa, respectively.

e. Respondent further agrees that nothing contained in any Personal Information Statement submitted by the Shift Coordinator in Alachua to date, and no information

received by Respondent as a result of that FBI Identification Record No. 942107LA9 to date will be considered a disqualifying event.

f. In addition, Respondent agrees that the legend drugs in inventory at Alachua, as disclosed on that inventory report attached hereto as Exhibit A and incorporated herein by reference, except controlled substances, may be transferred to Webster Veterinary Supply, Inc. in Ocala for further distribution for veterinary use only. Controlled substances may be transferred to PLSI's Sterling, Massachusetts location, which is authorized by the Drug Enforcement Agency to handle controlled substances, for further distribution for veterinary use only.

g. Upon the filing of the amended Application for Permit under paragraph 13.b., and passing the inspection required by paragraph 13.c., and its subparts, a fine of $25,000.00 shall be paid to Respondent by cashiers check or money order and made payable to the Florida Drugs, Devices and Cosmetics Trust Fund. This fine is unrelated to the usual and customary fees for application and inspection to obtain either a Prescription Drug Wholesaler permit or a Limited Veterinary Prescription Drug Wholesaler permit. The Parties agree that the fine to be paid under this Settlement Agreement encompasses any and all alleged violations described in the Notice of Intent, or contained in any inspection report generated as a result of any on-site inspection conducted prior to the effective date of this Agreement, or contained in the inspections and reports generated by Respondent's agents in Case Number 2007-11284, and satisfies any and all such alleged deficiencies and/or violations.

14. When the terms and conditions set forth in paragraphs 13.b., 13.c. and 13.g. have been satisfied, Respondent shall issue a permit to Applicant at the Establishment.

15. Approval of this Settlement Agreement by the State Surgeon General, issuance of a permit at the Establishment, and entry of a Final Order adopting this Settlement Agreement shall only occur when the terms and conditions set forth in paragraphs 13.b., 13.c. and 13.g. have been satisfied.

16. Upon the filing of this Settlement Agreement as a Final Order and issuance of the permit at the Establishment, Petitioners, as well as any person who may claim by or through either of them, hereby waive, release and discharge the State of Florida, the Department, and any of its employees, attorneys, agents or representatives from all claims arising out of any act or omission in the Department's investigation and permit denial. This release applies to any and all claims of any kind, whether known or unknown, and whether direct, indirect or derivative.

WHEREFORE the Parties request a final order adopting this Settlement Agreement as final agency action.

FOR PATTERSON LOGISTICS SERVICES, INC., AND WEBSTER VETERINARY SUPPLY, INC.

Signature

R. Stephen Armstrong, VP
Printed Name and Title

Dated: 4/24/08

ATTORNEYS FOR PATTERSON LOGISTICS SERVICES, INC., AND WEBSTER VETERINARY SUPPLY, INC.

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Dated: 30 June 2008

FOR THE DEPARTMENT OF HEALTH
Drugs, Devices and Cosmetics Program
4052 Bald Cypress Way, Bin C04
Tallahassee, Florida 32399

Rebecca R. Poston

Rebecca Poston, R. Ph.

Dated: 2 July 2008

ATTORNEY FOR THE DEPARTMENT

Gary L. Asbell, Esquire
Assistant General Counsel
Florida Bar No. 0853615
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Tallahassee, Florida 32399-1703
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Facsimile: 850-413-8743

Dated: 2 July 2008

EXHIBIT A

DC Identity Account	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78360021	SCHIRMEI	ALN	ALCON LABORAT	0	10.79	0	B02	B02-B06		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78491887	ALPHATR/	ABB	ABBOTT LABS	13	10.15	131.95	B06	B06-D02	7/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78384807	BARIUM E	EZM	EZM INC.	8	3.78	30.24	B23	B23-F03	2/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78158803	ROSE BEI	AKO	AKORN INC	6	15.85	93.9	C01	C01-D01	12/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78002352	ESOPHAG	EZM	EZM INC.	8	4.59	36.72	C02	C02-F01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78356085	GONAK 2	AKO	AKORN INC	14	7.16	100.24	C02	C02-G06	12/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78453143	DEX 2.5%	BAX	BAXTER CENTER	1	44.4	44.4	CS	A02-D20	11/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78453143	DEX 2.5%	BAX	BAXTER CENTER	0	44.4	0	CS	A12-B10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454069	DEX 2.5%	BAX	BAXTER CENTER	19	22.22	422.04	CS	A05-C30	4/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454069	DEX 2.5%	BAX	BAXTER CENTER	0	22.22	0	CS	A14-D10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454101	SALINE 0.(	BAX	BAXTER CENTER	42	17.52	735.84	CS	A03-C20	9/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454143	RINGERS	BAX	BAXTER CENTER	2	17.22	34.44	CS	A02-C40	5/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454143	RINGERS	BAX	BAXTER CENTER	0	17.22	0	CS	A07-B20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454309	DEXTROS	BAX	BAXTER CENTER	6	18.75	112.5	CS	A02-B40	8/2/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454309	DEXTROS	BAX	BAXTER CENTER	0	18.75	0	CS	A10-D30		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78542401	SALINE 0.(	BAX	BAXTER CENTER	1	21.8	21.8	CS	A18-A40	12/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78542856	STERILE V	BAX	BAXTER CENTER	0	20.86	0	CS	A16-B60		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78040578	CALPHOS	GLE	GLENWOOD LLC	0	71.27	641.43	D07	D07-F05	10/19/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78427302	VIAL STEF	WVG	WEBSTER GENEF	0	18.66	0	D17	D17-D03LCS		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78455788	RANITIDIN	WVG	WEBSTER GENEF	12	2.53	30.36	D17	D17-C02	2/14/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78441144	MURO 128	YAN	WILLOW BIRCH P	7	19.87	139.09	E05	E05-D02	6/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379063	WATER FI	CAI	CARDINAL HEALT	63	0.59	73.87	E14	E14-F02	5/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78070740	BENZ ALL	XTT	XTTRIUM LABOR/	14	20.25	283.5	G26	G26-E01R	12/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78434476	FAMOTIDI	WVG	WEBSTER GENEF	0	4.78	0	G30	G30-E01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062345	BARIUM E	EZM	EZM INC.	22	18.49	406.78	M13	M13-F01	4/8/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78436053	HUMULIN	YAN	WILLOW BIRCH P	1	34.78	34.78	PQ	CF0-C10	1/8/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78008860	PREDNISC	WVG	WEBSTER GENEF	1	9.57	9.57	94	RETURN	4/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380682	UROCIT-K	WVG	WEBSTER GENEF	3	46.02	138.06	94	RETURN	8/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78455994	DEPO PR(	WVG	WEBSTER GENEF	1	151.43	151.43	94	RETURN	9/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78484037	GABAPEN	WVG	WEBSTER GENEF	8	18.27	146.16	94	RETURN	4/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78011357	MYDRIAC	WVG	WEBSTER GENEF	4	42.75	171	95	NOPAPER	8/24/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78013423	PIROXICA	WVG	WEBSTER GENEF	1	4.4	4.4	95	NOPAPER	3/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78018431	FUROSEN	WVG	WEBSTER GENEF	1	11.9	11.9	95	NOPAPER	7/13/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78013456	DIPHENH	WVG	WEBSTER GENEF	1	26.41	26.41	95	NOPAPER	2/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014126	LACTULOS	WVG	WEBSTER GENEF	14	4.15	58.1	95	NOPAPER	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014415	CLOMIPR/	WVG	WEBSTER GENEF	1	9.34	9.34	95	NOPAPER	7/10/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014449	PREDNISC	WVG	WEBSTER GENEF	10	16.84	168.4	95	NOPAPER	10/27/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025851	CEFAZOLI	WVG	WEBSTER GENEF	1428	0.92	1311	95	NOPAPER	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78064494	NEO POLY	WVG	WEBSTER GENEF	4	18.6	74.4	95	NOPAPER	7/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056379	METRONI	WVG	WEBSTER GENEF	1	26.43	26.43	95	NOPAPER	8/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058213	METOCLO	WVG	WEBSTER GENEF	100	0.75	120	95	NOPAPER	7/26/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058239	METOCLO	WVG	WEBSTER GENEF	1	4.25	4.25	95	NOPAPER	3/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058290	METRONI	WVG	WEBSTER GENEF	2	5.88	11.76	95	NOPAPER	3/3/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058494	DOXYCYC	WVG	WEBSTER GENEF	3	2.75	8.25	95	NOPAPER	9/21/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058502	DOXYCYC	WVG	WEBSTER GENEF	1	18.51	18.51	95	NOPAPER	8/2/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058510	DOXYCYC	WVG	WEBSTER GENEF	1	19.4	19.4	95	NOPAPER	1/10/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058918	GLYCOPY	WVG	WEBSTER GENEF	1	4.5	4.5	95	NOPAPER	3/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058858	ENALAPRI	WVG	WEBSTER GENEF	12	1.37	16.44	95	NOPAPER	2/9/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058874	ENALAPRI	WVG	WEBSTER GENEF	72	1.83	131.76	95	NOPAPER	6/17/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058915	PREDNISC	WVG	WEBSTER GENEF	1	3.42	3.42	95	NOPAPER	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059973	AMINOPH	WVG	WEBSTER GENEF	11	21	231	95	NOPAPER	8/3/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059981	AMINOPH	WVG	WEBSTER GENEF	3	33.85	101.55	95	NOPAPER	11/30/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079021	SMZ TMP	WVG	WEBSTER GENEF	12	25	300	95	NOPAPER	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78053517	AMPICILL	WVG	WEBSTER GENEF	80	4.9	421.4	95	NOPAPER	7/6/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78054053	CHLORPR	WVG	WEBSTER GENEF	19	4.43	70.88	95	NOPAPER	4/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78054524	SUCRALF/	WVG	WEBSTER GENEF	7	13.9	97.3	95	NOPAPER	2/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78055229	TETRACYI	WVG	WEBSTER GENEF	1	30.8	30.8	95	NOPAPER	7/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78055565	PREDNISC	WVG	WEBSTER GENEF	2	9.57	19.14	95	NOPAPER	1/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78320748	PREDNISC	WVG	WEBSTER GENEF	1	32.95	32.95	95	NOPAPER	8/8/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78320852	SOLU MEL	WVG	WEBSTER GENEF	6	4.19	25.14	95	NOPAPER	3/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78321571	ENALAPRI	WVG	WEBSTER GENEF	6	16.21	97.26	95	NOPAPER	12/15/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78326010	PREDNISC	WVG	WEBSTER GENEF	4	17.63	70.52	95	NOPAPER	8/1/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78327547	ATENOLO	WVG	WEBSTER GENEF	2	2.97	5.94	95	NOPAPER	2/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328458	HYDROXY	WVG	WEBSTER GENEF	1	32.23	32.23	95	NOPAPER	3/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78317737	IBUPROFI	WVG	WEBSTER GENEF	1	13.5	13.5	95	NOPAPER	6/27/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78337748	PROPRAN	WVG	WEBSTER GENEF	1	3.08	3.08	95	NOPAPER	5/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78337893	FAMOTIDI	WVG	WEBSTER GENEF	3	7.29	21.87	95	NOPAPER	3/31/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342694	DILTIAZEM	WVG	WEBSTER GENEF	1	2.59	2.59	95	NOPAPER	7/10/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78344348	EPINEPHF	WVG	WEBSTER GENEF	4	0.65	2.6	95	NOPAPER	4/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346231	AMPICILL	WVG	WEBSTER GENEF	5	96.02	480.1	95	NOPAPER	2/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346132	AMOXICILL	WVG	WEBSTER GENEF	4	3	12	95	NOPAPER	7/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78349459	ATROPINE	PHO	PHOENIX PHARM	48	1.46	69.7	95	NOPAPER	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78357186	METOCLO	WVG	WEBSTER GENEF	1	4.84	4.84	95	NOPAPER	2/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78357844	AMOXICIL	WVG	WEBSTER GENEF	2	5.88	11.76	95	NOPAPER	7/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78378071	CALCIUM	WVG	WEBSTER GENEF	2	1.74	3.48	95	NOPAPER	6/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78378164	TRIAMCIN	WVG	WEBSTER GENEF	3	1.2	3.6	95	NOPAPER	5/22/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78378360	TIMOLOL	WVG	WEBSTER GENEF	2	1.38	2.76	95	NOPAPER	9/1/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78378378	NEOSTIGI	WVG	WEBSTER GENEF	7	3.79	26.53	95	NOPAPER	12/26/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78378493	TROPICAM	TOP	TOP RX	1	4.52	4.52	95	NOPAPER	1/16/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78378619	FUROSEM	WVG	WEBSTER GENEF	9	1.75	15.75	95	NOPAPER	9/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78378732	DEXAMET	WVG	WEBSTER GENEF	2	10.87	21.74	95	NOPAPER	1/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78378831	ZANTAC I	WVG	WEBSTER GENEF	1	7.69	7.69	95	NOPAPER	2/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78378972	SOLU MEI	WVG	WEBSTER GENEF	1	11.41	11.41	95	NOPAPER	3/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379980	KETOPRO	TOP	TOP RX	3	7.52	22.56	95	NOPAPER	2/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380138	RANITIDIN	WVG	WEBSTER GENEF	5	3.35	16.75	95	NOPAPER	5/24/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380286	THEOPHY	WVG	WEBSTER GENEF	1	13.75	13.75	95	NOPAPER	3/21/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380559	ETODOLA	WVG	WEBSTER GENEF	2	12.95	25.9	95	NOPAPER	3/25/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380563	HYDROXY	TOP	TOP RX	3	22.42	67.26	95	NOPAPER	6/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380858	FRED SP	TOP	TOP RX	3	3.59	10.77	93	NOPAPER	5/7/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380983	GASTROG	WVG	WEBSTER GENEF	5	66.27	331.35	95	NOPAPER	7/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380097	ZANTAC B	WVG	WEBSTER GENEF	2	50.2	100.4	95	NOPAPER	7/21/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380139	GENTAMI	WVG	WEBSTER GENEF	16	0.97	15.52	95	NOPAPER	2/22/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78381689	PENTOXIF	WVG	WEBSTER GENEF	1	7.45	7.45	95	NOPAPER	8/12/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78397089	ALBUTERI	WVG	WEBSTER GENEF	4	4.21	16.84	95	NOPAPER	7/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78308129	PREDNISO	WVG	WEBSTER GENEF	1	27.68	27.68	95	NOPAPER	7/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414071	ARTIFICIA	PHO	PHOENIX PHARM	24	1.15	27.6	95	NOPAPER	3/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414360	TRIPLE NI	WVG	WEBSTER GENEF	4	14.5	58	95	NOPAPER	1/10/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78427435	UROCIT-K	WVG	WEBSTER GENEF	3	33.19	99.57	95	NOPAPER	10/6/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78429148	DEXAMET	WVG	WEBSTER GENEF	2	29.75	59.5	95	NOPAPER	5/13/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DO Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	Do Restricted List?	Human Label?
883	78429284	FLUOXETI	WVG	WEBSTER GENEF	1	2.77	2.77	95	NOPAPER	1/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78433238	CYCLOSP	WVG	WEBSTER GENEF	2	58	116	95	NOPAPER	1/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78434574	FLUCONA	WVG	WEBSTER GENEF	1	3.25	3.25	95	NOPAPER	2/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78441219	VASOPRE	WVG	WEBSTER GENEF	1	74.89	74.89	95	NOPAPER	3/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78441515	POLYCITR	WVG	WEBSTER GENEF	1	31.5	31.5	95	NOPAPER		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78459758	TIMOLOL I	WVG	WEBSTER GENEF	2	2.93	5.86	95	NOPAPER	4/7/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78459020	HYDROCC	CKH	CK HEALTHCARE	7	10.25	71.75	95	NOPAPER		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78455882	METHOCA	WVG	WEBSTER GENEF	24	24.5	588	95	NOPAPER	1/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466680	NAPROXE	WVG	WEBSTER GENEF	1	4.74	4.74	95	NOPAPER	3/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466678	NAPROXE	WVG	WEBSTER GENEF	3	17.89	53.67	95	NOPAPER	12/16/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465804	DEPO PRO	WVG	WEBSTER GENEF	6	151.43	908.58	95	NOPAPER	8/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465902	FLOVENT	WVG	WEBSTER GENEF	1	169.18	169.18	95	NOPAPER	7/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78458936	TRIAMCIN	WVG	WEBSTER GENEF	2	9.04	18.08	95	NOPAPER	1/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466043	AMPICILLI	WVG	WEBSTER GENEF	11	99.6	1095.6	95	NOPAPER	4/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78470803	PEN G PO	WVG	WEBSTER GENEF	52	15.1	785.2	95	NOPAPER	3/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78474828	RIFAMPIN	WVG	WEBSTER GENEF	2	133	266	95	NOPAPER	4/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78475216	NEO POLY	WVG	WEBSTER GENEF	9	1.5	13.5	95	NOPAPER	11/2/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78475349	MAGNESI	INS	IN SOURCE	1	1.37	1.37	95	NOPAPER	2/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78489561	BRETHINE	WVG	WEBSTER GENEF	2	20.52	41.04	95	NOPAPER	2/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78558589	CLINDAM	WVG	WEBSTER GENEF	1	37.5	37.5	95	NOPAPER	3/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78558320	PHENYLPI	WVG	WEBSTER GENEF	12	55.19	673.02	500	CHEMICAI	9/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78428997	EPHEDRI	WVG	WEBSTER GENEF	1	21.3	21.3	500	CHEMICAI	9/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079688	ATROPINE	WVG	WEBSTER GENEF	47	24	1128	B14	B14-E02R1	8/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78054403	ATROPINE	WVG	WEBSTER GENEF	80	2.35	188	B16	B16-H02	10/2/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78054437	PILOCARF	WVG	WEBSTER GENEF	34	1.9	64.6	C06	C06-D02	5/7/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009341	SODIUM B	ABB	ABBOTT LABS	56	1.18	66.44	C06	C06-H03	9/26/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78378840	GELFOAM	YAN	WILLOW BIRCH P	74	8.76	649.72	C07	C07-D02	11/5/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78461226	AMINOCAI	ABB	ABBOTT LABS	167	1.02	170.34	C13	C13-H01	1/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78054429	PILOCARF	WVG	WEBSTER GENEF	81	2.05	161.55	C21	C21-D02	11/22/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009166	DEX 5% A	ABB	ABBOTT LABS	5	24.92	124.6	C8	A02-D30	9/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009169	DEX 5% A	ABB	ABBOTT LABS	0	24.92	0	C8	A15-B10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009325	LACTATEI	ABB	ABBOTT LABS	15	26.41	396.15	C8	A10-D50	2/3/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009333	LACTATEI	ABB	ABBOTT LABS	30	33.78	1013.7	C8	A03-B10	4/12/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009333	LACTATEI	ABB	ABBOTT LABS	0	33.78	0	C8	A03-C10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78009358	NORMOSC	ABB	ABBOTT LABS	3	23.4	70.2 CS		A02-B30	12/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009358	NORMOSC	ABB	ABBOTT LABS	0	23.4	0 CS		A06-B70		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009366	NORMOSC	ABB	ABBOTT LABS	12	50.39	604.68 CS		A04-C10	1/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009374	NORMOSC	ABB	ABBOTT LABS	0	50.39	0 CS		A19-D30	-	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009410	SALINE 0.9	ABB	ABBOTT LABS	183	18.81	3966.03 CS		A05-C10	4/14/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009418	SALINE 0.9	ABB	ABBOTT LABS	15	36	270 CS		A07-B30	3/19/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009424	SALINE 0.9	ABB	ABBOTT LABS	0	36	0 CS		A10-D50		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009473	SALINE IR	ABB	ABBOTT LABS	17	34.32	583.44 CS		A14-D20	4/26/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009473	SALINE IR	ABB	ABBOTT LABS	3	30.16	90.48 CS		A02-D10	1/12/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009481	SALINE IR	ABB	ABBOTT LABS	0	30.16	0 CS		A15-B20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009689	DEX 5.0%	ABB	ABBOTT LABS	71	16.69	1199.19 CS		A04-D10	3/9/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009697	DEX 5.0%	ABB	ABBOTT LABS	7	22.47	157.29 CS		A19-C30	4/13/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009713	LACTATEI	ABB	ABBOTT LABS	14	26.42	369.88 CS		A15-C20	3/19/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009721	SALINE 0.9	ABB	ABBOTT LABS	602	13.56	8870.1 CS		A01-C10	1/23/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009739	SALINE IR	ABB	ABBOTT LABS	282	19.49	4911.48 CS		A07.5-C30	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009739	SALINE IR	ABB	ABBOTT LABS	6	15.5	93 CS		A03-C20	4/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009747	RINGERS	ABB	ABBOTT LABS	0	15.5	0 CS		A11-C30		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009747	RINGERS	ABB	ABBOTT LABS	1	19.45	19.45 CS		A02-C30	11/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78092417	DEX 5% .9	ABB	ABBOTT LABS	0	19.45	0 CS		A16-B50		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78092417	DEX 5% .9	ABB	ABBOTT LABS	8	25.62	204.96 CS		A05-C20	4/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365486	WATER IR	BAX	BAXTER CENTER	0	25.62	0 CS		A11-B00		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365502	SALINE IR	BAX	BAXTER CENTER	30	14.02	420.6 CS		A14-D30	12/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365502	SALINE IR	BAX	BAXTER CENTER	8	33.12	264.04 CS		A02-B10	2/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365528	SALINE IR	BAX	BAXTER CENTER	0	33.13	0 CS		A10-C00	-	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365528	SALINE IR	BAX	BAXTER CENTER	9	13.82	124.38 CS		A04-C50	2/21/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365585	SALINE 0.9	BAX	BAXTER CENTER	0	13.82	0 CS		A13-B40		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365585	SALINE 0.9	BAX	BAXTER CENTER	3	46.33	138.99 CS		A05-C30	3/26/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365593	SALINE 0.9	BAX	BAXTER CENTER	0	46.33	0 CS		A11-C40		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365601	SALINE 0.9	BAX	BAXTER CENTER	4	44.31	177.24 CS		A06-C10	8/24/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365601	SALINE 0.9	BAX	BAXTER CENTER	7	25.7	179.9 CS		A05-C10	4/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365650	LACTATEI	BAX	BAXTER CENTER	0	25.7	0 CS		A11-C20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365668	LACTATEI	BAX	BAXTER CENTER	8	25.44	203.52 CS		A02-D50	3/26/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365675	DEX 5.0%	BAX	BAXTER CENTER	0	25.44	0 CS		A14-D40		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365675	DEX 5.0%	BAX	BAXTER CENTER	1	31.44	31.44 CS		A02-C10	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78365876	DEX 5/0%	BAX	BAXTER CENTER	0	31.44	0 CS		A05-B20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365734	DEXTROS	BAX	BAXTER CENTER	6	27.16	162.96 CS		A02-B50	12/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365734	DEXTROS	BAX	BAXTER CENTER	0	27.16	0 CS		A15-D20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78368981	AMINOSYI	ABB	ABBOTT LABS	4	114.5	458.4 CS		A02-C60	6/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78368981	AMINOSYI	ABB	ABBOTT LABS	0	114.5	0 CS		A15-A20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78421187	LACTATEI	BAX	BAXTER CENTER	3	31.63	94.89 CS		A02-B20	12/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78421187	LACTATEI	BAX	BAXTER CENTER	0	31.63	0 CS		A13-B20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78430081	AMINOSYI	ABB	ABBOTT LABS	4	103.8	415.2 CS		A02-B50	8/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78430081	AMINOSYI	ABB	ABBOTT LABS	0	103.8	0 CS		A10-D40		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454184	LACTATEI	BAX	BAXTER CENTER	87	15.62	1378.34 CS		A07-C10	8/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454184	PLASMAL	BAX	BAXTER CENTER	42	20.44	858.48 CS		A05-C20	12/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78456101	DEXTROS	ABB825	ABBOTT LABS	1	54.76	54.76 CS		A02-C50	9/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78456101	DEXTROS	ABB825	ABBOTT LABS	0	54.76	0 CS		A05-C35		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78459415	DEX 5% ,9	BAX	BAXTER CENTER	1	20.34	20.34 CS		A02-C20	4/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78459415	DEX 5% ,9	BAX	BAXTER CENTER	0	20.34	0 CS		A13-A50		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78460985	SARAPIN	HIG	HIGH CHEMICAL I	219	23.5	5005.5 DP		D01-E01	6/8/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78352405	PREDNISC	WVG	WEBSTER GENEI	6	11.03	55.15 DP		D13-E02	4/26/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	7807(823	F/M NALC	ABB	ABBOTT LABS	28	9	78 DP		D25-H01	6/10/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025513	AMPICILLI	WVG	WEBSTER GENEI	7	26.48	185.36 DP		A27-H10	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025521	AMPICILLI	WVG	WEBSTER GENEI	38	46.5	1748 DP		A27-D10	8/8/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025570	AMOXICIL	WVG	WEBSTER GENEI	28	14.67	410.28 DP		A23-C10	10/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043784	METHIMA	WVG	WEBSTER GENEI	1161	8.5	9868.5 DP		A23-E20	7/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043792	METHIMA	WVG	WEBSTER GENEI	47	22.85	1078.55 DP		A27-G10	8/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056288	THEOPHY	WVG	WEBSTER GENEI	34	11.43	388.62 DP		A25-F10	8/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056296	THEOPHY	WVG	WEBSTER GENEI	98	10.2	999.6 DP		A23-F10	8/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057452	CEPHALE	WVG	WEBSTER GENEI	329	4.5	1480.5 DP		A26-D10	11/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058436	DOXYCYC	WVG	WEBSTER GENEI	64	2.93	187.52 DP		A25-F20	7/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058502	DOXYCYC	WVG	WEBSTER GENEI	58	18.51	1073.58 DP		A27-F10	8/2/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058556	ENALAPRI	WVG	WEBSTER GENEI	123	1.37	168.51 DP		A27-C10	12/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058556	ENALAPRI	WVG	WEBSTER GENEI	165	1.57	290.45 DP		A23-E10	12/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058882	ENALAPRI	WVG	WEBSTER GENEI	118	2.32	282.16 DP		A27-E10	10/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059957	AMITRIPT	WVG	WEBSTER GENEI	43	4.39	188.77 DP		A26-E30	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059973	AMINOPH	WVG	WEBSTER GENEI	13	21	273 DP		A23-H20	9/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78065566	PREDNISC	WVG	WEBSTER GENEI	95	9.57	909.15 DP		A23-D20	11/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restriction List?	Human Label?
883	78321565	ENALAPRI	WVG	WEBSTER GENEF	11	12.63	138.83	DP	A23-G20	10/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78321563	ENALAPRI	WVG	WEBSTER GENEF	5	12.83	64.45	DP	A23-G20	10/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78321571	ENALAPRI	WVG	WEBSTER GENEF	10	18.21	182.1	DP	A23-G20	10/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78305681	ENALAPRI	WVG	WEBSTER GENEF	0	21.04	0	DP	A23-E10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380285	THEOPHY	WVG	WEBSTER GENEF	74	13.75	1017.5	DP	A23-H10	11/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380971	THEOPHY	WVG	WEBSTER GENEF	17	48.45	823.65	DP	A25-F20	9/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76367955	THERMAZ	KEN	KENDALL HEALTH	70	2.58	180.5	DP	A25-F30	8/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76367955	ALBUTERI	WVG	WEBSTER GENEF	34	4.21	143.14	DP	A25-D20	11/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78398053	HYDROCH	WVG	WEBSTER GENEF	38	2.15	81.7	DP	A23-B20	7/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78428564	THEOPHY	WVG	WEBSTER GENEF	12	54.26	651.36	DP	A25-H20	8/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78429138	CYCLOSP	WVG	WEBSTER GENEF	51	18	558	DP	A23-B10	7/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78430078	BENAZEPI	WVG	WEBSTER GENEF	134	4.95	663.3	DP	A25-E20	11/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78430097	BENAZEPI	WVG	WEBSTER GENEF	26	5.97	193.32	DP	A23-H30	12/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78430095	BENAZEPI	WVG	WEBSTER GENEF	0	7.5	67.5	DP	A25-F40	9/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78433236	CYCLOSP	WVG	WEBSTER GENEF	73	58	4334	DP	A25-H10	8/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78433228	FLUCONA	WVG	WEBSTER GENEF	2	6.04	12.08	DP	A25-G10	6/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78437970	PREDNISC	WVG	WEBSTER GENEF	22	3.89	85.58	DP	A27-I10	9/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466027	RANITIDI	WVG	WEBSTER GENEF	238	7	1645	DP	A23-D10	5/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78494607	CYCLOSP	WVG	WEBSTER GENEF	17	29	493	DP	A25-G30	6/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78500934	BUSPIRON	WVG	WEBSTER GENEF	23	4.29	98.67	DP	A23-H10	10/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78502223	AMANTAD	WVG	WEBSTER GENEF	7	8	56	DP	A23-G10	11/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057478	CEPHALEX	WVG	WEBSTER GENEF	24	7.1	170.4	DPR	DPR-A03	7/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079005	SMZ TMP	WVG	WEBSTER GENEF	36	31.35	1128.6	DPR	DPR-A01	8/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78085625	SMZ/TMP	WVG	WEBSTER GENEF	168	9	1512	DPR	DPR-A07	11/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380179	CIMETIDI	WVG	WEBSTER GENEF	24	6.69	159.36	DPR	DPR-A04	12/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78423740	CIPROFLC	WVG	WEBSTER GENEF	120	3.95	474	DPR	DPR-A05	11/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465850	NAPROXE	WVG	WEBSTER GENEF	6	4.74	28.44	DPR	DPR-A08	11/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78478406	GENTAMI	ABB	ABBOTT LABS	100	0.54	.54	DPR	DPR-A02	10/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76552244	OFLOXAC	WVG	WEBSTER GENEF	99	5.24	503.04	DPR	DPR-A06	11/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78005294	POTASSIL	ABB	ABBOTT LABS	2131	0.49	1044.19	E05	E05-C01	9/8/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78005985	DEXTROS	ABB	ABBOTT LABS	570	1.12	638.4	E07	E07-E01	8/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78419584	SODIUM B	ABB	ABBOTT LABS	0	8.29	0	E10	E10-E01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025851	CEFAZOLI	WVG	WEBSTER GENEF	7666	0.92	7051.8	F01	F01-G01	7/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78416527	POTASSIL	ABB	ABBOTT LABS	817	0.78	637.26	F04	F04-E01	7/5/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78481241	MEPIVACA	ABB	ABBOTT LABS	53	3.61	335.28	F17	F17-E01	11/3/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465678	NAPROXE	WVG	WEBSTER GENEF	45	17.89	805.05	F18	F18-E01	6/10/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78006630	BUPIVACA	ABB	ABBOTT LABS	2	104.5	209	F21	F21-B02	4/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78121128	J522 ACC	JOR	JORGENSEN LAB	3	10.5	31.5	G26	G26-B02	1/28/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78302981	NORMOS(	ABB	ABBOTT LABS	56	2.67	149.52	H06	H06-F02	5/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444595	NEO POL\	WVG	WEBSTER GENEF	588	1.85	1087.8	H13	H13-E02	9/15/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78343611	METRONI	ABB	ABBOTT LABS	307	2.4	736.8	L01	L01-F01	8/14/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78421211	STERILE\	ABB	ABBOTT LABS	388	1.49	578.34	L03	L03-F03	5/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78388351	THERMAZ	KEN	KENDALL HEALTH	74	16.58	1226.92	L05	L05-C04	9/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009002	CALCIUM	WVG	WEBSTER GENEF	6	1.44	8.64	PEDCR	PENDING	3/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78011407	NEO POL\	WVG	WEBSTER GENEF	4	25.2	100.8	PEDCR	PENDING	7/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78011415	NEO POL\	WVG	WEBSTER GENEF	3	17.4	52.2	PEDCR	PENDING	7/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78013407	SULFASAL	WVG	WEBSTER GENEF	1	32.21	32.21	PEDCR	PENDING	9/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78013431	FUROSEM	WVG	WEBSTER GENEF	2	11.9	23.8	PEDCR	PENDING	5/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78013449	FUROSEM	WVG	WEBSTER GENEF	2	14.2	28.4	PEDCR	PENDING	5/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78013466	DIPHENH\	WVG	WEBSTER GENEF	4	26.41	105.64	PEDCR	PENDING	9/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014084	MEGESTR	WVG	WEBSTER GENEF	2	12.66	25.32	PEDCR	PENDING	6/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014092	CORTROS	WVG	WEBSTER GENEF	20	118.43	2368.6	PEDCR	PENDING	5/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014126	LACTULOS	WVG	WEBSTER GENEF	2	4.15	8.3	PEDCR	PENDING	10/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014175	CIMETIDI	WVG	WEBSTER GENEF	9	1.9	17.1	PEDCR	PENDING	5/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014183	CLEMASTI	WVG	WEBSTER GENEF	3	9.15	27.45	PEDCR	PENDING	5/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014381	FLUOROC	WVG	WEBSTER GENEF	1	48.44	48.44	PEDCR	PENDING	5/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014399	CLOMIPR/	WVG	WEBSTER GENEF	5	4.88	24.4	PEDCR	PENDING	5/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014407	CLOMIPR/	WVG	WEBSTER GENEF	4	8.52	26.08	PEDCR	PENDING	5/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014415	CLOMIPR/	WVG	WEBSTER GENEF	5	9.34	46.7	PEDCR	PENDING	5/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014431	KETOCON	WVG	WEBSTER GENEF	5	15.61	78.05	PEDCR	PENDING	4/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78015001	REGLAN I	WVG	WEBSTER GENEF	9	2.25	20.25	PEDCR	PENDING	4/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78021042	SODIUM C	WVG	WEBSTER GENEF	1	11	11	PEDCR	PENDING	3/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78024316	ERYTHRO	ABB	ABBOTT LABS	1	17.5	17.5	PEDCR	PENDING	4/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025513	AMPICILLI	WVG	WEBSTER GENEF	1	28.48	28.48	PEDCR	PENDING	6/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025521	AMPICILLI	WVG	WEBSTER GENEF	1	48.5	48.5	PEDCR	PENDING	4/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025547	PENICILLI	WVG	WEBSTER GENEF	1	64.8	64.8	PEDCR	PENDING	5/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025554	ERYTHRO	ABB	ABBOTT LABS	3	30.25	100.75	PEDCR	PENDING	5/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025570	AMOXICIL	WVG	WEBSTER GENEF	3	14.87	44.61	PEDCR	PENDING	5/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOR	Updated	Created	On Restricted List?	Human Label?
883	78025508	AMOXICIL	WVG	WEBSTER GENEF	4	28.15	100.6	PEDCR	PENDING	4/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025544	CEFAZOLI	WVG	WEBSTER GENEF	33	5.4	319.2	PEDCR	PENDING	5/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025551	CEFAZOLI	WVG	WEBSTER GENEF	12	0.92	11.04	PEDCR	PENDING	5/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037975	LYSODRE	WVG	WEBSTER GENEF	2	415.88	831.76	PEDCR	PENDING	7/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043784	METHINA:	WVG	WEBSTER GENEF	9	8.5	76.5	PEDCR	PENDING	7/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043792	METHINA:	WVG	WEBSTER GENEF	24	22.95	550.8	PEDCR	PENDING	6/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78054403	ATROPINE	WVG	WEBSTER GENEF	10	2.35	23.5	PEDCR	PENDING	9/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78054494	NEO POLY	WVG	WEBSTER GENEF	18	18.5	334.8	PEDCR	PENDING	4/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056268	THEOPHY	WVG	WEBSTER GENEF	4	11.43	45.72	PEDCR	PENDING	3/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056286	THEOPHY	WVG	WEBSTER GENEF	1	10.2	10.2	PEDCR	PENDING	5/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056304	HYDROXY	WVG	WEBSTER GENEF	3	14.25	42.75	PEDCR	PENDING	10/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056320	HYDROXY	WVG	WEBSTER GENEF	6	6.6	84.4	PEDCR	PENDING	9/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056346	HYDROXY	WVG	WEBSTER GENEF	15	54.4	816	PEDCR	PENDING	4/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056361	METHOCA	WVG	WEBSTER GENEF	2	23.8	47.6	PEDCR	PENDING	9/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056379	METRONI	WVG	WEBSTER GENEF	8	26.43	211.44	PEDCR	PENDING	7/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057452	CEPHALE	WVG	WEBSTER GENEF	2	4.5	9	PEDCR	PENDING	8/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057460	CEPHALE	WVG	WEBSTER GENEF	10	5.05	50.5	PEDCR	PENDING	3/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057718	CLINDAMI	WVG	WEBSTER GENEF	4	7.22	28.88	PEDCR	PENDING	5/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057791	GENTAMI	WVG	WEBSTER GENEF	1	11	11	PEDCR	PENDING	2/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057825	VINCRISTI	WVG	WEBSTER GENEF	7	11	77	PEDCR	PENDING	5/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058148	AMOXICIL	WVG	WEBSTER GENEF	35	1.2	42	PEDCR	PENDING	5/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058166	AMOXICIL	WVG	WEBSTER GENEF	30	1.69	50.7	PEDCR	PENDING	6/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058213	METOCLO	WVG	WEBSTER GENEF	29	0.75	21.75	PEDCR	PENDING	7/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058239	METOCLO	WVG	WEBSTER GENEF	5	4.25	21.25	PEDCR	PENDING	4/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058254	METOCLO	WVG	WEBSTER GENEF	7	3.22	22.54	PEDCR	PENDING	4/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058262	HEPARIN	WVG	WEBSTER GENEF	1	5.45	5.45	PEDCR	PENDING	11/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058296	METRONI	WVG	WEBSTER GENEF	1	5.69	5.69	PEDCR	PENDING	6/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058304	METRONI	WVG	WEBSTER GENEF	1	12.68	12.68	PEDCR	PENDING	4/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058346	CHLORPR	WVG	WEBSTER GENEF	1	12.43	12.43	PEDCR	PENDING	4/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058486	DOXYCYC	WVG	WEBSTER GENEF	2	2.83	5.66	PEDCR	PENDING	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058494	DOXYCYC	WVG	WEBSTER GENEF	5	2.75	13.75	PEDCR	PENDING	9/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058502	DOXYCYC	WVG	WEBSTER GENEF	4	18.51	74.04	PEDCR	PENDING	4/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058510	DOXYCYC	WVG	WEBSTER GENEF	4	19.4	77.6	PEDCR	PENDING	6/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058519	GLYCOPY	WVG	WEBSTER GENEF	9	4.5	40.5	PEDCR	PENDING	8/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78058855	ENALAPRI	WVG	WEBSTER GENEF	8	1.37	10.96	PEDCR	PENDING	4/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058855	ENALAPRI	WVG	WEBSTER GENEF	9	1.57	14.13	PEDCR	PENDING	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058874	ENALAPRI	WVG	WEBSTER GENEF	14	1.83	25.62	PEDCR	PENDING	8/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058910	PREDNISC	WVG	WEBSTER GENEF	24	3.42	82.08	PEDCR	PENDING	5/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059582	CIMETIDIN	WVG	WEBSTER GENEF	1	3.33	3.33	PEDCR	PENDING	9/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059908	CIMETIDIN	WVG	WEBSTER GENEF	2	7.8	15.6	PEDCR	PENDING	10/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059918	AMITRIPT	WVG	WEBSTER GENEF	9	1.64	14.76	PEDCR	PENDING	4/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059965	MISOPROS	WVG	WEBSTER GENEF	1	41.97	41.97	PEDCR	PENDING	6/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78060573	AMINOPH	WVG	WEBSTER GENEF	1	21	21	PEDCR	PENDING	8/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78076869	ISOXSUPF	WVG	WEBSTER GENEF	1	11.89	11.89	PEDCR	PENDING	4/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78078997	SMZ TMP	WVG	WEBSTER GENEF	7	9.75	68.25	PEDCR	PENDING	3/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079005	SMZ TMP	WVG	WEBSTER GENEF	35	31.35	1097.25	PEDCR	PENDING	6/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079013	SMZ TMP	WVG	WEBSTER GENEF	3	8	24	PEDCR	PENDING	5/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079021	SMZ TMP	WVG	WEBSTER GENEF	14	25	350	PEDCR	PENDING	7/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079039	METRONI	WVG	WEBSTER GENEF	2	7.15	14.3	PEDCR	PENDING	8/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079696	ATROPINE	WVG	WEBSTER GENEF	17	24	408	PEDCR	PENDING	1/28/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080871	CEPHALE	WVG	WEBSTER GENEF	14	4.3	60.2	PEDCR	PENDING	9/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080889	CEPHALE	WVG	WEBSTER GENEF	6	25.5	153	PEDCR	PENDING	6/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080906	CEPHALE	WVG	WEBSTER GENEF	3	45.12	135.36	PEDCR	PENDING	4/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78082970	SELEGILI	WVG	WEBSTER GENEF	14	3.55	63.9	PEDCR	PENDING	4/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78083491	HEPARIN	WVG	WEBSTER GENEF	3	1.43	4.29	PEDCR	PENDING	3/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78083509	HEPARIN	WVG	WEBSTER GENEF	20	3.42	68.4	PEDCR	PENDING	5/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78083517	AMPICILL	WVG	WEBSTER GENEF	28	4.9	137.4	PEDCR	PENDING	7/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78085226	TETRACY	WVG	WEBSTER GENEF	1	30.6	30.6	PEDCR	PENDING	6/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78085236	TETRACY	WVG	WEBSTER GENEF	1	45.14	45.14	PEDCR	PENDING	4/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78085625	SMZ/TMP	WVG	WEBSTER GENEF	6	9	54	PEDCR	PENDING	5/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78085665	PREDNISC	WVG	WEBSTER GENEF	20	9.57	191.4	PEDCR	PENDING	4/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78085749	PREDNISC	WVG	WEBSTER GENEF	4	32.98	131.92	PEDCR	PENDING	2/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78145879	CHLORPH	WVG	WEBSTER GENEF	1	27.55	27.55	PEDCR	PENDING	11/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78145887	CHLORPH	WVG	WEBSTER GENEF	2	29.2	58.4	PEDCR	PENDING	5/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78319499	PREDNISC	WVG	WEBSTER GENEF	1	17.3	17.3	PEDCR	PENDING	11/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78325910	PREDNISC	WVG	WEBSTER GENEF	1	17.83	17.83	PEDCR	PENDING	10/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78326423	HYDROXY	WVG	WEBSTER GENEF	3	4.93	14.79	PEDCR	PENDING	7/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78326449	HYDROXY	WVG	WEBSTER GENEF	2	6.48	12.96	PEDCR	PENDING	7/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78330208	DOXYCYC	WVG	WEBSTER GENEF	1	29.84	29.84	PEDCR	PENDING	9/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78337737	IBUPROFE	WVG	WEBSTER GENEF	1	13.5	13.5	PEDCR	PENDING	7/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78338218	CEPHALE	WVG	WEBSTER GENEF	6	52.63	315.18	PEDCR	PENDING	8/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78338667	ACETAZOI	WVG	WEBSTER GENEF	8	19.71	118.26	PEDCR	PENDING	11/21/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342680	BUSPIRO	WVG	WEBSTER GENEF	1	3.4	3.4	PEDCR	PENDING	3/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342710	PREDNISC	WVG	WEBSTER GENEF	3	3.85	11.55	PEDCR	PENDING	10/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342726	SILVADEN	WVG	WEBSTER GENEF	5	2.27	11.35	PEDCR	PENDING	8/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342736	SILVADEN	WVG	WEBSTER GENEF	10	3.2	32	PEDCR	PENDING	5/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342744	SPIRONOI	WVG	WEBSTER GENEF	3	11.68	35.04	PEDCR	PENDING	8/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346231	AMPICILLI	WVG	WEBSTER GENEF	1	96.02	96.02	PEDCR	PENDING	9/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78347034	METHYLPI	WVG	WEBSTER GENEF	4	7.83	31.32	PEDCR	PENDING	7/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78348132	AMOXI SU	WVG	WEBSTER GENEF	118	3	354	PEDCR	PENDING	4/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78348181	DOXORUE	CAI	CARDINAL HEALT	1	56.25	56.25	PEDCR	PENDING	1/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78349488	ATROPINE	PHO	PHOENIX PHARM	8	1.45	11.6	PEDCR	PENDING	6/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78354253	PROPARA	BLO	BLOODWORTH	9	3.56	32.04	PEDCR	PENDING	9/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78356498	HYDROXY	WVG	WEBSTER GENEF	1	3.2	3.2	PEDCR	PENDING	5/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78357158	METOCLO	WVG	WEBSTER GENEF	7	4.54	31.78	PEDCR	PENDING	4/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78357810	LIDOCAIN	WVG	WEBSTER GENEF	1	8.23	8.23	PEDCR	PENDING	7/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365981	ENALAPRI	WVG	WEBSTER GENEF	2	21.04	42.08	PEDCR	PENDING	4/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370907	ALBUTERI	WVG	WEBSTER GENEF	1	15	15	PEDCR	PENDING	9/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78372236	TRIAMCIN	WVG	WEBSTER GENEF	6	0.58	3.48	PEDCR	PENDING	5/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379071	CALCIUM	WVG	WEBSTER GENEF	8	1.74	10.44	PEDCR	PENDING	5/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78376303	PREDNISC	TOP	TOP RX	2	1.57	3.14	PEDCR	PENDING	6/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379360	TIMOLOL	WVG	WEBSTER GENEF	3	1.38	4.14	PEDCR	PENDING	10/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379481	COLCHICI	GEE	GENETCO INC	2	3.39	6.78	PEDCR	PENDING	3/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379493	TROPICAI	TOP	TOP RX	2	4.52	0.04	PEDCR	PENDING	4/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379934	DEXAMET	WVG	WEBSTER GENEF	2	6.74	13.48	PEDCR	PENDING	7/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379717	TETRACYI	WVG	WEBSTER GENEF	3	4.75	14.25	PEDCR	PENDING	4/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379774	FLUOXETI	WVG	WEBSTER GENEF	3	4.82	14.46	PEDCR	PENDING	7/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379782	DEXAMET	WVG	WEBSTER GENEF	3	10.87	32.61	PEDCR	PENDING	7/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379790	MARCAINI	WVG	WEBSTER GENEF	4	3.58	14.32	PEDCR	PENDING	7/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379931	ZANTAC I	WVG	WEBSTER GENEF	10	7.89	78.9	PEDCR	PENDING	10/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379956	LIDOCAIN	TOP	TOP RX	6	6.71	40.26	PEDCR	PENDING	4/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379972	BOLUMEI	WVG	WEBSTER GENEF	1	11.41	11.41	PEDCR	PENDING	6/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identify	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplanOK	Updated	Created	On Restricted List?	Human Label?
883	76380047	PREDNISC	WVG	WEBSTER GENEF	3	5.15	15.45	PEDCR	PENDING	6/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76380138	RANITIDIN	WVG	WEBSTER GENEF	6	3.35	16.75	PEDCR	PENDING	4/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76380179	CIMETIDIN	WVG	WEBSTER GENEF	1	8.89	8.89	PEDCR	PENDING	11/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76380237	CHLORPR	WVG	WEBSTER GENEF	1	10.86	10.86	PEDCR	PENDING	4/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76380576	EPOGEN (	WVG	WEBSTER GENEF	3	23.41	70.23	PEDCR	PENDING	4/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76380740	CARAFATI	WVG	WEBSTER GENEF	1	50.85	50.85	PEDCR	PENDING	5/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76380849	TERBUTAI	TOP	TOP RX	1	22.26	22.26	PEDCR	PENDING	7/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76381161	CARAFATI	WVG	WEBSTER GENEF	2	114.59	229.18	PEDCR	PENDING	4/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76381186	BETHANEI	WVG	WEBSTER GENEF	2	12.91	25.82	PEDCR	PENDING	5/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76381237	TIMENTIN	WVG	WEBSTER GENEF	2	132.64	265.28	PEDCR	PENDING	5/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76391832	DOXYCYC	WVG	WEBSTER GENEF	4	2.75	11	PEDCR	PENDING	5/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76391885	FLUPHEN/	WVG	WEBSTER GENEF	2	5.6	11.2	PEDCR	PENDING	7/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76391889	PENTOXIF	WVG	WEBSTER GENEF	2	7.45	14.9	PEDCR	PENDING	4/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76392442	ALBUTERI	WVG	WEBSTER GENEF	2	43.9	87.8	PEDCR	PENDING	6/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76397970	GLIPIZIDE	WVG	WEBSTER GENEF	3	2.7	8.1	PEDCR	PENDING	5/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76397989	ALBUTERI	WVG	WEBSTER GENEF	1	4.21	4.21	PEDCR	PENDING	7/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76398087	ESTRADIC	TOP	TOP RX	1	3.82	3.82	PEDCR	PENDING	2/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76398128	PREDNISC	WVG	WEBSTER GENEF	1	27.88	27.88	PEDCR	PENDING	5/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76398070	METHOCA	WVG	WEBSTER GENEF	10	4.9	49	PEDCR	PENDING	6/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78410543	ELSPAR D	WVG	WEBSTER GENEF	2	56.7	113.4	PEDCR	PENDING	11/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78410768	MARCAIN	WVG	WEBSTER GENEF	1	7.35	7.35	PEDCR	PENDING	6/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78410824	RENOGRA	WVG	WEBSTER GENEF	2	15.79	31.58	PEDCR	PENDING	7/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78413231	REGLAN I	WVG	WEBSTER GENEF	6	6.64	39.84	PEDCR	PENDING	6/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414063	TOBRAMY	WVG	WEBSTER GENEF	12	1.26	15	PEDCR	PENDING	10/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414071	ARTIFICIA	PHO	PHOENIX PHARM	48	1.15	55.2	PEDCR	PENDING	11/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414089	DEXAMET	WVG	WEBSTER GENEF	24	9.2	220.8	PEDCR	PENDING	1/11/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414105	GENTAMI	WVG	WEBSTER GENEF	49	1	49	PEDCR	PENDING	5/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414380	TRIPLE NI	WVG	WEBSTER GENEF	4	14.5	58	PEDCR	PENDING	5/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78423757	CIPROFLC	WVG	WEBSTER GENEF	4	11.07	44.28	PEDCR	PENDING	11/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78427443	ROFERON	WVG	WEBSTER GENEF	2	40.56	81.1	PEDCR	PENDING	5/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78427488	CLINDAMI	WVG	WEBSTER GENEF	2	39.58	79.16	PEDCR	PENDING	2/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78428864	THEOPHY	WVG	WEBSTER GENEF	1	54.28	54.28	PEDCR	PENDING	1/11/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78429294	FLUOXETI	WVG	WEBSTER GENEF	1	2.77	2.77	PEDCR	PENDING	7/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78429302	FLUOXETI	WVG	WEBSTER GENEF	1	2.77	2.77	PEDCR	PENDING	10/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78430078	BENAZEPI	WVG	WEBSTER GENEI	6	4.95	29.7	PEDCR	PENDING	5/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78430087	BENAZEPI	WVG	WEBSTER GENEI	6	5.37	32.22	PEDCR	PENDING	2/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78430095	BENAZEPI	WVG	WEBSTER GENEI	4	7.5	30	PEDCR	PENDING	5/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78433236	CYCLOSP	WVG	WEBSTER GENEI	2	58	116	PEDCR	PENDING	2/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78433764	URSODIOI	WVG	WEBSTER GENEI	2	39.27	78.54	PEDCR	PENDING	5/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78433863	ANZEMET	WVG	WEBSTER GENEI	1	30	30	PEDCR	PENDING	8/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78434572	FLUCONA	WVG	WEBSTER GENEI	2	3.25	6.5	PEDCR	PENDING	7/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78434772	MARCAIN	WVG	WEBSTER GENEI	1	22.49	22.49	PEDCR	PENDING	6/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78435690	DOXYCYC	WVG	WEBSTER GENEI	1	14.49	14.49	PEDCR	PENDING	3/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78436160	ALBUTER	WVG	WEBSTER GENEI	13	2.84	36.22	PEDCR	PENDING	5/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78437227	RANITIDI	WVG	WEBSTER GENEI	1	1.02	1.02	PEDCR	PENDING	11/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78437658	SPIRONOI	WVG	WEBSTER GENEI	2	30.19	60.38	PEDCR	PENDING	1/11/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78437870	PREDNISC	WVG	WEBSTER GENEI	4	3.89	15.56	PEDCR	PENDING	6/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78438378	GRIS-PEG	WVG	WEBSTER GENEI	2	145.91	291.82	PEDCR	PENDING	4/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78441177	METHOCA	WVG	WEBSTER GENEI	3	5.04	29.7	PEDCR	PENDING	1/11/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444565	NEO POLY	WVG	WEBSTER GENEI	24	1.85	82.8	PEDCR	PENDING	9/19/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454485	VINBLAST	CAI	CARDINAL HEALT	1	23.07	20.37	PEDCR	PENDING	4/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78455705	TRAMADC	WVG	WEBSTER GENEI	2	15.69	31.32	PEDCR	PENDING	5/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78456747	GUANABE	WVG	WEBSTER GENEI	1	155.26	155.26	PEDCR	PENDING	6/0/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465682	METHOCA	WVG	WEBSTER GENEI	1	24.8	24.8	PEDCR	PENDING	10/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465678	SUCRALF	WVG	WEBSTER GENEI	3	57.95	173.85	PEDCR	PENDING	6/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465678	NAPROXE	WVG	WEBSTER GENEI	1	17.89	17.89	PEDCR	PENDING	9/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465894	DEPO PRI	WVG	WEBSTER GENEI	1	151.43	151.43	PEDCR	PENDING	8/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465936	TRIAMCIN	WVG	WEBSTER GENEI	1	9.04	9.04	PEDCR	PENDING	8/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465951	POLYMYX	WVG	WEBSTER GENEI	230	12.89	2791.8	PEDCR	PENDING	4/24/2007	FALSE	FALSE	3/10/2008 4:31	3/18/2008	YES	YES
883	78466018	SILVER SU	WVG	WEBSTER GENEI	6	8.82	46.56	PEDCR	PENDING	9/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466027	RANITIDIN	WVG	WEBSTER GENEI	6	7	42	PEDCR	PENDING	7/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466803	SMZ INJEC	WVG	WEBSTER GENEI	4	20.3	81.2	PEDCR	PENDING	9/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78470093	PEN G PO	WVG	WEBSTER GENEI	217	15.1	3276.7	PEDCR	PENDING	9/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78474628	RIFAMPIN	WVG	WEBSTER GENEI	3	133	399	PEDCR	PENDING	4/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78475043	TAMIFLU	WVG	WEBSTER GENEI	1	36.82	36.82	PEDCR	PENDING	7/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78475091	ZOFRAN 2	WVG	WEBSTER GENEI	9	213.67	1923.03	PEDCR	PENDING	2/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78475218	NEO POLY	WVG	WEBSTER GENEI	20	1.5	30	PEDCR	PENDING	3/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78475846	CEFTRIAX	WVG	WEBSTER GENEI	1	30.56	30.56	PEDCR	PENDING	5/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DO Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78477093	ZITHROMA	WVG	WEBSTER GENEF	1	62.39	62.39	PEDCR	PENDING	9/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78450827	LEVOTHYI	WVG	WEBSTER GENEF	.2	6.25	12.5	PEDCR	PENDING	6/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78450864	CLINDAM	WVG	WEBSTER GENEF	1	89.43	89.43	PEDCR	PENDING	6/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78481761	NEOMYCII	WVG	WEBSTER GENEF	1	123.53	123.53	PEDCR	PENDING	6/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78464546	CYTOXAN	WVG	WEBSTER GENEF	2	12.65	25.3	PEDCR	PENDING	6/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78492735	AZITHROI	WVG	WEBSTER GENEF	1	174.19	174.19	PEDCR	PENDING	11/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78494784	AMIKACIN	WVG	WEBSTER GENEF	1	50	50	PEDCR	PENDING	9/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78495040	LIDOCAINI	WVG	WEBSTER GENEF	20	1.71	34.2	PEDCR	PENDING	4/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78497750	PROPOFC	WVG	WEBSTER GENEF	3	37.4	112.2	PEDCR	PENDING	6/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78501405	POTASSIL	WVG	WEBSTER GENEF	1	18.46	18.46	PEDCR	PENDING	8/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78507223	AZITHRO	WVG	WEBSTER GENEF	1	14.95	14.95	PEDCR	PENDING	8/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78507468	FROCALA	WVG	WEBSTER GENEF	3	33.41	100.23	PEDCR	PENDING	10/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78508223	MELOXIC	WVG	WEBSTER GENEF	1	2	2	PEDCR	PENDING	10/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78514086	AMINOPH	WVG	WEBSTER GENEF	11	18.49	203.39	PEDCR	PENDING	2/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78544922	FLUCONA	WVG	WEBSTER GENEF	1	16.39	16.39	PEDCR	PENDING	10/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78545757	AMINOPH	CAI	CARDINAL HEALT	4	15.03	60.12	PEDCR	PENDING	5/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78555772	POTASSR	WVG	WEBSTER GENEF	2	13.23	26.46	PEDCR	PENDING	11/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78557921	DILTYCLO	WVG	WEBSTER GENEF	1	12.28	12.28	PEDCR	PENDING	7/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78566389	CLINDAM	WVG	WEBSTER GENEF	2	37.5	75	PEDCR	PENDING	5/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78581169	METRONI	WVG	WEBSTER GENEF	1	3.1	3.1	PEDCR	PENDING	6/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78000002	CALCIUM	WVG	WEBSTER GENEF	124	1.44	178.56	PG	A10-G10	7/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78011357	MYDRIAC	WVG	WEBSTER GENEF	7	42.75	299.25	PG	A07-A30	4/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78011407	NEO POLY	WVG	WEBSTER GENEF	27	20.2	550.4	PG	A09-H10	12/14/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78011415	NEO POLY	WVG	WEBSTER GENEF	93	17.4	1618.2	PG	A07-D10	12/21/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78013399	SULFASAI	WVG	WEBSTER GENEF	23	6.42	147.66	PG	A07-G30	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78013407	SULFASAI	WVG	WEBSTER GENEF	17	32.21	547.57	PG	A09-D20	9/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78013415	PROXICA	WVG	WEBSTER GENEF	21	3.51	73.71	PG	A07-C35	5/5/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78013423	PROXICA	WVG	WEBSTER GENEF	17	4.4	74.8	PG	A19-I20	8/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78013431	FUROSEN	WVG	WEBSTER GENEF	27	11.9	321.3	PG	A21-D10	10/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78013449	FUROSEN	WVG	WEBSTER GENEF	0	14.2	0	PG	A17-P10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78013456	DIPHENH	WVG	WEBSTER GENEF	81	26.41	2139.21	PG	A14-E20	7/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014084	MEGESTR	WVG	WEBSTER GENEF	15	12.66	189.9	PG	A07-B30	8/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014092	CORTROS	WVG	WEBSTER GENEF	130	118.43	15395.9	PG	A09-F20	9/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014126	LACTULOI	WVG	WEBSTER GENEF	419	4.15	1739.85	PG	A08-C20	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickDK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78014142	CIMETIDIN	WVG	WEBSTER GENEF	46	3.31	148.05 PG		A03-C10	11/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014175	CIMETIDIN	WVG	WEBSTER GENEF	419	1.9	796.1 PG		A01-F10	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014183	CLEMAST	WVG	WEBSTER GENEF	44	9.15	402.6 PG		A12-C10	10/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014217	CEPHALE	WVG	WEBSTER GENEF	101	28.9	2918.9 PG		A01-G20	7/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014266	DIGOXIN T	WVG	WEBSTER GENEF	5	68.06	401.76 PG		A19-A10RI	7/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014282	LOPERAM	WVG	WEBSTER GENEF	23	4.8	105.8 PG		A19-A20	5/13/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014357	CYPROHE	WVG	WEBSTER GENEF	1	92.29	92.29 PG		A17-G10	9/26/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014357	CYPROHE	WVG	WEBSTER GENEF	24	92.29	2214.96 PG		AUTHEN	12/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014365	CYPROHE	WVG	WEBSTER GENEF	73	8.25	469.25 PG		A19-D10	6/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014381	FLUDROC	WVG	WEBSTER GENEF	17	48.44	789.48 PG		A19-C20	1/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014390	CLOMIPR/	WVG	WEBSTER GENEF	117	4.88	570.96 PG		A12-D30	8/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014407	CLOMIPR/	WVG	WEBSTER GENEF	104	8.62	878.08 PG		A08-C10	3/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014416	CLOMIPR/	WVG	WEBSTER GENEF	68	9.34	887.3 PG		A19-E10	7/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014423	KETOCON	WVG	WEBSTER GENEF	10	8.51	85.1 PG		A19-D20	11/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014431	KETOCON	WVG	WEBSTER GENEF	619	15.61	9662.59 PG		A05-F20	4/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014449	PREDNIS(	WVG	WEBSTER GENEF	43	18.84	810.12 PG		A19-C30	10/27/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78015001	REGLAN I	WVG	WEBSTER GENEF	391	2.26	870.76 PG		A09-F10	1/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78021042	SODIUM C	WVG	WEBSTER GENEF	67	11	737 PG		A17-I10	8/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78024316	ERYTHRO	ABB	ABBOTT LABS	11	17.6	192.5 PG		A12-I20	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025547	PENICILLI	WVG	WEBSTER GENEF	3	64.8	194.4 PG		A12-B30	5/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025854	ERYTHRO	ABB	ABBOTT LABS	11	38.25	398.75 PG		A11-I110	4/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025896	AMOXICIL	WVG	WEBSTER GENEF	127	25.15	3194.05 PG		A14-G30	6/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025844	CEFAZOLI	WVG	WEBSTER GENEF	93	8.4	781.2 PG		A11-F20	10/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037975	LYSODRE	WVG	WEBSTER GENEF	1	415.58	415.58 PG		A15-E30	7/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78054494	NEO.POLY	WVG	WEBSTER GENEF	312	18.6	5803.2 PG		A10-B20	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056304	HYDROXY	WVG	WEBSTER GENEF	139	14.25	1980.75 PG		A12-G10	10/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056320	HYDROXY	WVG	WEBSTER GENEF	102	6.5	663.5 PG		A21-C20	11/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056340	HYDROXY	WVG	WEBSTER GENEF	12	54.4	652.8 PG		A06-F10	12/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056346	HYDROXY	WVG	WEBSTER GENEF	24	54.4	1305.6 PG		AUTHEN	12/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056361	METHOCA	WVG	WEBSTER GENEF	136	23.8	3236.8 PG		A14-B30	6/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056379	METRONI	WVG	WEBSTER GENEF	169	26.43	4200.27 PG		A08-A10	4/5/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057460	CEPHALE	WVG	WEBSTER GENEF	708	5.05	3576.4 PG		A08-D10	12/30/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057478	CEPHALE	WVG	WEBSTER GENEF	24	7.1	170.4 PG		A10-D20	7/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057718	CLINDAM	WVG	WEBSTER GENEF	0	7.22	0 PG		A12-C20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOk	Updated	Created	On Restricted List?	Human Label?
883	78057791	GENTAMI	WVG	WEBSTER GENEF	25	11	275 PG		A07-I30	12/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057835	VINCRISTI	WVG	WEBSTER GENEF	22	11	242 PG		AUTHEN	12/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057625	VINCRISTI	WVG	WEBSTER GENEF	200	11	2026 PG		CPD-B40	7/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058148	AMOXICIL	WVG	WEBSTER GENEF	384	1.2	4248 PG		A14-D10	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058165	AMOXICIL	WVG	WEBSTER-GENEF	0	1.69	0 PG		A09-C30		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058163	PREMARI	WVG	WEBSTER GENEF	1	137.02	137.02 PG		A05-J40	11/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058183	PREMARI	WVG	WEBSTER GENEF	1	137.92	137.02 PG		AUTHEN	11/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058171	PREMARI	WVG	WEBSTER GENEF	6	130.11	780.66 PG		A05-C10	9/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058189	PREMARI	WVG	WEBSTER GENEF	1	137.92	137.92 PG		A03-I50	8/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058219	METOCLO	WVG	WEBSTER GENEF	632	0.75	399 PG		A03-D10	7/26/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058239	METOCLO	WVG	WEBSTER GENEF	60	4.25	255 PG		A10-D10	7/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058247	METOCLO	WVG	WEBSTER GENEF	13	37.44	486.72 PG		A19-E20	4/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058254	METOCLO	WVG	WEBSTER GENEF	114	3.22	367.05 PG		A00-B10	3/10/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058262	HEPARIN	WVG	WEBSTER GENEF	247	5.45	1346.15 PG		A21-C30	5/11/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058202	HEPARIN	WVG	WEBSTER GENEF	278	5.45	1466.75 PG		AUTHEN	12/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058286	METRONI	WVG	WEBSTER GENEF	31	6.69	182.69 PG		A12-E20	3/3/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058304	METRONI	WVG	WEBSTER GENEF	128	12.56	1607.68 PG		A14-E10	7/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058320	PHENYLPI	WVG	WEBSTER GENEF	0	56.16	0 PG		A12-F20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058348	CHLORPR	WVG	WEBSTER GENEF	10	12.43	108.86 PG		A15-E20	4/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058494	DOXYCYC	WVG	WEBSTER GENEF	85	2.75	233.75 PG		A14-F15	9/21/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058510	DOXYCYC	WVG	WEBSTER GENEF	578	19.4	11174.4 PG		A05-F20	10/8/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058510	DOXYCYC	WVG	WEBSTER GENEF	288	19.4	5587.2 PG		AUTHEN	1/25/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058519	GLYCOPY	WVG	WEBSTER GENEF	30	4.5	135 PG		A07-E20	11/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058874	ENALAPRI	WVG	WEBSTER GENEF	302	1.23	717.36 PG		A10-C10	5/17/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058916	PREDNISC	WVG	WEBSTER GENEF	85	3.42	290.7 PG		A12-E10	11/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058940	TETRACAI	WVG	WEBSTER GENEF	100	2.8	280 PG		A11-E10	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059866	TAPAZOLI	WVG	WEBSTER GENEF	17	65.45	1112.65 PG		A07-G25	11/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059874	TAPAZOLI	WVG	WEBSTER GENEF	2	113.07	226.14 PG		A03-J20	4/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059882	CIMETIDI	WVG	WEBSTER GENEF	12	3.33	39.96 PG		A17-F20	12/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059890	CIMETIDI	WVG	WEBSTER GENEF	11	4.1	45.1 PG		A03-H10	3/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059908	CIMETIDI	WVG	WEBSTER GENEF	77	7.8	600.6 PG		A21-H30	3/8/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059916	AMITRIPT	WVG	WEBSTER GENEF	234	1.64	383.76 PG		A00-E10	8/16/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059924	AMITRIPT	WVG	WEBSTER GENEF	50	1.89	94.5 PG		A10-B10	7/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059932	AMITRIPT	WVG	WEBSTER GENEF	42	2.26	94.92 PG		A12-F10	7/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78059940	AMITRIPT	WVG	WEBSTER GENEF	28	3.53	102.37 PG		A03-G20	8/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059965	MISOPROS	WVG	WEBSTER GENEF	11	41.97	461.67 PG		A09-E30	10/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059981	AMINOPH	WVG	WEBSTER GENEF	5	33.85	169.25 PG		A12-J45	5/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78076899	ISOXSUPF	WVG	WEBSTER GENEF	355	11.89	6804.85 PG		A10-G30	9/20/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78078090	ISOXSUPF	WVG	WEBSTER GENEF	168	11.89	1983.92 PG		AUTHEN	12/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78078997	SMZ TMP	WVG	WEBSTER GENEF	77	9.75	760.75 PG		A21-D20	8/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079005	SMZ TMP	WVG	WEBSTER GENEF	190	31.35	5956.5 PG		A08-B30	7/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079013	SMZ TMP	WVG	WEBSTER GENEF	81	8	648 PG		A14-D20	5/2/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079021	SMZ TMP	WVG	WEBSTER GENEF	1970	25	49400 PG		A13-B10	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079039	METRONI	WVG	WEBSTER GENEF	22	7.15	157.3 PG		A03-C20	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080871	CEPHALE	WVG	WEBSTER GENEF	126	4.3	541.8 PG		A17-E10	5/12/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080889	CEPHALE	WVG	WEBSTER GENEF	292	25.6	7475 PG		A13-A10	7/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080897	CEPHALE	WVG	WEBSTER GENEF	191	17.48	3338.68 PG		A12-H10	8/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080806	CEPHALE	WVG	WEBSTER GENEF	1160	45.12	52294.06 PG		A02-CART	7/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080905	CEPHALE	WVG	WEBSTER GENEF	108	45.12	4872.96 PG		AUTHEN	12/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78082970	SELEGILIN	WVG	WEBSTER GENEF	551	3.85	2121.35 PG		A17-D20	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78083491	HEPARIN	WVG	WEBSTER GENEF	364	1.43	506.22 PG		A07-H30	5/26/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78083509	HEPARIN	WVG	WEBSTER GENEF	352	3.42	1308.44 PG		A14-H20	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78083517	AMPICILL	WVG	WEBSTER GENEF	1138	4.9	5576.2 PG		A05-D20	5/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78083517	AMPICILL	WVG	WEBSTER GENEF	290	4.9	1421 PG		AUTHEN	2/15/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78084053	CHLORPR	WVG	WEBSTER GENEF	132	4.43	584.76 PG		A12-D10	4/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78084824	SUCRALF	WVG	WEBSTER GENEF	112	13.9	1556.8 PG		A07-E10	11/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78085238	TETRACY	WVG	WEBSTER GENEF	3	30.8	92.4 PG		A09-G20	9/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78085246	TETRACY	WVG	WEBSTER GENEF	4	45.14	180.56 PG		A11-B30	10/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78085629	SMZ/TMP	WVG	WEBSTER GENEF	46	9	414 PG		A14-D30	2/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78085749	PREDNISC	WVG	WEBSTER GENEF	189	32.98	6233.22 PG		A05-E20	11/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78145879	CHLORPH	WVG	WEBSTER GENEF	20	27.66	551.2 PG		A03-J40	5/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78148887	CHLORPH	WVG	WEBSTER GENEF	7	29.2	204.4 PG		A21-G10	4/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78210612	FLUOCINC	WVG	WEBSTER GENEF	0	1.27	0 PG		A15-H20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78309409	ATENOLO	WVG	WEBSTER GENEF	15	8.13	121.95 PG		NW	10/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78317461	ROFERON	WVG	WEBSTER GENEF	1	35.65	35.65 PG		CF0-SO	1/15/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78319499	PREDNISC	WVG	WEBSTER GENEF	0	17.3	0 PG		A19-B10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78320832	SOLU MEI	WVG	WEBSTER GENEF	156	4.19	653.21 PG		A09-F30	8/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78324605	DOBUTAM	WVG	WEBSTER GENEF	31	9.75	302.25 PG		A01-A40	8/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78328910	PREDNISC	WVG	WEBSTER GENEF	11	17.53	192.83 PG		A12-G20	11/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328142	DOXEPIN	WVG	WEBSTER GENEF	54	2.97	160.06 PG		A17-C20	2/3/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328159	DOXEPIN	WVG	WEBSTER GENEF	16	3.23	51.68 PG		A12-J10	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328167	DOXEPIN	WVG	WEBSTER GENEF	0	28.82	0 PG		A17-A20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328175	DOXEPIN	WVG	WEBSTER GENEF	4	3.58	14.32 PG		A14-A05R3	1/25/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328183	DOXEPIN	WVG	WEBSTER GENEF	22	31.62	695.64 PG		A14-B10	3/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328191	DOXEPIN	WVG	WEBSTER GENEF	48	4.96	238.03 PG		A01-I30	12/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328423	HYDROXY	WVG	WEBSTER GENEF	9	44.06	396.54 PG		A11-J10R3	8/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328431	HYDROXY	WVG	WEBSTER GENEF	4	4.93	19.72 PG		A07-C10	7/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328431	HYDROXY	WVG	WEBSTER GENEF	0	23.49	0 PG		A14-C20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328449	HYDROXY	WVG	WEBSTER GENEF	24	23.49	563.76 PG		AUTHEN	2/15/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328456	HYDROXY	WVG	WEBSTER GENEF	0	8.48	0 PG		A07-F20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328456	HYDROXY	WVG	WEBSTER GENEF	0	32.23	0 PG		A17-D10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78330190	CLEMAST	WVG	WEBSTER GENEF	99	32.23	3094.08 PG		AUTHEN	2/15/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78330208	DOXYCYC	WVG	WEBSTER GENEF	34	13.5	459 PG		A01-D20	6/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78337757	IBUPROFE	WVG	WEBSTER GENEF	23	29.64	688.32 PG		A01-E20	7/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78337748	PROPRAN	WVG	WEBSTER GENEF	41	13.5	553.5 PG		A21-F20	9/27/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78337782	IBUPROFE	WVG	WEBSTER GENEF	1	3.06	3.06 PG		A19-G10	8/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78337869	FAMOTIDI	WVG	WEBSTER GENEF	22	6.99	153.78 PG		A11-G10	1/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78337877	FAMOTIDI	WVG	WEBSTER GENEF	7	2.45	17.15 PG		CF0-A10	11/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78337885	FAMOTIDI	WVG	WEBSTER GENEF	197	8.5	1674.5 PG		CF0-C40	7/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78337893	FAMOTIDI	WVG	WEBSTER GENEF	69	3.05	178.95 PG		A05-G10	7/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78336216	CEPHALE	WVG	WEBSTER GENEF	10	22.83	526.3 PG		A19-F50	3/31/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78336667	ACETAZO	WVG	WEBSTER GENEF	145	19.71	2857.95 PG		A07-B30	7/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342581	ALLOPURI	WVG	WEBSTER GENEF	3	33.62	101.76 PG		A14-H10	6/5/2003	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342579	ALLOPURI	WVG	WEBSTER GENEF	94	6.48	609.12 PG		A17-B10	2/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342587	ALLOPURI	WVG	WEBSTER GENEF	2	27.03	54.16 PG		A19-G20	12/19/2000	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342595	ATENOLO	WVG	WEBSTER GENEF	142	3.05	433.1 PG		A14-J25	2/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342660	BUSPIRO	WVG	WEBSTER GENEF	15	3.4	51 PG		A19-G30	11/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342694	DILTIAZE	WVG	WEBSTER GENEF	44	2.89	127.16 PG		A19-H10	10/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342710	PREDNISC	WVG	WEBSTER GENEF	19	3.85	73.15 PG		A19-I10	10/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342728	SILVADEN	WVG	WEBSTER GENEF	130	2.27	295.1 PG		A09-G10	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342736	SILVADEN	WVG	WEBSTER GENEF	136	3.2	432 PG		A19-A30	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78342744	SPIRONOI	WVG	WEBSTER GENEF	53	11.88	629.64	PG	A19-A40	7/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342777	DIGOXIN .	WVG	WEBSTER GENEF	7	28.56	199.92	PG	A14-F20RJ	12/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78344348	EPINEPHF	WVG	WEBSTER GENEF	376	0.65	244.4	PG	A12-B20	8/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346009	CLINDAM)	WVG	WEBSTER GENEF	108	4.87	530.83	PG	A19-B40	1/21/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346231	AMPICILLI	WVG	WEBSTER GENEF	6	96.02	480.1	PG	A09-A20	7/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78347034	METHYLPI	WVG	WEBSTER GENEF	45	7.83	352.35	PG	A12-A10	7/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78348181	DOXORUE	CAI	CARDINAL HEALT	17	58.28	955.26	PG	A11-H20	9/11/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78348488	ATROPINE	PHO	PHOENIX PHARM	207	1.45	300.15	PG	CF0-A20	10/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78348488	ATROPINE	PHO	PHOENIX PHARM	144	1.45	208.8	PG	A11-E25R	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360764	BUSPIRON	WVG	WEBSTER GENEF	17	7.39	125.63	PG	AUTHEN	12/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78354263	PROPARA	BLO	BLOODWORTH	180	3.05	658.8	PG	A14-J10	2/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78354479	PRIMIDON	WVG	WEBSTER GENEF	7	21.8	152.6	PG	CF0-A30	9/14/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78355495	HYDROXY	WVG	WEBSTER GENEF	0	3.2	0	PG	A19-B00	10/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78356603	PROGEST	WVG	WEBSTER GENEF	1	33.3	33.3	PG	A09-I20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78357166	METOCLO	WVG	WEBSTER GENEF	274	4.64	1243.95	PG	A14-A16	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78357184	METOCLO	WVG	WEBSTER GENEF	82	21.44	1758.08	PG	A21-D10	12/1/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78357610	LIDOCAIN	WVG	WEBSTER GENEF	44	8.23	362.12	PG	A08-B20	12/11/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78357636	PROPRAN	WVG	WEBSTER GENEF	1	3.61	3.61	PG	A09-D10	11/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78357644	AMOXICIL	WVG	WEBSTER GENEF	37	5.88	217.56	PG	A09-I30	10/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370907	ALBUTERI	WVG	WEBSTER GENEF	6	13	78	PG	A19-G40	2/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370916	PROCHLO	TOP	TOP RX	2	3.67	7.34	PG	A05-H16	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370072	DARAPRI	WVG	WEBSTER GENEF	29	48.23	1398.67	PG	A05-A30	6/20/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78372238	TRIAMCIN	WVG	WEBSTER GENEF	20	0.58	11.6	PG	A07-A20	9/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370071	CALCIUM	WVG	WEBSTER GENEF	0	1.74	0	PG	A14-B25	11/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370154	TRIAMCIN	WVG	WEBSTER GENEF	3	1.2	3.6	PG	A09-C20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370212	AMINOPH	WVG	WEBSTER GENEF	24	4.76	114.24	PG	A01-J30	11/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370220	HYDRALA	WVG	WEBSTER GENEF	2	11.7	23.4	PG	A01-G10	12/13/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370303	PREDNISC	TOP	TOP RX	0	1.57	0	PG	NW	11/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370350	TIMOLOL	WVG	WEBSTER GENEF	55	1.38	75.9	PG	A05-B10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370378	NEOSTIG	WVG	WEBSTER GENEF	0	3.78	0	PG	A01-H10	10/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370378	NEOSTIG	WVG	WEBSTER GENEF	10	3.79	37.9	PG	A07-B40		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370402	MECLIZIN	WVG	WEBSTER GENEF	0	2.96	0	PG	AUTHEN	1/2/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370444	FUROSEM	WVG	WEBSTER GENEF	31	1.55	48.05	PG	A01-C20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
									A03-B5	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78379451	COLCHICI	GEE	GENETCO INC	19	3.39	64.41 PG		A21-A10	11/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379483	TROPICAA	TOP	TOP RX	31	4.62	140.12 PG		A03-A20	11/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379538	IBUPROFE	WVG	WEBSTER GENEF	19	1.75	33.25 PG		A03-E10	9/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379600	FLURBIPR	WVG	WEBSTER GENEF	0	3.36	0 PG		A00-E40		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379616	ALLOPURI	WVG	WEBSTER GENEF	126	4.31	533.58 PG		A19-F30R0	12/5/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379634	DEXAMET	WVG	WEBSTER GENEF	2	3.28	6.56 PG		A10-A10	10/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379642	NITROGLY	WVG	WEBSTER GENEF	68	6.74	458.32 PG		A01-E10	7/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379717	TETRACYI	WVG	WEBSTER GENEF	22	3.43	75.46 PG		A01-A60R1	9/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379756	DEXAMET	WVG	WEBSTER GENEF	17	4.78	80.78 PG		A19-C40	10/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379774	FLUOXETI	WVG	WEBSTER GENEF	12	9.9	118.8 PG		A19-B60	11/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379782	DEXAMET	WVG	WEBSTER GENEF	70	4.82	337.4 PG		A18-D40	8/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379790	MARCAINI	WVG	WEBSTER GENEF	29	10.87	315.23 PG		A12-B10	10/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379891	TRAMADC	WVG	WEBSTER GENEF	39	3.58	125.3 PG		A07-H10	9/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379931	ZANTAC II	WVG	WEBSTER GENEF	199	3.56	708.44 PG		A01-D10	2/1/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379956	LIDOCAIN	TOP	TOP RX	3	7.69	23.07 PG		A03-B40	9/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379972	SOLU MEI	WVG	WEBSTER GENEF	0	8.71	0 PG		A03-A40		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379980	KETOPRO	TOP	TOP RX	20	11.41	228.2 PG		A19-C30	7/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379998	CLAFORAI	WVG	WEBSTER GENEF	2	7.52	15.04 PG		A19-I50	12/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380047	PREDNISC	WVG	WEBSTER GENEF	0	4.8	0 PG		A05-I10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380096	DIGOXIN 2	WVG	WEBSTER GENEF	31	6.16	190.83 PG		A08-E20	11/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380112	DIGOXIN 1	WVG	WEBSTER GENEF	34	7.51	255.34 PG		A12-C20	10/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380138	RANITIDIN	WVG	WEBSTER GENEF	17	7.51	127.67 PG		A01-B20	6/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380153	PREDNISC	TOP	TOP RX	12	3.35	40.2 PG		A19-H50	7/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380179	CIMETIDIN	WVG	WEBSTER GENEF	0	8.53	0 PG		A21-F10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380237	CHLORPR	WVG	WEBSTER GENEF	14	5.89	82.46 PG		A11-A10	5/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380302	METHAZO	WVG	WEBSTER GENEF	16	10.85	196.3 PG		A03-J00	4/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380344	AMITRIPT	WVG	WEBSTER GENEF	2	12.12	24.24 PG		A14-J15	2/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380393	SOLU MEI	WVG	WEBSTER GENEF	30	13.69	410.7 PG		A01-C30	10/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380450	AMITRIPT	WVG	WEBSTER GENEF	14	19.3	270.2 PG		A21-B20	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380559	ETODOLA	WVG	WEBSTER GENEF	5	18.03	90.15 PG		A17-B30	8/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380575	EPOGEN 1	WVG	WEBSTER GENEF	14	12.96	181.3 PG		A01-B30	10/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380563	HYDROXY	TOP	TOP RX	61	23.41	1606.21 PG		CF0-D30	12/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380558	FRED 5P (	TOP	TOP RX	26	22.42	627.76 PG		A11-B10	10/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
					3	3.59	10.77 PG		A05-I30	3/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

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883	78380682	UROCIT-K	WVG	WEBSTER GENEF	11	48.02	528.22	PG	A01-H10	9/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380724	AZATHIOP	GEE	GENETCO INC	0	11.57	0	PG	A16-I50		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380740	CARAFATI	WVG	WEBSTER GENEF	50	50.85	2542.5	PG	A03-D20	8/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380740	CARAFATI	WVG	WEBSTER GENEF	9	50.85	457.65	PG	AUTHEN	12/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380781	OCUFLOX	BLO	BLOODWORTH	27	2.85	76.95	PG	A16-I30D8	6/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380849	TERBUTAI	TOP	TOP RX	9	22.29	200.61	PG	A09-B20	12/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380864	CILOXAN (	WVG	WEBSTER GENEF	1	50.92	50.92	PG	A07-J40	12/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380880	MEDROXY	TOP	TOP RX	10	28.47	284.7	PG	A09-A30	11/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380908	TOBREX C	WVG	WEBSTER GENEF	7	51.94	363.58	PG	A17-A50	10/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380963	GASTROG	WVG	WEBSTER GENEF	16	56.27	904.05	PG	A09-H20	5/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380969	ETODOLA	WVG	WEBSTER GENEF	3	11.3	33.9	PG	A21-G30	10/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380969	ETODOLA	WVG	WEBSTER GENEF	1	11.3	11.3	PG	AUTHEN	12/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380997	ZANTAC B	WVG	WEBSTER GENEF	0	50.2	0	PG	A07-I20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78381161	CARAFATI	WVG	WEBSTER GENEF	8	114.59	916.72	PG	A03-I50	8/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78381195	BETHANE	WVG	WEBSTER GENEF	25	12.91	322.75	PG	A17-H10	11/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78381211	CHLORPR	WVG	WEBSTER GENEF	2	122.75	245.5	PG	NW	11/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78381257	TIMENTIN	WVG	WEBSTER GENEF	50	132.54	6632	PG	A10-G20	12/19/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78381310	SANDIMM	WVG	WEBSTER GENEF	5	315.95	1579.75	PG	A07-J10RC	9/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78382158	GENTAMI	WVG	WEBSTER GENEF	9	0.97	8.73	PG	A11-B15	4/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78382168	TETRACY	WVG	WEBSTER GENEF	21	3.12	65.52	PG	A19-F40	11/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391632	DOXYCYC	WVG	WEBSTER GENEF	62	2.75	170.5	PG	A07-G10	10/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391665	FLUPHEN	WVG	WEBSTER GENEF	119	5.6	666.4	PG	A17-C30	10/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391665	FLUPHEN	WVG	WEBSTER GENEF	100	5.6	560	PG	AUTHEN	12/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391689	PENTOXIF	WVG	WEBSTER GENEF	42	7.45	312.9	PG	A01-F20	9/12/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78392236	METOCLC	WVG	WEBSTER GENEF	29	19	551	PG	A14-E20	7/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78392442	ALBUTERI	WVG	WEBSTER GENEF	25	40.9	1022.5	PG	A14-G20	6/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78392467	ISOXSUPF	NEO	NEOGEN CORPOI	75	53.85	3965	PG	A14-J30	8/22/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78397970	GLIPIZIDE	WVG	WEBSTER GENEF	13	2.7	35.1	PG	A03-G10	1/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78397988	ALBUTERI	WVG	WEBSTER GENEF	14	4.21	58.94	PG	A09-B10	11/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78397996	NYSTATIN	WVG	WEBSTER GENEF	0	5.25	0	PG	A14-A20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78398004	LACTULOS	WVG	WEBSTER GENEF	51	2.62	133.62	PG	A16-H10	8/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78398045	DEXAMET	WVG	WEBSTER GENEF	0	11.2	0	PG	A01-H20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78398087	ESTRADIC	TOP	TOP RX	0	3.82	0	PG	A01-I20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78398129	PREDNISC	WVG	WEBSTER GENEF	1	27.68	27.68	PG	A15-H50	7/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78395150	AMPICILLI	WVG	WEBSTER GENEF	2	30.4	60.8 PG		A09-I40	12/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78396178	VINCRISTI	WVG	WEBSTER GENEI	5	22	110 PG		CF0-NW	9/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78396188	AMPICILLI	WVG	WEBSTER GENEI	2	33.08	66.16 PG		NW	10/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78399970	METHOCA	WVG	WEBSTER GENEF	82	4.9	401.8 PG		A11-C10	7/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78410428	METHAZO	WVG	WEBSTER GENEF	17	8.54	145.18 PG		A09-A30	10/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78410535	NITROFUF	WVG	WEBSTER GENEF	2	49.63	99.26 PG		A12-J20	7/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78410543	ELSPAR D	WVG	WEBSTER GENEF	10	58.7	587 PG		CF0-B10	9/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78410725	RIFAMPIN	WVG	WEBSTER GENEF	3	74.12	222.36 PG		NW	7/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78410786	MARCAINI	WVG	WEBSTER GENEF	7	7.83	81.48 PG		A05-A10	11/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78410824	RENOGRA	WVG	WEBSTER GENEF	76	15.79	1184.25 PG		A07-B20	8/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78413261	REGLAN II	WVG	WEBSTER GENEF	23	5.94	136.62 PG		A06-B10	1/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78413261	REGLAN II	WVG	WEBSTER GENEF	50	5.94	297 PG		AUTHEN	12/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414069	TOBRAMY	WVG	WEBSTER GENEF	1343	1.25	1678.75 PG		A10-F10	2/6/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414071	ARTIFICIA	PHO	PHOENIX PHARM	543	1.15	624.45 PG		A17-E20	2/6/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414071	ARTIFICIA	PHO	PHOENIX PHARM	72	1.15	82.8 PG		AUTHIN	3/7/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414089	DEXAMET	WVG	WEBSTER GENEF	26	9.2	239.2 PG		A19-H40	7/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414105	GENTAMIC	WVG	WEBSTER GENEF	1389	1	1389 PG		A11-D20	2/5/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414360	TRIPLE MI	WVG	WEBSTER GENEF	152	14.5	2204 PG		A15-G20	1/10/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414360	TRIPLE MI	WVG	WEBSTER GENEF	144	14.5	2088 PG		AUTHEN	12/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78423591	HYPAQUE	WVG	WEBSTER GENEF	0	17.31	0 PG		A07-B10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78423740	CIPROFLC	WVG	WEBSTER GENEF	44	3.85	173.8 PG		A05-B20	4/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78423757	CIPROFLC	WVG	WEBSTER GENEF	82	11.07	875.64 PG		A10-E10	10/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78427344	GLIPIZIDE	WVG	WEBSTER GENEF	4	3.45	13.84 PG		A15-H10	7/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78427369	ESTRADIC	WVG	WEBSTER GENEF	0	4.23	0 PG		A17-B40		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78427385	DILTIAZEN	WVG	WEBSTER GENEF	2	9.1	18.2 PG		A16-I20	12/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78427393	SOLU-MEI	WVG	WEBSTER GENEF	5	17.59	88.45 PG		A05-J50	4/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78427405	UROCIT-K	WVG	WEBSTER GENEF	4	33.19	132.76 PG		A19-I30	7/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78427488	CLINDAM	WVG	WEBSTER GENEF	8	29.56	237.48 PG		A15-F20	9/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78427492	TERBUTAI	TOP	TOP RX	3	27.88	83.64 PG		NW	12/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78428256	AMITRIPT	WVG	WEBSTER GENEF	18	18.2	348.6 PG		A19-I40	4/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78428328	ACETYLC	BIH	BIONICHE ANIMA	131	9.9	1295.9 PG		A07-D20	8/15/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78428356	NORVASC	WVG	WEBSTER GENEF	1	164.66	164.66 PG		A09-J50	8/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78429104	HYDROXY	WVG	WEBSTER GENEF	0	3.78	0 PG		A17-I20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78429112	ALBUTERI	WVG	WEBSTER GENEF	31	2.42	75.02 PG		A03-F10	6/30/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

OC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Procurement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78429120	DOPAMINE	WVG	WEBSTER GENEF	76	0.75	57 PG		A01-C10	11/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78429146	DEXAMET	WVG	WEBSTER GENEF	24	29.76	.714 PG		A03-A50	4/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78429294	FLUOXETI	WVG	WEBSTER GENEF	26	2.77	72.02 PG		A03-D10	8/24/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78429302	FLUOXETI	WVG	WEBSTER GENEF	314	2.77	869.78 PG		A03-E20	8/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78429898	VERAMYC	CAI	CARDINAL HEALT	01	17.34	1577.94 PG		A03-H30	10/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78430103	BENAZEPI	WVG	WEBSTER GENEF	9	7.5	67.5 PG		A03-B30	9/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78433764	URSODIOL	WVG	WEBSTER GENEF	0	39.27	0 PG		A10-C10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78433883	ANZEMET	WVG	WEBSTER GENEF	20	39	780 PG		A14-I16	9/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78433990	ACYCLOV	WVG	WEBSTER GENEF	11	6.73	74.03 PG		A05-J10	10/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78434063	SOTALOL	WVG	WEBSTER GENEF	11	8.64	95.04 PG		A01-J40	10/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78434491	MINOCYCI	WVG	WEBSTER GENEF	0	14.99	0 PG		A01-J20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78434566	FLUCONA	WVG	WEBSTER GENEF	12	2.69	32.28 PG		A09-H30	11/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78434574	FLUCONA	WVG	WEBSTER GENEF	100	3.25	649.25 PG		A07-F10	2/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78434582	PREDNISC	WVG	WEBSTER GENEF	19	8.02	152.38 PG		A15-F30	8/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78434784	BENZOYL	WVG	WEBSTER GENEF	1	18.7	18.7 PG		AUTHEN	12/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78434784	BENZOYL	WVG	WEBSTER GENEF	1	18.7	18.7 PG		SO	12/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78434772	MARCAIN	WVG	WEBSTER GENEF	3	22.49	67.47 PG		NW	9/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78435210	FLUCONA	WVG	WEBSTER GENEF	83	16.74	1380.42 PG		A17-B20	1/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78435236	FLUCONA	WVG	WEBSTER GENEF	63	3.27	206.01 PG		A15-G10	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78435442	LISINOPRI	WVG	WEBSTER GENEF	21	4.71	98.91 PG		A17-A40	6/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78435491	NORVASC	WVG	WEBSTER GENEF	1	155.6	155.6 PG		NW	5/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78435690	DOXYCYC	WVG	WEBSTER GENEF	75	14.40	1036.75 PG		A14-B20	7/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78435160	ALBUTERI	WVG	WEBSTER GENEF	13	2.94	38.22 PG		A21-H10	8/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78437327	RANITIDIN	WVG	WEBSTER GENEF	102	1.02	104.04 PG		A03-H20	7/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78437533	PHENYLEI	WVG	WEBSTER GENEF	2	22.5	45 PG		A21-A30	12/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78437566	SPIRONOI	WVG	WEBSTER GENEF	4	30.19	120.76 PG		A14-G15	10/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78437568	MECLIZIN	WVG	WEBSTER GENEF	0	2.81	0 PG		A12-B06		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78437647	EPINEPHF	WVG	WEBSTER GENEF	9	5.97	53.73 PG		A17-A50	11/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78438378	GRIS-PEG	WVG	WEBSTER GENEF	2	145.91	291.82 PG		A15-I40	10/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78438798	PROPRAH	WVG	WEBSTER GENEF	2	82.06	164.18 PG		NW	11/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78439089	METOPRC	WVG	WEBSTER GENEF	2	3	6 PG		A15-F10	11/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78440722	TERBUTAI	WVG	WEBSTER GENEF	1	259.8	259.8 PG		NW	9/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78441177	METHOCA	WVG	WEBSTER GENEF	35	5.94	207.9 PG		A21-G40	10/19/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78441219	VASOPRE	WVG	WEBSTER GENEF	1	74.99	74.99 PG		A09-J30	10/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78441616	POLYCITR	WVG	WEBSTER GENEI	0	31.5	0 PG		A05-J50		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78443840	PAMINE T.	WVG	WEBSTER GENEI	0	188.05	0 PG		A09-J10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444011	MEXILETI	WVG	WEBSTER GENEI	4	18.88	82.72 PG		NW	12/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444326	GRIFULVI	WVG	WEBSTER GENEI	0	16.19	0 PG		A11-H10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78445486	PREDNISC	WVG	WEBSTER GENEI	0	1.05	0 PG		A09-A40		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78446824	PROCHLO	WVG	WEBSTER GENEI	3	41.61	124.83 PG		A21-A20	9/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78448409	LINASYN F	WVG	WEBSTER GENEI	9	75.6	680.4 PG		A09-H26	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78449888	NITROPRI	WVG	WEBSTER GENEI	20	8.26	165.2 PG		A09-J40	11/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78450242	XALATAN	WVG	WEBSTER GENEI	1	56.48	56.48 PG		CF0-C20	10/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454485	VINBLAST	CAI	CARDINAL HEALT	7	20.37	164.59 PG		CF0-NW	12/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78458705	TRAMADC	WVG	WEBSTER GENEI	292	15.68	4572.72 PG		A10-D30	8/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78459788	TIMOLOL I	WVG	WEBSTER GENEI	111	2.93	325.23 PG		A01-H40	10/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78459804	TRIAMCIN	WVG	WEBSTER GENEI	4	6.09	24.36 PG		A05-A40	8/31/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78459820	HYDROCC	OKH	OK HEALTHCARE	56	10.25	320.8 PG		A05-I50	5/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78461671	INTAL CR	WVG	WEBSTER GENEI	1	16.5	16.5 PG		A07-A40	12/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78463256	ALBUTER	TOP	TOP RX	10	7.89	78.9 PG		A15-H40	10/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78463266	PENTOXI	WVG	WEBSTER GENEI	36	92.67	3103.65 PG		A21-E20	9/29/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78463571	CARBOPL	WVG	WEBSTER GENEI	97	18.7	1813.9 PG		A11-D10	12/30/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78463682	METHOCA	WVG	WEBSTER GENEI	40	24.5	980 PG		A06-C15	8/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465670	SUCRALF/	WVG	WEBSTER GENEI	28	57.95	1622.6 PG		A21-E10	1/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465670	SUCRALF/	WVG	WEBSTER GENEI	48	57.98	2781.6 PG		AUTHEN	12/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465860	NAPROXE	WVG	WEBSTER GENEI	5	4.74	23.7 PG		A09-B30	9/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465886	CIMETIDI	WVG	WEBSTER GENEI	8	18.21	145.68 PG		A17-H30	11/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465894	DEPO PRO	WVG	WEBSTER GENEI	6	151.43	908.58 PG		A03-B20	4/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465902	FLOVENT	WVG	WEBSTER GENEI	1	169.18	169.18 PG		A01-A50	1/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465910	FLOVENT	WVG	WEBSTER GENEI	2	83.2	166.4 PG		A05-I30	9/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465936	TRIAMCIN	WVG	WEBSTER GENEI	324	9.04	2928.96 PG		A14-C10	10/26/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465936	TRIAMCIN	WVG	WEBSTER GENEI	213	9.04	1926.52 PG		AUTHEN	12/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465944	NITRO-BIC	WVG	WEBSTER GENEI	28	6.3	183.6 PG		A19-F10,E	7/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465951	POLYMYX	WVG	WEBSTER GENEI	891	12.59	11306.79 PG		A11-F10	5/15/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465969	MECLOFE	WVG	WEBSTER GENEI	0	69.8	0 PG		A19-H20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465993	CIMETIDI	WVG	WEBSTER GENEI	29	46.99	1362.71 PG		A12-H20	11/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466001	DANTRIU	WVG	WEBSTER GENEI	8	198.29	1586.32 PG		A09-C10	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466019	SILVER-SI	WVG	WEBSTER GENEI	74	5.82	430.68 PG		A05-G20	9/17/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78486043	AMPICILLI	WVG	WEBSTER GENEF	14	99.8	1394.4	PG	A01-H30	8/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78489803	SMZ INJEC	WVG	WEBSTER GENEF	4	20.3	81.2	PG	A07-J60	11/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78470893	PEN G PO	WVG	WEBSTER GENEF	2470	15.1	37297	PG	A17-G20	3/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78470976	CELESTOI	WVG	WEBSTER GENEF	60	82.25	2350	PG	A01-A10	3/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78471554	METHOTR	WVG	WEBSTER GENEF	31	6.02	186.62	PG	A05-J10	6/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78474828	RIFAMPIN	WVG	WEBSTER GENEF	10	133	1330	PG	A05-I20	4/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78475075	KETOCON	WVG	WEBSTER GENEF	14	4.25	59.5	PG	A03-I40	10/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78476083	TAMIFLU	WVG	WEBSTER GENEF	0	36.82	0	PG	A17-C10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78475091	ZOFRAN 2	WVG	WEBSTER GENEF	1	213.67	213.67	PG	NW	10/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78476218	NEO POLY	WVG	WEBSTER GENEF	294	1.5	441	PG	A07-H20	11/2/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78476349	MAGNESII	INS	IN SOURCE	351	1.37	480.87	PG	A05-C20	9/17/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78476406	GENTAMI	ABB	ABBOTT LABS	88	0.64	56.32	PG	A11-I20	3/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78476844	ROCEPHI	WVG	WEBSTER GENEF	8	41.67	334.96	PG	A15-E10	10/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78479018	TAMIFLU	WVG	WEBSTER GENEF	2	73.69	147.3	PG	NW	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78479968	CLARITHR	WVG	WEBSTER GENEF	43	30.27	1301.61	PG	A12-J35	4/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78480827	LEVOTHY	WVG	WEBSTER GENEF	0	5.25	0	PG	A01-A20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78480884	CLINDAM	WVG	WEBSTER GENEF	10	39.43	394.3	PG	A05-H10	7/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78481811	LIDOCAIN	WVG	WEBSTER GENEF	0	40.24	0	PG	A09-J50		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78484546	CYTOXAN	WVG	WEBSTER GENEF	12	12.65	151.8	PG	A09-J20	11/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78484561	MEXILETI	WVG	WEBSTER GENEF	0	17.55	0	PG	A03-I10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78484637	GABAPEN	WVG	WEBSTER GENEF	33	18.27	597.72	PG	A01-J10	11/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78484645	GABAPEN	WVG	WEBSTER GENEF	3	39.47	118.41	PG	A01-J60	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78485868	CYCLOBE	WVG	WEBSTER GENEF	2	4.57	9.14	PG	NW	12/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78486827	FORTAZ 1	WVG	WEBSTER GENEF	3	118.8	356.8	PG	A01-B10	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78487322	TENORMI	WVG	WEBSTER GENEF	1	89.99	39.99	PG	AUTHEN	12/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78487804	FLURESS	WVG	WEBSTER GENEF	20	0	180	PG	CFO-NW	0/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78488165	DAPSONE	WVG	WEBSTER GENEF	5	17.08	86.4	RG	SO	12/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78489581	BRETHINE	WVG	WEBSTER GENEF	0	20.62	0	PG	A09-A50		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78489579	BOD CHL 1	WVG	WEBSTER GENEF	2	10.75	21.5	PG	SO	12/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78489645	PROMETH	WVG	WEBSTER GENEF	0	17.65	0	PG	A14-J20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78490701	MIRTAZAF	WVG	WEBSTER GENEF	0	2.99	0	PG	A01-A50		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78491019	IMIPRAMI	WVG	WEBSTER GENEF	0	18.04	0	PG	A07-J60		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78491877	CYPROHE	WVG	WEBSTER GENEF	0	24.42	0	PG	A09-A10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78492180	AMOXICIL	WVG	WEBSTER GENEF	11	12.26	134.86	PG	A15-H30	6/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	Replenish	Updated	Created	On Restricted List?	Human Label?
863	78492735	AZITHROM	WVG	WEBSTER GENEF	29	174.19	5051.51	PG	A01-J50	7/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78492749	AZITHROM	WVG	WEBSTER GENEF	42	76.76	3223.5	PG	A03-B10	11/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78492776	OMEPRAZ	WVG	WEBSTER GENEF	1	87.99	87.99	PG	NW	10/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78492842	AMANTAD	WVG	WEBSTER GENEF	44	24.87	1094.28	PG	A05-H20	7/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78493099	PIPERACII	WVG	WEBSTER GENEF	1	69.91	69.91	PG	NW	12/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78494764	AMIKACIN	WVG	WEBSTER GENEF	43	50	2150	PG	A09-B40	9/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78495040	LIDOCAINI	WVG	WEBSTER GENEF	2	1.71	3.42	PG	A21-A40	6/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78497750	PROPOFC	WVG	WEBSTER GENEF	92	37.4	3440.8	PG	A15-A10	8/18/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78498032	PRAZOSIN	WVG	WEBSTER GENEF	11	10.69	117.59	PG	A07-A10	9/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78501033	BACTERIC	WVG	WEBSTER GENEF	2	10.75	21.5	PG	NW	11/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78501280	BUSPIRO	WVG	WEBSTER GENEF	0	10.25	0	PG	A05-A20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78501406	POTASSIL	WVG	WEBSTER GENEF	3	16.46	49.38	PG	A07-J20	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78506288	DORZOLA	WVG	WEBSTER GENEF	1	65.81	65.81	PG	NW	12/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78506367	PREDNISC	WVG	WEBSTER GENEF	17	3.68	62.62	PG	A12-A20	6/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78507041	HYDROCC	WVG	WEBSTER GENEF	1	1.55	1.55	PG	NW	10/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78507223	AZITHRO	WVG	WEBSTER GENEF	116	14.85	1719.26	PG	A09-H10	11/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78507488	PROCALA	WVG	WEBSTER GENEF	1	33.41	33.41	PG	A12-Q30	7/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78508228	MELOXIC/	WVG	WEBSTER GENEF	112	2	224	PG	A21-Q30R	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78509231	MELOXIC/	DLD	BLOODWORTH	8	3	24	PG	A07-110RX	10/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78520437	LANTUS 1	WVG	WEBSTER GENEF	1	70.18	70.18	PG	OF0-NW	12/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78540533	PROTAMI	WVG	WEBSTER GENEF	2	16	32	PG	NW	10/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78544068	AMINOPH	WVG	WEBSTER GENEF	5	18.49	92.45	PG	A05-A10	2/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78544066	TAZICEF 1	WVG	WEBSTER GENEF	1	231.34	231.34	PG	SO	12/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78544185	HEPARIN 1	WVG	WEBSTER GENEF	10	12.91	129.1	PG	A07-D30	9/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78544922	FLUCONA	WVG	WEBSTER GENEF	47	18.39	864.33	PG	A03-J10	11/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78545757	AMINOPH	CAI	CARDINAL HEALT	8	15.03	120.24	PG	A10-B15	7/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78552244	OFLOXAC	WVG	WEBSTER GENEF	36	5.24	188.4	PG	A07-H40	10/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78553784	DIMENHYD	WVG	WEBSTER GENEF	1	447.73	447.73	PG	SO	12/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78556185	CLINDAMY	WVG	WEBSTER GENEF	12	2.63	31.56	PG	A21-B40	6/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78556749	ONDANSE	WVG	WEBSTER GENEF	131	2.28	298.68	PG	A21-B10	7/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78556784	POTASSIL	WVG	WEBSTER GENEF	8	18.09	144.72	PG	A03-A30	7/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78556772	POTASSIL	WVG	WEBSTER GENEF	10	13.23	132.3	PG	A05-J20	8/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78559869	CLINDAM	WVG	WEBSTER GENEF	0	37.5	0	PG	A14-I30		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
863	78559869	CLINDAM	WVG	WEBSTER GENEF	120	37.5	4500	PG	PG-AUTHI	2/29/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78581189	METRONI	WVG	WEBSTER GENEF	32	3.1	99.2 PG		A21-B30	7/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78587102	BETAMET	WVG	WEBSTER GENEF	1	2.89	2.89 PG		SOR03	5/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78579440	NIFEDIPIN	WVG	WEBSTER GENEF	1	76.56	76.56 PG		SO	12/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78579457	AMLODIPI	WVG	WEBSTER GENEF	20	2.85	58 PG		A14-G10	11/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78579473	AMLODIPI	WVG	WEBSTER GENEF	6	8.55	51.3 PG		A14-J10	10/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78580696	IMIQUIMO	YAN	WILLOW BIRCH P	2	239.1	478.2 PG		SO	9/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78582157	CLINDAMY	WVG	WEBSTER GENEF	8	49.2	393.6 PG		A09-D16	10/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78582500	TERCONA	BLO	BLOODWORTH	1	8.75	8.75 PG		SO	10/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78583324	CLINDAMY	WVG	WEBSTER GENEF	105	12	1260 PG		NW	10/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78585100	LIDODERM	WVG	WEBSTER GENEF	2	188.34	376.68 PG		SO	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78586736	AMANTAD	WVG	WEBSTER GENEF	9	49.55	445.95 PG		SO	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	70000796	HETASTAI	ABB	ABBOTT LABS	241	17	4097 R10		R15-C01	5/20/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78355610	SALINE JR	BAX	BAXTER CENTER	0	20.05	0 R17		R17-C01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014308	DIAZEPAM	WVG	WEBSTER GENEF	1	17.9	17.9 VAULT		PENDING	9/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014308	DIAZEPAM	WVG	WEBSTER GENEF	6	17.9	107.4 VAULT		SL2-D50	11/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014316	DIAZEPAM	WVG	WEBSTER GENEF	6	33.74	202.44 VAULT		SL2-D60RI	8/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014324	PHENOBA	WVG	WEBSTER GENEF	135	4.01	541.35 VAULT		SL2-A30RI	9/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014951	DIAZEPAM	ABB	ABBOTT LABS	4048	0.99	4007.52 VAULT		SL4-B10RI	3/17/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026612	PHENOBA	WVG	WEBSTER GENEF	1	3.8	3.8 VAULT		PENDING	12/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026612	PHENOBA	WVG	WEBSTER GENEF	156	3.8	592.8 VAULT		SL2-B10RI	9/24/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026620	PHENOBA	WVG	WEBSTER GENEF	1	4.2	4.2 VAULT		PENDING	11/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026620	PHENOBA	WVG	WEBSTER GENEF	1	4.2	4.2 VAULT		QUARANT	1/18/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026620	PHENOBA	WVG	WEBSTER GENEF	97	4.2	407.4 VAULT		SL2-D20RI	5/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026638	PHENOBA	WVG	WEBSTER GENEF	3	7.75	23.25 VAULT		PENDING	7/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026638	PHENOBA	WVG	WEBSTER GENEF	87	7.75	674.25 VAULT		SL2-E20RI	8/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026646	PHENOBA	WVG	WEBSTER GENEF	5	1.71	8.55 VAULT		PENDING	7/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026646	PHENOBA	WVG	WEBSTER GENEF	5	1.71	8.55 VAULT		SL2-E10RI	8/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026646	PHENOBA	WVG	WEBSTER GENEF	43	1.71	73.53 VAULT		SL6-B10DI	7/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026653	PHENOBA	WVG	WEBSTER GENEF	34	11.09	377.06 VAULT		SL2-E40RI	7/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057320	DIAZEPAM	WVG	WEBSTER GENEF	12	9.48	113.76 VAULT		SL2-D30RI	3/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057338	DIAZEPAM	WVG	WEBSTER GENEF	5	9.16	45.8 VAULT		PENDING	9/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057338	DIAZEPAM	WVG	WEBSTER GENEF	7	9.16	64.12 VAULT		SL2-D40RI	9/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78188271	BELLADO	WVG	WEBSTER GENEF	3	6.83	20.49 VAULT		SL2-A20RI	8/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78136547	PENTOTH	ABB	ABBOTT LABS	414	8.94	3701.16 VAULT		SL4-C10RI	9/13/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78342686	DIAZEPAM	WVG	WEBSTER GENER	34	2.21	75.14	VAULT	SL2-C30RI	7/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342702	DIPHENOX	WVG	WEBSTER GENER	105	4.59	482.45	VAULT	SL2-C40RI	12/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78357701	DIAZEPAM	WVG	WEBSTER GENER	1	1.9	1.9	VAULT	PENDING	11/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78357701	DIAZEPAM	WVG	WEBSTER GENER	64	1.9	121.6	VAULT	SL2-D30RI	10/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78357710	DIAZEPAM	WVG	WEBSTER GENER	22	2.1	46.2	VAULT	SL2-B20RI	10/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370984	PHENOBA	WVG	WEBSTER GENER	3	37.75	113.25	VAULT	PENDING	11/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370984	PHENOBA	WVG	WEBSTER GENER	1	37.75	37.75	VAULT	QUARANT	1/18/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370984	PHENOBA	WVG	WEBSTER GENER	9	37.75	339.75	VAULT	SL2-C10RI	3/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379576	PHENOBA	WVG	WEBSTER GENER	20	3.63	72.6	VAULT	SL2-E30RI	6/19/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380377	DIAZEPAM	WVG	WEBSTER GENER	3	11.53	34.59	VAULT	PENDING	10/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380377	DIAZEPAM	WVG	WEBSTER GENER	9	11.53	103.77	VAULT	SL2-D10RI	9/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380534	ALPRAZOL	WVG	WEBSTER GENER	9	13.49	121.41	VAULT	SL2-A40RI	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380812	ALPRAZOL	WVG	WEBSTER GENER	21	3	63	VAULT	SL2-A10RI	7/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78429884	ALPRAZOL	WVG	WEBSTER GENER	139	4.02	558.78	VAULT	SL2-A50RI	10/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78433255	ALPRAZOL	WVG	WEBSTER GENER	9	7.81	70.29	VAULT	SL2-C50RI	7/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78437251	MIDAZOLA	WVG	WEBSTER GENER	13	15.7	204.1	VAULT	SL2-A60RI	7/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78560003	DIPHENOX	WVG	WEBSTER GENER	1	7.42	7.42	VAULT	PENDING	10/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78575508	PHENOBA	WVG	WEBSTER GENER	108	3.58	384.48	VAULT	SL2-B20RI	7/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78575606	PHENOBA	WVG	WEBSTER GENER	1	7.95	7.95	VAULT	PENDING	9/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78575606	PHENOBA	WVG	WEBSTER GENER	1	7.95	7.95	VAULT	QUARANT	2/11/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78575609	PHENOBA	WVG	WEBSTER GENER	95	7.95	755.25	VAULT	SL2-B30RI	7/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

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DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78008294	POTASSIU	ABB	ABBOTT LABS	4	0.49	1.96	MS	CC08C3	9/6/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78008326	LACTATEI	ABB	ABBOTT LABS	2	26.41	52.82	MS	EE03C2	2/3/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78008333	LACTATEI	ABB	ABBOTT LABS	6	33.79	202.74	MS	EE02D1	4/12/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78008341	SODIUM E	ABB	ABBOTT LABS	12	1.18	14.16	MS	EE10D4	9/26/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78008374	NORMOSI	ABB	ABBOTT LABS	12	18.81	225.72	MS	H03B2	4/14/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78008416	SALINE 0.9	ABB	ABBOTT LABS	7	36	256	MS	DD12D1	3/19/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78008539	DEX 5.0%	ABB	ABBOTT LABS	3	22.47	67.41	MS	EE02C1	4/12/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78009697	DEX 5.0%	ABB	ABBOTT LABS	1	26.42	26.42	MS	EE03C1	3/18/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009713	LACTATED	ABB	ABBOTT LABS	131	13.55	1775.05	MS	H04B2	1/28/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009721	SALINE 0.9	ABB	ABBOTT LABS	10	19.49	194.9	MS	H01B2	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009739	SALINE IR	ABB	ABBOTT LABS	2	15.5	31	MS	H04A1	4/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009796	HETASTAI	ABB	ABBOTT LABS	96	17	1632	MS	EE04C2	5/20/2003	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78011407	NEO POLY	WVG	WEBSTER GENER	9	25.2	226.8	MS	P05C2	12/14/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78011415	NEO POLY	WVG	WEBSTER GENER	28	17.4	487.2	MS	P05C1	12/21/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78013407	SULFASAL	WVG	WEBSTER GENER	1	32.21	32.21	MS	P05A2	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014082	CORTROS	WVG	WEBSTER GENER	2	118.43	236.86	MS	P04B5	10/18/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014142	CIMETIDI	WVG	WEBSTER GENER	1	3.31	3.31	MS	P05C4	7/22/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014176	CIMETIDI	WVG	WEBSTER GENER	18	1.9	34.2	MS	P05E3	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014356	CYPROHE	WVG	WEBSTER GENER	6	6.25	37.5	MS	P07B2	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014431	KETOCON	WVG	WEBSTER GENER	7	15.61	109.27	MS	P05E2	4/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014449	PREDNISC	WVG	WEBSTER GENER	19	15.84	301.44	MS	P07A2	10/27/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78021042	SODIUM C	WVG	WEBSTER GENER	15	11	165	MS	P03D1	5/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78024315	ERYTHRO	ABB	ABBOTT LABS	3	17.5	52.5	MS	P06C3	9/29/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025821	AMPICILL	WVG	WEBSTER GENER	1	48.8	48.8	MS	P07B6		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025570	AMOXICIL	WVG	WEBSTER GENER	2	14.87	29.74	MS	P02C6	10/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025596	AMOXICIL	WVG	WEBSTER GENER	2	25.15	50.3	MS	P06C4	6/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025844	CEFAZOLI	WVG	WEBSTER GENER	37	8.4	310.8	MS	P05C2	12/6/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78025851	CEFAZOLI	WVG	WEBSTER GENER	155	0.92	143.52	MS	P03C1	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043784	METHIMA	WVG	WEBSTER GENER	1	8.5	8.5	MS	P06B5	3/22/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78054403	ATROPINE	WVG	WEBSTER GENER	4	2.35	9.4	MS	P04A6	10/2/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78054494	NEO POLY	WVG	WEBSTER GENER	9	19.6	167.4	MS	P04C6	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056320	HYDROXY	WVG	WEBSTER GENER	1	6.6	6.6	MS	P02B4	1/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056346	HYDROXY	WVG	WEBSTER GENER	14	54.4	761.6	MS	P02B6	7/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056361	METHOCA	WVG	WEBSTER GENER	67	23.6	1594.8	MS	P05C1	9/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056378	METRONI	WVG	WEBSTER GENER	32	26.43	845.76	MS	P03B1	4/6/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056239	METOCLO	WVG	WEBSTER GENER	2	4.25	8.5	MS	TEMP	7/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056262	HEPARIN	WVG	WEBSTER GENER	293	5.46	1624.1	MS	P03B3	5/11/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056296	METRONI	WVG	WEBSTER GENER	14	5.59	82.46	MS	P05B2	3/3/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056304	METRONI	WVG	WEBSTER GENER	2	12.56	25.12	MS	P05A1	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056494	DOXYCYC	WVG	WEBSTER GENER	5	2.75	13.75	MS	P07C4	9/21/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056502	DOXYCYC	WVG	WEBSTER GENER	15	18.51	277.65	MS	I101B4	8/2/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78058610	DOXYCYC	WVG	WEBSTER GENEF	137	19.4	2657.8	MS	P05B2	10/8/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058619	GLYCOPY	WVG	WEBSTER GENEF	9	4.5	40.5	MS	P03B1	9/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058858	ENALAPRI	WVG	WEBSTER GENEF	2	1.37	2.74	MS	DD10A2	10/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058856	ENALAPRI	WVG	WEBSTER GENEF	4	1.57	6.28	MS	TEMP	12/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058882	ENALAPRI	WVG	WEBSTER GENEF	1	2.32	2.32	MS	DD10A1		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058916	PREDNISC	WVG	WEBSTER GENEF	6	3.42	20.52	MS	P04A5	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058940	TETRACAI	WVG	WEBSTER GENEF	12	2.8	33.6	MS	P04D3	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058998	CIMETIDI	WVG	WEBSTER GENEF	13	7.8	101.4	MS	P08C1	3/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059065	MISOPRO	WVG	WEBSTER GENEF	4	41.97	167.88	MS	P05E5	10/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059973	AMINOPH	WVG	WEBSTER GENEF	2	21	42	MS	DD10A5	9/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059981	AMINOPH	WVG	WEBSTER GENEF	2	33.85	67.7	MS	P05E4	5/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78071823	PSN NALO	ABB	ABBOTT LABS	21	3	63	MS	CC03B3	5/10/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78078869	ISOXSUP	WVG	WEBSTER GENEF	134	11.89	1593.46	MS	P02D1	8/20/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78078997	SMZ TMP	WVG	WEBSTER GENEF	4	9.75	39	MS	P05A6	6/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079013	SMZ TMP	WVG	WEBSTER GENEF	73	8	584	MS	P05B1	8/2/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079021	SMZ TMP	WVG	WEBSTER GENEF	249	25	6225	MS	P01A1	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079039	METRONI	WVG	WEBSTER GENEF	2	7.15	14.3	MS	TEMP	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079569	ATROPINE	WVG	WEBSTER GENEF	9	24	216	MS	P04A8	8/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080871	CEPHALE	WVG	WEBSTER GENEF	1	4.3	4.3	MS	P02C1	5/12/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080889	CEPHALE	WVG	WEBSTER GENEF	1	25.8	25.8	MS	P02C3	7/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080897	CEPHALE	WVG	WEBSTER GENEF	2	17.40	34.92	MS	P02C2	8/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080905	CEPHALE	WVG	WEBSTER GENEF	3	45.12	135.36	MS	P02C4	7/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78083491	HEPARIN	WVG	WEBSTER GENEF	31	1.43	44.33	MS	P03B2	5/26/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78083509	HEPARIN	WVG	WEBSTER GENEF	25	3.42	85.5	MS	P03B4	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78083517	AMPICILL	WVG	WEBSTER GENEF	88	4.8	418.8	MS	P06B3	7/8/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78084024	SUCRALF	WVG	WEBSTER GENEF	15	13.6	205.5	MS	P06D1	4/12/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78085226	TETRACY	WVG	WEBSTER GENEF	1	30.8	30.8	MS	P02B2	6/30/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78085526	SMZ/TMP	WVG	WEBSTER GENEF	29	9	261	MS	P03A4	2/1/2007	FALSE	FALSE	3/18/2008 4:31	3/19/2008	YES	YES
883	78085585	PREDNISC	WVG	WEBSTER GENEF	1	9.57	9.57	MS	P08C5	9/2/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78085748	PREDNISC	WVG	WEBSTER GENEF	3	33.06	99.94	MS	P07A1	11/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78092417	DEX 5%	ABB	ABBOTT LABS	11	25.62	281.82	MS	EE0181	8/27/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78334605	DOBUTAM	WVG	WEBSTER GENEF	4	9.75	39	MS	P04D1	7/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78325910	PREDNISC	WVG	WEBSTER GENEF	1	17.63	17.63	MS	P02A4	9/1/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328449	HYDROXY	WVG	WEBSTER GENEF	14	6.48	90.72	MS	P05A4	4/26/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DO Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78328458	HYDROXY	WVG	WEBSTER GENEF	3	32.73	98.09	MS	P02B7	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78337737	IBUPROFE	WVG	WEBSTER GENEF	8	13.5	108	MS	P05A2	6/27/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78337752	IBUPROFE	WVG	WEBSTER GENEF	6	6.99	41.94	MS	P05A1	1/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78338587	ACETAZOI	WVG	WEBSTER GENEF	26	19.11	512.16	MS	P07A3	5/5/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342694	DILTIAZEI	WVG	WEBSTER GENEF	2	2.59	5.78	MS	TEMP	6/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342710	PREDNISC	WVG	WEBSTER GENEF	3	3.85	11.55	MS	P02A3	2/13/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342728	SILVADEN	WVG	WEBSTER GENEF	17	2.27	38.59	MS	P04B1	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78342730	SILVADEN	WVG	WEBSTER GENEF	16	3.2	51.2	MS	P04B3	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	70343011	METRONI	ABB	ABBOTT LABS	96	2.4	230.4	MS	A07A1	8/14/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346231	AMPICILLI	WVG	WEBSTER GENEF	17	96.02	1632.34	MS	P05A5	7/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346132	AMOXI SU	WVG	WEBSTER GENEF	11	3	33	MS	P07A9	9/11/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78349433	ATROPINI	PHO	PHOENIX PHARM	18	1.45	26.1	MS	P04A7	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78354283	PROPARA	BLO	BLOODWORTH	3	3.65	10.95	MS	AA02D3	8/14/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78357644	AMOXICIL	WVG	WEBSTER GENEF	6	5.88	35.28	MS	P02C5	2/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78362981	NORMOSC	ABB	ABBOTT LABS	7	2.87	18.69	MS	SE03C3	11/28/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365465	WATER IR	BAX	BAXTER CENTER	15	14.02	210.3	MS	B12D1	11/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365528	SALINE IR	BAX	BAXTER CENTER	9	13.82	124.38	MS	A10D1	2/21/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365593	SALINE 0.9	BAX	BAXTER CENTER	1	44.31	44.31	MS	A12D1	8/24/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365734	DEXTROS	BAX	BAXTER CENTER	1	27.15	27.15	MS	A12D3	6/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370907	ALBUTER	WVG	WEBSTER GENEF	2	15	30	MS	TEMP	6/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379303	PREDNISC	TOP	TOP RX	3	1.57	4.71	MS	P05C5	4/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379360	TIMOLOL	WVG	WEBSTER GENEF	1	1.38	1.38	MS	P04D4	8/1/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379444	FUROSEM	WVG	WEBSTER GENEF	2	1.55	3.1	MS	TEMP	6/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379461	COLCHICI	GEE	GENETCO INC	2	3.39	6.78	MS	P05C3	5/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379483	TROPICAI	TOP	TOP RX	1	4.52	4.52	MS	P04D2	5/12/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76370519	FUROSEM	WVG	WEBSTER GENEF	3	1.75	5.25	MS	TEMP	3/13/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379500	FLURBIPR	WVG	WEBSTER GENEF	16	4.21	67.36	MS	P04C2	12/8/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379534	DEXAMET	WVG	WEBSTER GENEF	1	6.74	6.74	MS	P07A5	6/22/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379717	TETRACYI	WVG	WEBSTER GENEF	4	4.75	19	MS	P02B9	10/31/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379782	DEXAMET	WVG	WEBSTER GENEF	52	10.67	555.24	MS	P07A4	10/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379790	MARCAINI	WVG	WEBSTER GENEF	2	3.58	7.16	MS	P03A2	8/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379881	TRAMADC	WVG	WEBSTER GENEF	3	3.56	10.68	MS	P05C4	2/1/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78379931	ZANTAC	WVG	WEBSTER GENEF	1	7.69	7.69	MS	P06A4	8/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380135	RANITIDI	WVG	WEBSTER GENEF	3	3.35	10.05	MS	P05C6	5/24/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78380575	EPOGEN ; WVG		WEBSTER GENEF	60	23.41	1404.6	MS	AA02D6	12/12/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380533	HYDROXY TOP		TOP RX	2	22.42	44.84	MS	P02B6	6/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380781	OCUFLOX BLO		BLOODWORTH	23	2.86	65.58	MS	P04C4	6/14/2007	FALSE	FALSE	3/10/2008 4:31	3/10/2008	YES	YES
883	78380880	MEDROXY TOP		TOP RX	21	29.47	618.87	MS	P08C6	7/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78380997	ZANTAC B WVG		WEBSTER GENEF	5	50.2	251	MS	P08A3	8/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78381161	CARAFATI WVG		WEBSTER GENEF	12	114.59	1375.08	MS	P05C2	2/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78381237	TIMENTIN WVG		WEBSTER GENEF	16	132.64	1724.32	MS	P05B1	12/19/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78383351	THERMAZ KEN		KENDALL HEALTH	37	18.56	613.46	MS	DD06B1	9/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391585	FLUPHEN WVG		WEBSTER GENEF	53	3.8	200.8	MS	P02B8	10/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391669	PENTOXIF WVG		WEBSTER GENEF	3	7.48	22.28	MS	P07B5	9/12/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78392442	ALBUTERI WVG		WEBSTER GENEF	2	40.9	81.8	MS	P07B3	6/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78392467	ISOXSUPF NEO		NEOGEN CORPO	18	52.88	940.08	MS	P03D2	8/23/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78397968	ALBUTER WVG		WEBSTER GENEF	4	4.21	16.84	MS	P03A3	1/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78399070	METHOCA WVG		WEBSTER GENEF	33	4.9	161.7	MS	P05A5	7/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78410261	REGLAN II WVG		WEBSTER GENEF	9	5.94	53.46	MS	P03A1	1/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414093	TOBRAMY WVG		WEBSTER GENEF	14	1.25	17.5	MS	P04G8	2/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414105	GENTAMI WVG		WEBSTER GENEF	12	1	12	MS	P04A4	2/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414389	TRIPLE NF WVG		WEBSTER GENEF	11	14.5	159.5	MS	P04C6	1/10/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78418527	POTASSR ABB		ABBOTT LABS	700	0.78	546	MS	CC03B2	7/5/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78421211	STERILE V ABB		ABBOTT LABS	119	1.49	171.35	MS	EE09B2	3/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78423757	CIPROFLC WVG		WEBSTER GENEF	25	11.07	276.75	MS	P04A3	10/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78429329	ACETYLC BIN		BIONICHE ANIMAI	23	0.8	227.7	MS	P03B5	8/18/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78429129	DOPAMINI WVG		WEBSTER GENEF	4	0.75	3	MS	P04B6	1/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78430091	AMINOSYI ABB		ABBOTT LABS	5	103.8	519	MS	DD12C1	5/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78437327	RANITIDIN WVG		WEBSTER GENEF	12	1.02	12.24	MS	P05D5	7/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78441177	METHOCA WVG		WEBSTER GENEF	10	5.94	59.4	MS	P07C3	10/18/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444566	NEO POLY WVG		WEBSTER GENEF	91	1.85	57.35	MS	FF01D1	9/15/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454188	LACTATEI BAX		BAXTER CENTER	1	15.82	15.82	MS	A10D2	6/22/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78459804	TRIAMCIN WVG		WEBSTER GENEF	2	6.09	12.18	MS	P03A8	8/31/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78460985	SARAPIN HIG		HIGH CHEMICAL I	74	23.5	1739	MS	GG13C1	5/8/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78461225	AMINOCAI ABB		ABBOTT LABS	110	1.02	112.2	MS	CC05B1	1/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78461241	MEPIVACA ABB		ABBOTT LABS	38	3.61	137.18	MS	EE11A1	11/3/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78461571	INTAL CRI WVG		WEBSTER GENEF	1	16.8	16.8	MS	P02A1	12/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78463268	ALBUTERI TOP		TOP RX	3	7.89	23.67	MS	P05D2	10/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DO Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Human Label?
883	78463268	PENTOXIF	WVG	WEBSTER GENEF	29	32.67	947.43	MS	P07B4	9/29/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466571	CARISOPF	WVG	WEBSTER GENEF	28	16.7	466.2	MS	P08D3	12/30/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466662	METHOCA	WVG	WEBSTER GENEF	60	24.6	1225	MS	P08A1	9/13/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466870	SUCRALF	WVG	WEBSTER GENEF	21	57.95	1216.95	MS	P08D2	1/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466860	NAPROXE	WVG	WEBSTER GENEF	6	4.74	23.7	MS	P08B4	3/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466878	NAPROXE	WVG	WEBSTER GENEF	39	17.89	690.37	MS	P08A2	8/10/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466888	CIMETIDI	WVG	WEBSTER GENEF	2	18.21	36.42	MS	P08C2	10/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466894	DEPO PRO	WVG	WEBSTER GENEF	3	151.43	454.29	MS	P04A1	4/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466902	FLOVENT	WVG	WEBSTER GENEF	1	169.18	169.18	MS	P03A5	8/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466936	TRIAMCIN	WVG	WEBSTER GENEF	57	9.04	605.68	MS	P02A5	10/26/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466944	NITRO-BI	WVG	WEBSTER GENEF	5	6.3	31.5	MS	P04B4	7/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466951	POLYMYX	WVG	WEBSTER GENEF	400	12.69	5076	MS	P05B4	8/16/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466993	CIMETIDI	WVG	WEBSTER GENEF	18	46.99	845.82	MS	P08C3	11/2/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466001	DANTRIU	WVG	WEBSTER GENEF	3	198.23	594.67	MS	P08B3	6/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466019	SILVER SU	WVG	WEBSTER GENEF	33	5.82	192.06	MS	P04B2	9/1/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466027	RANITIDIN	WVG	WEBSTER GENEF	159	7	1113	MS	P06D1	8/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466043	AMPICILLI	WVG	WEBSTER GENEF	14	99.6	1394.4	MS	P06B2	6/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78470893	PEN G PO	WVG	WEBSTER GENEF	580	16.1	9458	MS	P03C3	3/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78470976	CELESTON	WVG	WEBSTER GENEF	54	32.25	1741.5	MS	P02A2	3/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78474828	RIFAMPIN	WVG	WEBSTER GENEF	2	133	266	MS	P07B1	4/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78475216	NEO POLY	WVG	WEBSTER GENEF	11	1.6	16.8	MS	P04A3	11/2/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78475349	MAGNESI	INB	IN SOURCE	202	1.37	276.74	MS	P07C1	9/17/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78475044	ROCEPHI	WVG	WEBSTER GENEF	3	41.87	125.61	MS	P06D1	3/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78479986	CLARITHR	WVG	WEBSTER GENEF	6	30.27	181.62	MS	P05D4	4/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78492736	AZITHROI	WVG	WEBSTER GENEF	3	174.19	522.57	MS	P05A3	7/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78492745	AZITHROI	WVG	WEBSTER GENEF	28	76.75	2149	MS	P03E1	10/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78484784	AMIKACIN	WVG	WEBSTER GENEF	11	50	550	MS	P06D6	9/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78507223	AZITHRO	WVG	WEBSTER GENEF	3	14.98	44.85	MS	P05D3	8/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78544922	FLUCONA	WVG	WEBSTER GENEF	12	18.39	220.68	MS	TEMP	11/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78078740	BENZ ALL	XTT	XTTRIUM LABORA	4	20.25	81	MS	TEMP	12/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454069	DEX 2.5%	BAX	BAXTER CENTER	2	22.26	44.52	MS	A11D2	4/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454101	SALINE 0.	BAX	BAXTER CENTER	4	17.52	70.08	MS	A11D1	5/12/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454509	DEXTROS	BAX	BAXTER CENTER	2	18.78	37.6	MS	A12D2	6/2/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
Alachua:																
883	78407412	SETTLE IV	BIN	BIOMICHE AI	122	30	3660	CFZ	AC2-G10-E	4/5/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78401745	CALVENZ/	BIO	BOEHRINGE	115	0	0	B18	B18-G01	5/12/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466142	GENTOZE	SCH	SCHERING P	518	34.67	17959.06	H17	H17-D01	12/20/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	70465472	EQUINE T	PAA	PALA-TECH I	6	91.52	549.72	J02	J02-G02	6/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014600	ROBINUL	FTD	FORT DODG	53	18.78	994.28		94 RETURN	5/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014804	VIOKASE	FTD	FORT DODG	1	40.04	40.04		94 RETURN	9/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78020331	MICONAZ/	EVS	VETOQUINO	14	10.67	152.18		94 RETURN	5/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78020349	MICONAZ/	EVS	VETOQUINO	1	6.52	6.52		94 RETURN	5/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78035116	EQUIMUN	BIN	BIOMICHE AI	2	30	60		94 RETURN	7/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036207	FLUNIXAN	FTD	FORT DODG	1	14	14		94 RETURN	9/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037017	CEFA DRC	FTD	FORT DODG	6	11.48	68.88		94 RETURN	7/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037439	SEDAZINE	FTD	FORT DODG	12	25.58	306.96		94 RETURN	1/17/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043495	UROEZE T	VIR	VIRBAC AN I	1	8.16	8.16		94 RETURN	8/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043529	UROEZE 2	VIR	VIRBAC AN I	1	23.77	23.77		94 RETURN	8/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043644	TUMIL K P	VIR	VIRBAC AN I	2	12.01	24.02		94 RETURN	11/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043659	TUMIL K G	VIR	VIRBAC AN I	2	7.52	15.04		94 RETURN	11/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043677	SOLOXINE	VIR	VIRBAC AN I	2	5.27	10.54		94 RETURN	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043686	SOLOXINE	VIR	VIRBAC AN I	3	7.43	22.29		94 RETURN	8/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043727	SOLOXINE	VIR	VIRBAC AN I	1	16.97	16.97		94 RETURN	7/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043743	SOLOXINE	VIR	VIRBAC AN I	1	20.18	20.18		94 RETURN	10/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058114	FUROSEM	PHO	PHOENIX PH	1	22.7	22.7		94 RETURN	8/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062832	PANOLOG	FTD	FORT DODG	6	61.56	367.36		94 RETURN	12/19/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062840	PANOLOG	FTD	FORT DODG	2	98.84	197.28		94 RETURN	1/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062857	PANOLOG	FTD	FORT DODG	1	55.92	55.92		94 RETURN	12/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062873	PANOLOG	FTD	FORT DODG	1	472.32	472.32		94 RETURN	3/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78063105	PANOLOG	FTD	FORT DODG	1	597.39	597.39		94 RETURN	1/29/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78064204	SOLU DEL	PFI	PFIZER	7	24.39	170.73		94 RETURN	5/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78064253	HYLARTIN	PFI	PFIZER	2	45.07	90.14		94 RETURN	12/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066283	CLOTRIM/	VES	VET SOLUTI	2	3.28	6.56		94 RETURN	6/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78071872	CONOFITI	SCH	SCHERING P	3	80.25	240.75		94 RETURN	8/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073153	RAPINOVI	SCH	SCHERING P	6	109.27	674.16		94 RETURN	5/4/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78073849	OTOMAX (	SCH	SCHERING P	4	54.13	216.52	94	RETURN	7/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073864	OTOMAX (	SCH	SCHERING P	1	66.6	66.6	94	RETURN	7/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074070	ORBAX TA	SCH	SCHERING P	1	82.45	82.45	94	RETURN	9/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074098	ORBAX TA	SCH	SCHERING P	0	161.26	0	94	RETURN		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074229	BANAMINI	SCH	SCHERING P	8	17.15	137.2	94	RETURN	9/6/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074250	BANAMINI	SCH	SCHERING P	0	16.02	0	94	RETURN		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074478	NUFLOR '	SCH	SCHERING P	1	48.5	48.5	94	RETURN	1/25/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074526	MOMETAI	SCH	SCHERING P	2	116.33	232.66	94	RETURN	8/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074642	MOMETAI	SCH	SCHERING P	3	71.97	215.91	94	RETURN	11/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78349207	OTOMAX (	SCH	SCHERING P	2	86.6	173.2	94	RETURN	11/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78500619	ANIMAX D	DEC	DECHRA VET	22	3.35	73.62	94	RETURN	12/7/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78503210	NAXCEL 1	PFI	PFIZER	24	17.41	417.84	94	RETURN	11/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78441235	VETSULIN	IVT	INTERVET IN	5	36.11	180.55	94	RETURN	3/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78441243	VETSULIN	IVT	INTERVET IN	30	14.16	424.8	94	RETURN	11/29/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444573	VETRACH	WVG	WEBSTER G	20	1.83	36.6	94	RETURN	8/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444856	VETROPO	WVG	WEBSTER G	8	1.81	10.68	94	RETURN	8/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447066	RIMADYL (	PFI	PFIZER	1	82.18	82.18	94	RETURN	5/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447227	RIMADYL (	PFI	PFIZER	2	12.79	25.58	94	RETURN	1/25/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447284	RIMADYL (	PFI	PFIZER	6	15.81	94.86	94	RETURN	6/2/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447425	RIMADYL (	PFI	PFIZER	11	55.85	614.35	94	RETURN	9/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78459980	METACAM	BID	BOEHRINGE	80	37.71	2564.28	94	RETURN	6/24/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78460986	METACAM	BID	BOEHRINGE	4	49.54	198.16	94	RETURN	7/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78468124	LEVENTA	IVT	INTERVET IN	4	11.61	46.44	94	RETURN	1/23/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78501804	ZUBRIN T/	SCH	SCHERING P	1	35.89	35.89	94	RETURN	8/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78543716	SOLOXINE	VIR	VIRBAC AN I	2	67.72	135.44	94	RETURN	10/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78551921	TRI HEART	SCH	SCHERING P	1	62.6	62.6	94	RETURN	4/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78551939	TRI HEART	SCH	SCHERING P	2	101	202	94	RETURN	4/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78551947	TRI HEART	SCH	SCHERING P	4	136.6	546.4	94	RETURN	11/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78553357	MURICIN (	DEC	DECHRA VET	5	48.6	243.5	94	RETURN	8/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78558957	PROIN CH	PRN	PRN PHARM	501	4.87	2439.87	500	CHEMICAI	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78558966	PROIN CH	PRN	PRN PHARM	337	16.77	5651.49	500	CHEMICAI	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78558973	PROIN CH	PRN	PRN PHARM	273	8.37	2285.01	500	CHEMICAI	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78558981	PROIN LIC	PRN	PRN PHARM	101	5.25	530.25	500	CHEMICAI	1/29/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78558999	PROIN CH	PRN	PRN PHARM	2435	6.27	15267.45	500	CHEMICAI	1/29/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DO Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	FlckOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78032573	TRI HIST (	NEO	NEOGEN CO	92	16.76	1541.92	500	CHEMICAL	8/22/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78032581	TRI HIST (	NEO	NEOGEN CO	0	50.66	0	500	CHEMICAL		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346041	PROPALIN	EVS	VETOQUINO	202	4.39	886.78	500	CHEMICAI	9/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346058	PROPALIN	EVS	VETOQUINO	276	5.6	1600.8	500	CHEMICAI	2/12/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346080	PROPALIN	EVS	VETOQUINO	27	15.11	407.97	500	CHEMICAI	0/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78354776	PROPALIN	EVS	VETOQUINO	3	7.36	22.08	500	CHEMICAI	9/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346090	MICOTIL 3	ELN	ELANCO ANI	1	63	63	B01	B01-J04	8/11/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78570879	GRISEOFL	DER	IVX ANIMAL I	2	62.8	106.6	B02	B02-D06	2/9/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360748	DERMA VI	MEP	MEDPHARMI	71	3.85	273.35	B03	B03-H06	8/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026497	CHONDRO	NEO	NEOGEN CO	759	32.76	25647.84	B07	B07-D01	9/12/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78477497	VETROGE	WVG	WEBSTER G	322	4.5	1449	B08	B08-G03	9/19/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062949	VETALOG	FTD	FORT DODG	0	29.06	0	B09	B09-E05		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062964	VETALOG	FTD	FORT DODG	103	16.56	1736.8	B11	B11-B08	7/29/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074443	MU-SE 10	SCH	SCHERING P	8	17	136	B11	B11-B02	11/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014894	VIOKASE '	FTD	FORT DODG	18	46.84	843.12	B13	B13-C04	9/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058123	FUROSEM	PHO	PHOENIX PH	25	43	1075	B13	B13-C01	11/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058593	THYROZIN	PHO	PHOENIX PH	37	10.22	378.14	B13	B13-G04	11/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78445823	THYRO TA	LLO	LLOYD LABO	28	10.96	285.48	B13	B13-F01	4/25/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447088	RIMADYL I	PFI	PFIZER	83	82.15	7639.95	B13	B13-I02	4/18/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062972	VETALOG	FTD	FORT DODG	24	67.62	1627.68	B15	B15-G01	5/1/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78359059	CLINTABS	VIR	VIRBAC AN I	17	52.61	889.77	B15	B15-D02	5/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360269	HYCOAT I	NEO	NEOGEN CO	55	30.52	2394.2	B15	B15-F01	8/22/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78352277	PROSTAN	PHO	PHOENIX PH	2	27.82	55.64	B15	B15-F02	6/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78437095	LIDOCAIN	WVG	WEBSTER G	42	27	1134	B15	B15-G03	7/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058581	THYROZIN	PHO	PHOENIX PH	36	6.2	223.2	B17	B17-E01	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78061749	PIPA TAB	LLO	LLOYD LABO	6	14.21	85.26	B17	B17-F03	11/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78352449	PROSTAN	PHO	PHOENIX PH	159	9.87	1568.33	B17	B17-F01	2/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360835	BETAGEN	MEP	MEDPHARMI	144	2.64	380.16	B17	B17-I01	11/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	7839(285	THYROID	PAA	PALA-TECH I	4	28	112	B17	B17-D03	8/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447169	RIMADYL I	PFI	PFIZER	15	19.9	267.4	B17	B17-D04	1/4/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78354776	PROPALIN	EVS	VETOQUINO	0	7.36	0	B18	B18-J01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058577	THYROZIN	PHO	PHOENIX PH	54	8	432	B19	B19-H03	5/10/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78368022	THYRO TA	LLO	LLOYD LABO	1	29.27	29.27	B19	B19-G04	6/30/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447128	RIMADYL I	PFI	PFIZER	81	33.49	2712.69	B19	B19-E01	3/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78391681	CAL PHO I	NEO	NEOGEN CO	15	5.45	98.75	B21	B21-E01	9/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447045	RIMADYL I	PFI	PFIZER	6	13.69	82.14	B21	B21-G01	12/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78547708	SOLOXINE	VIR	VIRBAC AN I	12	21.01	252.12	B21	B21-J04	9/27/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78441029	AEROPUL	WVG	WEBSTER G	11	116.79	1284.69	B22	B22-H04	1/17/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058589	THYROZI	PHO	PHOENIX PH	44	7.48	329.12	B23	B23-B06	3/26/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391947	PHOS P 2	PHO	PHOENIX PH	7	13.35	93.45	B23	B23-H06	8/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447102	RIMADYL I	PFI	PFIZER	8	16.7	133.6	B23	B23-E04	6/2/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78451681	SEDIVET	BIO	BOEHRINGE	69	43.37	2992.53	B23	B23-G03	5/13/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78061947	ANASED 2	LLO	LLOYD LABO	215	14.75	3171.25	C01	C01-F03	11/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78068830	ACEPROV	PHO	PHOENIX PH	208	19.2	4569.6	C01	C01-E04	10/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78319481	NEXABAN	ABS	ABBOTT LAB	0	16.45	0	C01	C01-G02		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78433020	APOMORF	JKL	J K LEVI CO I	30	32	960	C02	C02-H05	12/28/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78388914	THYRO TA	LLO	LLOYD LABO	2	20.23	40.46	C03	C03-G03	8/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78377642	BIO MYCIN	BIO	BOEHRINGE	2	20.71	41.42	C04	C04-D03	7/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043727	SOLOXINE	VIR	VIRBAC AN I	38	16.97	610.92	C05	C05-E01R	1/24/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043735	SOLOXINE	VIR	VIRBAC AN I	29	19.12	497.12	C05	C05-D04	8/21/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78054569	DEXAMET	PHO	PHOENIX PH	259	4	1036	C05	C05-H01	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78049453	SOLOXINE	VIR	VIRBAC AN I	18	39.97	759.43	C06	C06-E01	6/8/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043556	PANCREZ	VIR	VIRBAC AN I	22	54.26	1194.18	C06	C06-J03	11/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78047702	SYNOTIC	FTD	FORT DODG	57	35.29	2011.53	C06	C06-I01	12/20/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026331	EQSTIM S	NEO	NEOGEN CO	97	112.09	10872.73	C07	C07-F04	12/4/2000	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391194	THYROID	PAA	PALA-TECH I	21	9.8	205.8	C07	C07-G01	2/7/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043851	TUMIL K T	VIR	VIRBAC AN I	32	10.81	345.92	C08	C08-B01	11/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043577	SOLOXINE	VIR	VIRBAC AN I	31	5.27	163.37	C08	C08-B02RI	4/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043701	SOLOXINE	VIR	VIRBAC AN I	24	12.46	299.04	C08	C08-D01R	8/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043743	SOLOXINE	VIR	VIRBAC AN I	31	20.18	625.58	C08	C08-F01R	2/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036885	AMGLYDE	FTD	FORT DODG	2	30.11	76.22	C09	C09-D02	2/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043420	SOLOXINE	VIR	VIRBAC AN I	23	11.42	262.66	C10	C10-B01RI	5/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043446	SOLOXINE	VIR	VIRBAC AN I	16	31.83	509.28	C10	C10-D01R	7/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043461	SOLOXINE	VIR	VIRBAC AN I	17	48.09	817.53	C10	C10-F01RI	8/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043487	UROEZE F	VIR	VIRBAC AN I	11	9.4	103.4	C10	C10-H01	6/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043495	UROEZE T	VIR	VIRBAC AN I	1	8.15	8.15	C10	C10-H02	12/28/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043503	UROEZE T	VIR	VIRBAC AN I	6	29.74	178.44	C10	C10-I01	4/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043511	UROEZE 2	VIR	VIRBAC AN I	13	6.52	84.76	C10	C10-I02	4/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78043529	UROEZE 2	VIR	VIRBAC AN	10	23.77	237.7	C10	C10-J01	11/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043545	SOLOXINE	VIR	VIRBAC AN	18	59.12	1062.16	C10	C10-C02R	2/14/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043644	TUMOL K P	VIR	VIRBAC AN	9	12.01	108.09	C10	C10-I03	12/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043659	TUMOL K G	VIR	VIRBAC AN	41	7.52	308.32	C10	C10-J03	4/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78047743	DOMOSO	FTD	FORT DODG	28	15.93	414.18	C10	C10-E01	10/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78359073	CLINTABS	VIR	VIRBAC AN	11	98.92	1088.12	C10	C10-F03	11/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026364	EQSTM 6	NEO	NEOGEN CO	32	21.48	687.36	C12	C12-F01	12/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78042164	ESTRUMA	SCH	SCHERING P	50	21.2	1060	C12	C12-F04	2/4/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78345258	RENAKAR	NEO	NEOGEN CO	2	7.9	15.8	C12	C12-J07	2/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78038182	MAP 5 10	BIN	BIONICHE AI	20	16	320	C14	C14-B01	11/8/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037439	SEDAZINE	FTD	FORT DODG	35	25.56	894.6	C14	C14-D03	1/17/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043602	PANCREZ	VIR	VIRBAC AN	17	50.91	865.47	C16	C15-D01	11/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78359107	CLINSOL I	VIR	VIRBAC AN	28	2.66	74.48	C16	C16-E01	11/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78413527	ERYTHRO	WVG	WEBSTER G	270	1.55	418.5	C16	C16-D01	7/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043479	SOLOXINE	VIR	VIRBAC AN	27	64.54	1742.58	C17	C17-H01R	7/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043578	PANCREZ	VIR	VIRBAC AN	24	27.68	664.54	C19	C19-C01	10/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043585	SOLOXINE	VIR	VIRBAC AN	43	7.43	319.49	C19	C19-C03	4/19/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043458	SOLOXINE	VIR	VIRBAC AN	12	22	264	C21	C21-C03R	6/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78047738	DOMOSO	FTD	FORT DODG	8	9.04	72.32	C22	C22-E03	8/1/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036140	MAP 5 50	BIN	BIONICHE AI	223	33	7359	C24	C24-H01	9/8/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057783	PANAKAR	NEO	NEOGEN CO	17	43.85	745.45	C24	C24-G03	7/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78356877	CESTA TA	PHO	PHOENIX PH	30	229.88	6896.5	C24	C24-E01	8/2/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043537	SOLOXINE	VIR	VIRBAC AN	27	54.43	1469.61	C25	C25-E01R	7/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057981	VITAMIN E	NEO	NEOGEN CO	129	5	645	CF	A03-B20 N	5/12/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056759	PEN G 25	PHO	PHOENIX PH	488	9.5	4712	CF	A07-B20	6/14/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056757	PEN G 10	PHO	PHOENIX PH	761	5.75	4319.25	CF	A03-C30	1/19/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78002493	HYALOVE	FTD	FORT DODG	430	29.98	12891.4	CF	A05-A10	5/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78002501	HYALOVE	FTD	FORT DODG	124	31.99	3966.76	CF	A07-B40	5/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78063182	PEN G W/I	PHO	PHOENIX PH	684	5.87	2254.08	CF	A05-D10	5/14/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78063170	PEN G W/I	PHO	PHOENIX PH	0	9.7	0	CF	A13-D40		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78064253	HYLARTIN	PFI	PFIZER	235	45.07	10591.45	CF	A09-A70	5/4/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073153	RAPINOVE	SCH	SCHERING P	30	109.27	3278.1	CF	A01-D30	5/4/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78088301	EPINEPHF	PHO	PHOENIX PH	441	2.03	895.23	CF	A06-B20	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78088457	PHENYLBI	PHO	PHOENIX PH	1317	5.75	7572.75	CF	A03-D30 N	9/6/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78391715	PEN G PR	WVG	WEBSTER G	223	5.4	1204.2	CF	A13-D20	9/14/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78399202	PEN G PR	WVG	WEBSTER G	251	8.9	2233.9	CF	A03-C10	1/16/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78415477	VITA 15 IN	NEO	NEOGEN CO	72	8.51	612.72	CF	A07-B35	1/8/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78441243	VETSULIN	IVT	INTERVET IN	1549	14.16	21933.84	CF	A09-C20	8/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447425	RIMADYL (	PFI	PFIZER	328	65.85	18318.8	CF	A01-C10	4/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78456845	HY-50 3ML	BEX	HYDREX PH	106	28.9	3121.2	CF	A09-B20	7/9/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78032883	STAPH A I	DEM	DELMONT LA	27	55.75	1505.25	CF2	A10-C10	2/25/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78035116	EQUIMUN	BIN	BIONICHE AI	12	30	360	CF2	A02-D30D1	9/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036134	REGRESS	BIN	BIONICHE AI	3	56	168	CF2	A02-D10D1	8/3/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78067734	FERTAGY	IVT	INTERVET IN	1	16.65	16.65	CF2	A04-D10	4/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074104	IMIZOL 1(	SCH	SCHERING P	8	36.43	291.44	CF2	A02-B30	6/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78377040	EQUIMUN	BIN	BIONICHE AI	6	90	540	CF2	A04-E50D1	8/15/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78385047	FACTREL	FTD	FORT DODG	22	13.03	286.66	CF2	A02-H10	4/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414519	DUAL CILL	PHO	PHOENIX PH	2	13	26	CF2	A10-H30	8/23/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78420065	LIVER 7 IN	NEO	NEOGEN CO	16	9.21	147.36	CF2	A12-C20D1	11/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78441299	VETSULIN	IVT	INTERVET IN	6	38.11	228.66	CF2	A10-F10	3/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78468124	LEVENTA	IVT	INTERVET IN	9	11.81	104.49	CF2	A06-E20	4/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78468207	LUTALYSE	PFI	PFIZER	8	34.95	269.7	CF2	A14-J20	12/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78562186	BOTVAX E	NEO	NEOGEN CO	40	42.68	1707.2	CF2	A12-H10	12/1/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78008879	LACTATEI	ABB	ABBOTT LAB	22	15.5	341	CS	A13-C10	10/18/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78008887	LACTATEI	ABB	ABBOTT LAB	232	15.5	3597.5	CS	A08-C20	8/17/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009392	NORMOSI	ABB	ABBOTT LAB	30	15.5	465	CS	A13-C20	3/7/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009408	NORMOSI	ABB	ABBOTT LAB	114	17.94	2045.16	CS	A03-D10	12/15/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009408	NORMOSI	ABB	ABBOTT LAB	0	17.94	0	CS	A11-C10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009768	SALINE 0.(	ABB	ABBOTT LAB	42	21.96	923.16	CS	A12-D30	8/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78050049	LACTATEI	PHO	PHOENIX PH	28	33	924	CS	A05-D10	11/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365668	LACTATEI	BAX	BAXTER CEN	222	15.8	3463.2	CS	A07-C20	4/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365700	PLASMAL	BAX	BAXTER CEN	184	15.8	2870.4	CS	A08-D20	12/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78601819	ZUBRIN PI	SCH	SCHERING P	1	1037.3	1037.26	CS	P03-E05	8/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057809	PANAKAR	NEO	NEOGEN CO	30	65.4	1962	D01	D01-E02	12/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391178	THYROID	PAA	PALA-TECH I	21	7.65	160.65	D01	D01-D02	11/16/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391699	THIAMINE	NEO	NEOGEN CO	88	6.31	555.28	D01	D01-H01	8/22/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465621	VITAMIN E	PHO	PHOENIX PH	31	4.55	141.05	D01	D01-F03	3/14/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78068814	ACEPROM	PHO	PHOENIX PH	0	12.1	0	D02	D02-H01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78088822	ACEPROM	PHO	PHOENIX PH	0	48.5	0	D02	D02-I01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78088848	ACEPROM	PHO	PHOENIX PH	65	79	5135	D02	D02-I02	9/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014928	VIOKASE	FTD	FORT DODG	52	22.98	1194.96	D03	D03-D02	11/22/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78403828	DORMOSE	PFI	PFIZER	117	55.50	6532.65	D03	D03-F02RJ	6/30/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074068	OREAX TA	SCH	SCHERING P	67	160.92	10781.64	D04	D04-D01	3/22/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78088286	TRIAMCIN	WVG	WEBSTER G	3	62.19	310.95	D04	D04-I05	9/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78453253	HYCOAT :	NEO	NEOGEN CO	10	13.2	132	D04	D04-G04	12/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78035025	ETOGESIC	FTD	FORT DODG	54	25.46	865.84	D05	D05-C05R	4/19/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058536	THYROZID	PHO	PHOENIX PH	62	2.53	156.1	D05	D05-E03	4/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78068442	SODIUM B	PHO	PHOENIX PH	31	3.92	121.52	D05	D05-G01	7/13/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78338364	CESTAJEC	PHO	PHOENIX PH	256	198.09	50655.1	D05	D05-E02	9/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78068491	VITAMIN K	PHO	PHOENIX PH	79	7.99	631.21	D06	D06-F01	7/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057429	AMIKACIN	PHO	PHOENIX PH	505	99.65	50291.75	D07	D07-G01	3/9/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073724	NEOBACIN	SCH	SCHERING P	35	53.72	1880.2	D07	D07-C02	4/25/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78370700	TYLOSIN I	BIO	BOEHRINGE	2	27.75	55.5	D07	D07-F04	11/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414842	D PANTHE	PHO	PHOENIX PH	21	5.3	111.3	D07	D07-D03	9/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073716	NEOBACIN	SCH	SCHERING P	41	48.02	2056.72	D09	D09-D04	5/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365869	CESTA-TA	PHO	PHOENIX PH	60	63.35	6001	D09	D09-E02	2/15/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78392244	OVACYST	PHO	PHOENIX PH	0	28.78	0	D09	D09-G02		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365054	DRY CLO	FTD	FORT DODG	3	20.16	60.48	D11	D11-C01	3/0/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391111	THYROID	PAA	PALA-TECH I	15	5.16	83.24	D11	D11-E03	11/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043603	BOLOXIN	VIR	VIRBAC AN I	13	9.85	126.05	D12	D12-D02	4/16/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78301871	PANAKAR	NEO	NEOGEN CO	13	11.37	147.81	D13	D13-E04	10/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78081939	ANASED 1	LLO	LLOYD LABO	284	14.9	4231.6	D14	D14-D02	4/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78081954	YOBINE IA	LLO	LLOYD LABO	222	37.19	8256.18	D14	D14-E03	2/2/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78081962	TOLAZINE	LLO	LLOYD LABO	8	53.95	431.6	D14	D14-E04	8/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78082145	THYRO TA	LLO	LLOYD LABO	12	1.01	22.52	D14	D14-F03	3/11/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78082152	THYRO TA	LLO	LLOYD LABO	11	3.31	36.41	D14	D14-F04	12/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78082160	THYRO TA	LLO	LLOYD LABO	20	4.56	97	D14	D14-G02	3/11/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78082178	THYRO TA	LLO	LLOYD LABO	16	5.51	89.18	D14	D14-G03	11/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78082186	THYRO TA	LLO	LLOYD LABO	14	9.66	93.24	D14	D14-H02	7/19/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78082194	THYRO TA	LLO	LLOYD LABO	14	7.54	105.56	D14	D14-H03	4/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78082202	THYRO TA	LLO	LLOYD LABO	0	8.52	0	D14	D14-I02		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78082210	THYRO TA	LLO	LLOYD LABO	8	8.93	71.44	D14	D14-I04	9/1/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78057411	AMIKACIN	PHO	PHOENIX PH	333	22.85	7609.05	D15	D15-C01	1/31/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78420070	SPEC TUS	NEO	NEOGEN CO	13	7	91	D15	D15-F03	9/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78573276	SOURCOX	MRK	MERIAL LTD	266	5.25	1399.2	D16	D16-F01	6/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78078583	VETRO BI	WVG	WEBSTER G	71	12.72	903.12	D16	D16-G01F	3/30/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78078591	HYDROCC	WVG	WEBSTER G	141	7.14	1006.74	D16	D16-G02	12/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78070708	ANIMAX O	DEC	DECHRA VET	189	38	7182	D16	D16-G03	9/10/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444673	VETRACH	WVG	WEBSTER G	524	1.83	958.92	D16	D16-G03.E	2/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444684	VETROPO	WVG	WEBSTER G	3156	2.07	6533.95	D16	D16-E03.E	1/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057573	VITAMIN E	PHO	PHOENIX PH	85	3.5	297.5	D17	D17-F02	1/26/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058585	THYROZIN	PHO	PHOENIX PH	84	9.32	698.43	D19	D19-C06	1/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78052899	RECOVR I	FTD	FORT DODG	38	12.83	454.66	D19	D19-D01	5/4/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074070	ORBAX TA	SCH	SCHERING P	1	82.45	82.45	D20	D20-I01	1/24/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074096	ORBAX TA	SCH	SCHERING P	73	161.28	11773.44	D20	D20-J01	3/2/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78078781	ANTIZOLA	ORP	JAZZ PHARM	2	192.25	384.5	D20	D20-G03	1/19/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391830	OVACYST	PHO	PHOENIX PH	13	10.25	133.84	D22	D22-F04	9/8/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78384716	MICOTIL 3	ELN	ELANCO ANI	5	289	1445	D23	D23-H02	12/12/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78396715	DERMA VI	MEP	MEDPHARM	22	2.5	50.6	D23	D23-E01	4/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78325068	CLINDAM	PHO	PHOENIX PH	14	45.76	640.6	D24	D24-H03	9/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391327	THYROID	PAA	PALA-TECH I	2	44.27	88.54	D24	D24-H04	12/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043710	SOLOXINE	VIR	VIRBAC ANI	27	15	405	D25	D25-E02	5/2/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78319473	NEXABAN	ABB	ABBOTT LAB	0	12.06	0	D25	D25-B01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78362565	THYROID	PAA	PALA-TECH I	18	2.39	43.04	D26	D26-I01	10/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391036	THYROID	PAA	PALA-TECH I	19	3.88	73.72	D26	D26-I02	9/6/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391137	THYROID	PAA	PALA-TECH I	26	6.44	167.44	D26	D26-J02	11/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391188	THYROID	PAA	PALA-TECH I	20	8.78	175.6	D26	D26-F02	11/18/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391301	THYROID	PAA	PALA-TECH I	1	37.06	37.06	D26	D26-G03	4/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058114	FUROSEM	PHO	PHOENIX PH	96	22.7	2179.2	D27	D27-C03	12/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391883	MAXIM-20	PHO	PHOENIX PH	255	8.22	2027.7	D27	D27-D01	10/18/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78393890	EXCENEL	WAL	WALCO INTE	9	55.47	524.23	D28	D28-E02	7/11/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78063007	RANCLOG	FTD	FORT DODG	11	134.04	1474.44	E01	E01-E02	11/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76377111	DERMA VI	MEP	MEDPHARM	13	40.03	532.35	E02	E02-D01	8/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78005596	ISOVOFLO	ABB	ABBOTT LAB	110	174.64	19210.4	E03	E03-C01R	2/26/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78551760	IVERHART	VIR	VIRBAC ANI	124	85.2	10564.8	E05	E05-G01	10/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056437	SALIX TAB	IVT	INTERVET A	60	29.25	1755	E05	E05-F02	6/19/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78047760	DOMOSO	FTD	FORT DODG	63	33.44	2106.72	E07	E07-G01	6/23/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78413873	WATER S	PHO	PHOENIX PH	98	1.96	190.08	E07	E07-F01	3/13/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074401	E-SE INJE	SCH	SCHERING P	24	61.83	1483.92	E08	E08-C02	5/16/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074418	BO-SE 10	SCH	SCHERING P	8	11.8	87.6	E08	E08-D01	10/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78345248	RENAKAR	NEO	NEOGEN CO	19	7.67	145.73	E08	E08-E02	3/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78345264	RENAKAR	NEO	NEOGEN CO	15	6.26	93.9	E08	E08-E01	4/24/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78345306	URIKARE	NEO	NEOGEN CO	2	20.92	41.84	E08	E08-E03	10/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328060	CLINDAM	PHO	PHOENIX PH	32	82.4	2636.8	E09	E09-E02	3/14/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346041	PROPALIN	EVS	VETOQUIND	0	4.39	0	E09	E09-D01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78060038	M-CONOS	MEP	MEDPHARM	18	7.99	161.81	E10	E10-B02P2	6/30/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78463639	VITAMIN E	PHO	PHOENIX PH	9	13	117	E10	E10-C03	8/25/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447185	RIMADYL	PFI	PFIZER	92	39.91	3671.72	E11	E11-E02	10/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78060244	TRI OTIC	MEP	MEDPHARM	1	39.12	39.12	E12	E12-C02	7/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78361582	LIDOCAIN	PHO	PHOENIX PH	72	2.97	213.84	E12	E12-D01	1/24/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78064204	SOLU DEL	PFI	PFIZER	219	24.39	5341.41	E13	E13-E01	6/13/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78396780	DERMA VE	MEP	MEDPHARM	59	6.66	345.74	E13	E13-E03	5/16/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78071690	CONOFITT	SCH	SCHERING P	72	12.71	915.12	E14	E14-D01	11/16/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391228	THYROID	PAA	PALA-TECH	6	15.32	91.92	E14	E14-B04	8/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037380	KETOFEN	FTD	FORT DODG	34	63.43	2156.62	E16	E16-F01	8/26/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78477010	FUROSEM	WVG	WEBSTER G	113	3.75	423.75	E16	E16-G01	12/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78454733	ECVALAN	MRX	MERIAL LTD	44	23.08	1026.72	E17	E17-D02	9/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78067882	CHLORAM	BIM	BIMEDA INC	14	31.45	440.3	E18	E18-D01	11/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056445	SALIX INJ	INT	INTERVET N	026	9.33	8832.58	E21	E21-E01	3/8/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78338356	CESTAJEC	PHO	PHOENIX PH	354	44.05	15593.7	E21	E21-D02	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037298	POLYFLEX	FTD	FORT DODG	24	32.62	782.88	E24	E24-G02	8/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78443201	P BLOO 1	BTL	CEVA ANIMA	205	37.5	6937.5	E24	E24-F01	11/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360027	ANIMAX O	DEC	DECHRA VET	616	5.48	3363.36	E25	E25-D01	3/1/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444606	LEVOXINE	PHO	PHOENIX PH	8	9	72	E27	E27-B03	12/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062873	PANOLOG	FTD	FORT DODG	6	472.32	2833.92	E29	E29-D01	3/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444636	PRIBUTAZ	FIR	FIRST PRIOF	120	8.95	1074	E29	E29-F01	12/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058501	THYROZIN	PHO	PHOENIX PH	75	9	675	E30	E30-F01	8/2/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78416108	FUROSEM	PHO	PHOENIX PH	91	10.4	946.4	E30	E30-B01	12/12/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78393210	NAXCEL 1	PFI	PFIZER	101	17.41	1758.41	F01	F01-E01	8/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78551913	IVERHART	VIR	VIRBAC AN	90	267.93	25913.7	F02	F02-G01	1/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78447144	RIMADYL	PFI	PFIZER	124	100.39	12448.36	F04	F04-C01	4/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78047764	SYNOTIC	FTD	FORT DODG	139	76	10562	F08	F08-D01	12/8/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036322	CENTRINE	FTD	FORT DODG	72	55.17	3972.24	F06	F06-E02	2/27/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78478802	VETALOG	FTD	FORT DODG	79	69.3	5730.7	F07	F07-D02	10/11/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447201	RIMADYL	PFI	PFIZER	113	118.62	13404.06	F09	F09-C01	4/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78403916	DORMOSE	PFI	PFIZER	261	200.3	52270.3	F12	F12-D01	11/16/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78043594	PANCREZ	VIR	VIRBAC AN	22	78.15	1719.3	F13	F13-D02	1/17/2003	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036272	DICURAL	FTD	FORT DODG	13	98.75	1283.75	F15	F15-B02	4/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036280	DICURAL	FTD	FORT DODG	12	405.25	4863	F15	F15-B04	12/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036288	DICURAL	FTD	FORT DODG	10	139.74	1397.4	F15	F15-F02	11/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444656	VETROPO	WVG	WEBSTER G	5719	1.81	10361.39	F15	F15-G01	2/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036230	DICURAL	FTD	FORT DODG	22	49.38	1086.36	F16	F16-B01	6/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014910	VIOKASE	FTD	FORT DODG	23	118.82	2733.16	F18	F18-B02	1/8/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036185	CENTRINE	FTD	FORT DODG	182	36.21	6590.22	F18	F18-D02	4/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036306	DICURAL	FTD	FORT DODG	12	549.05	6588.6	F19	F19-B01	8/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036470	PROMACI	FTD	FORT DODG	55	13.35	734.25	F19	F19-F01	4/20/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036878	AMIGLYDE	FTD	FORT DODG	17	150.22	2553.74	F19	F19-B02	12/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057742	FLUMEGU	PHO	PHOENIX PH	216	12.78	2760.48	F19	F19-E01	7/8/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073849	OTOMAX	SCH	SCHERING P	133	54.13	7199.29	F20	F20-D01	3/30/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036953	AMFOROL	FTD	FORT DODG	34	91.02	3094.68	F21	F21-C01	1/10/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036961	AMFOROL	FTD	FORT DODG	36	91.02	3276.72	F21	F21-C02	3/4/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78560350	RESPIRAI	MOD	MODERN VE	44	40	1760	F21	F21-D01	2/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037903	ETOGESIC	FTD	FORT DODG	13	21.31	277.03	F23	F23-B03R2	4/27/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78038009	ETOGESIC	FTD	FORT DODG	6	52.28	311.4	F24	F24-C04R	6/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037397	KETOFEN	FTD	FORT DODG	165	103.26	17037.9	F25	F25-C01	4/8/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058544	THYROZO	PHO	PHOENIX PH	72	4.25	306	F25	F25-E02	7/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78353911	FLUCORT	FTD	FORT DODG	0	26.78	0	F26	F26-B02		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447227	RIMADYL	PFI	PFIZER	51	12.79	652.29	F28	F28-F01	6/30/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014902	VIOKASE	FTD	FORT DODG	14	82.07	1149.98	F27	F27-C01	11/2/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78038041	ETOGESIC	FTD	FORT DODG	25	75.42	1885.5	F27	F27-B02R	8/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066588	CHORION	IVT	INTERVET IN	161	14.13	2274.93	G01	G01-D02	4/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78081765	PIPA TAB	LLO	LLOYD LABO	6	52.17	193.02	G06	G06-E01	10/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78441011	AEROPUL	PHO	PHOENIX PH	6	50.02	300.12	G06	G06-E04	8/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78578788	THYROID	PAA	PALA-TECH I	6	52	312	G08	G08-E02	8/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78037009	CEFA DRO	FTD	FORT DODG	316	18.53	5901.68	G11	G11-E01	6/5/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78576770	THYROID	PAA	PALA-TECH I	6	46.12	288.72	G12	G12-D02	8/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78560219	RECONCIL	ELN548	ELANCO AN	123	18.52	2281.97	G13	G13-G01	3/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447060	RIMADYL (	PFI	PFIZER	70	27.41	1918.7	G18	G18-D01	10/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78576785	THYROID	PAA	PALA-TECH I	4	11.34	45.36	G18	G18-D03	8/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056502	PANACUR	IVT	INTERVET IN	53	157.89	8368.17	G19	G19-F01	9/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074237	BANAMINE	SCH	SCHERING P	24	35.2	844.8	G19	G19-C02	6/5/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78846066	PROPALIN	EVS	VETOQUINO	0	15.11	0	G19	G19-D01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78377451	DISAL INJ	BIO	BOEHRINGE	10	10.31	103.1	G22	G22-C03	8/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057361	IVERCIDE	PHO	PHOENIX PH	67	18.2	1589.4	G23	G23-F01	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78456985	METACAM	BIO	BOEHRINGE	283	49.54	18073.82	G24	G24-E01	9/22/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78576504	THYROID	PAA	PALA-TECH I	11	18.25	134.75	G26	G26-D01	8/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057359	IVERCIDE	PHO	PHOENIX PH	151	9.65	1442.05	G27	G27-E01	7/28/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78356294	DOMOSO	FTD	FORT DODG	11	238.74	2626.14	G27	G27-G01	1/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447441	RIMADYL (	PFI	PFIZER	40	51.8	2072	G27	G27-C01	9/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78464779	GASTROG	MRK	MERIAL LTD	3	712.32	2136.96	G27	G27-G02	9/28/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78556003	UNIPRIM F	MCL	MAC LEOD P	81	16	1088	H01	H01-C01	4/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78416237	CAL PHOS	PHO	PHOENIX PH	12	2.81	33.72	H02	H02-E01D1	2/21/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78071929	PHENYLZI	SCH	SCHERING P	23	6.2	142.6	H03	H03-B02	7/27/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78364580	DARICLOX	SCH	SCHERING P	1	21.7	21.7	H03	H03-B04_D	10/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447482	RIMADYL (	PFI	PFIZER	46	60.4	2657.6	H07	H07-D01	4/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066288	MANNITOL	NEO	NEOGEN CO	61	4.1	250.1	H08	H08-E02	5/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062685	PANOLOG	FTD	FORT DODG	80	68.44	4422	H11	H11-D02.C	11/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78456134	GENTOCIE	SCH	SCHERING P	1398	13.68	19376.28	H11	H11-C01	1/27/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062857	PANOLOG	FTD	FORT DODG	23	55.92	1286.16	H12	H12-D02.D	11/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062840	PANOLOG	FTD	FORT DODG	0	98.64	0	H15	H15-F01.D2		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062956	VETALOG	FTD	FORT DODG	300	80.26	24093.6	H16	H16-E01	7/7/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78063108	PANOLOG	FTD	FORT DODG	2	567.36	1134.72	H17	H17-B01	11/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78064154	DEPO MEI	PFI	PFIZER	447	28.96	12944.06	H17	H17-E01	2/7/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059726	MAXIM-20	PHO	PHOENIX PH	0	13.05	0	H18	H18-E02		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78345272	UROKARE	NEO	NEOGEN CO	1	4.45	4.45	H18	H18-B02	11/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78464761	GASTROG	MRK	MERIAL LTD	3	356.16	1068.48	H18	H18-G01.C	8/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78064162	DEPO MEI	PFI	PFIZER	1868	14.82	24690.12	H19	H19-C01	8/10/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78064196	SOLU DEL	PFI	PFIZER	187	10.17	1901.79	H19	H19-E02	6/30/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78303314	NAXCEL 4	PFI	PFIZER	200	44.83	8966	H18	H19-D01	12/13/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360488	CAL PHOS	PHO	PHOENIX PH	98	2.97	265.12	H20	H20-C01	2/16/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056312	HYPERTO	PHO	PHOENIX PH	14	2.76	38.92	H21	H21-F01	8/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346068	PROPALIN	EVS	VETOQUINO	0	6.8	0	H21	H21-E01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360061	LUTALYSE	PFI	PFIZER	35	11	385	H21	H21-D02	6/30/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056445	XYLA JEC	PHO	PHOENIX PH	0	11.73	0	H22	H22-D01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056718	MAXIM 20	PHO	PHOENIX PH	6	6.65	39.26	H22	H22-B04	9/6/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78430483	CLINDAM	PHO	PHOENIX PH	10	97	970	H22	H22-D02	8/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78551809	IVERHART	VIR	VIRBAC AN	28	226.13	6331.64	H22	H22-G01	1/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056973	PROIN CH	PRN	PRN PHARM	24	8.37	200.88	H23	H23-E01	3/13/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062932	PANOLOG	FTD	FORT DODG	0	64.56	0	H23	H23-C02.DZ		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78068269	CLOTRIM	VES	VET SOLUTI	320	3.26	1049.6	H28	H23-D01	2/26/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058429	THYROZIN	PHO	PHOENIX PH	24	33.05	793.2	H24	H24-B01	4/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058452	XYLA JEC	PHO	PHOENIX PH	2239	13.26	29688.14	H24	H24-C01	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058365	THYROZIN	PHO	PHOENIX PH	29	24.65	714.85	H25	H25-C02	1/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057636	GUAIFENI	PHO	PHOENIX PH	0	9.22	0	H26	H26-C01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057768	FLUMEGL	PHO	PHOENIX PH	105	29.25	3071.25	H26	H26-C01	8/19/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058387	THYROZIN	PHO	PHOENIX PH	25	20.2	505	H26	H26-F01	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058411	THYROZIN	PHO	PHOENIX PH	59	30.05	1772.95	H26	H26-E02	10/3/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058437	THYROZIN	PHO	PHOENIX PH	61	29.45	1795.45	H26	H26-C02	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058261	CLOTRIM	VES	VET SOLUTI	85	4.23	359.55	H27	H27-D01	1/17/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057006	CHLORAN	WVG	WEBSTER G	26	62.8	1627.8	H28	H28-F02	12/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057065	VITAMIN C	PHO	PHOENIX PH	230	1.72	395.6	H28	H28-C02	12/15/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058098	THIAMINE	NEO	NEOGEN CO	113	2.47	279.11	H28	H28-D01	8/10/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058378	THYROZIN	PHO	PHOENIX PH	42	13.75	577.5	H28	H28-D02	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78404167	UNIPRIM E	MCL	MAC LEOD P	5	48	240	H28	H28-B03	6/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057643	TRIENAMI	PHO	PHOENIX PH	6	11.8	70.8	H30	H30-B02	11/21/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057700	PHENYLBI	PHO	PHOENIX PH	6	26	156	H30	H30-C01	8/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057775	PANAKAR	NEO	NEOGEN CO	14	26.35	368.9	H30	H30-C03	2/2/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057833	PANAKAR	NEO	NEOGEN CO	3	41.03	123.09	H30	H30-E02	4/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057874	CHLORAV	BIM	BIMEDA INC	35	27.65	964.25	H30	H30-F01	1/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058361	THYROZIN	PHO	PHOENIX PH	28	7.4	207.2	H30	H30-D02	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058403	THYROZIN	PHO	PHOENIX PH	35	26.9	935.5	H30	H30-E01	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328043	CLINDAM	PHO	PHOENIX PH	34	88.4	3003.6	H30	H30-D01	8/16/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78071072	CONOFFTI	SCH	SCHERING P	32	80.25	6580.5	J01	J01-C01	6/24/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78071880	CONOFFTI	SCH	SCHERING P	26	77.77	1944.26	J01	J01-D01	5/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78071897	PHENYLZI	SCH	SCHERING P	110	9	990	J02	J02-D01	3/17/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073732	OPTIMMU	SCH	SCHERING P	220	96.16	21163	J05	J05-D07	5/1/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080535	ATROPINE	NEO	NEOGEN CO	623	1.81	1127.63	J06	J06-E01	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78501800	ZUBRIN T/	SCH	SCHERING P	26	80.75	2099.5	J06	J06-B02	11/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78531657	IVERHART	VIR	VIRBAC AN I	39	155.93	6613.48	J06	J06-F01	3/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073925	CTOMAX I	SCH	SCHERING P	205	77.95	15979.75	J07	J07-F01	3/31/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074219	BANAMINI	SCH	SCHERING P	183	17.15	3138.45	J07	J07-E01	8/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080277	TRI OTIC I	MEP	MEDPHARMI	44	43.36	1907.84	J11	J11-D02	1/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78501627	ZUBRIN T/	SCH	SCHERING P	30	84.47	1034.1	J11	J11-C01	1/25/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78501635	ZUBRIN T/	SCH	SCHERING P	0	80.11	0	J11	J11-F02.EX		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074478	NUFLOR	SCH	SCHERING P	25	48.5	1102.5	J12	J12-C01	6/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78068327	VITAMIN E	PHO	PHOENIX PH	64	8.2	682.8	J12	J12-C02	7/20/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056429	BALIX TAE	IVT	INTERVET In	26	54.87	1371.75	J13	J13-E01	3/17/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074484	NUFLOR 1	SCH	SCHERING P	8	112	896	J13	J13-D02	11/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074482	NUFLOR (	SCH	SCHERING P	4	218.5	874	J13	J13-E02	10/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78551689	IVERHART	VIR	VIRBAC AN I	26	149.83	3895.58	J14	J14-C01	1/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78054562	AMOXI MA	SCH	SCHERING P	0	20.3	0	J16	J16-C01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78501692	ZUBRIN T/	SCH	SCHERING P	13	70.72	919.36	J16	J16-C03	6/7/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78572250	UNIPRIM E	MCL	MAC LEOD P	21	50	1050	J16	J16-F01	9/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080053	BETAGEN	MEP	MEDPHARMI	130	12.19	1584.7	J16	J16-F01R0	1/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080269	TRI OTIC I	MEP	MEDPHARMI	24	77.88	1869.12	J17	J17-F02.EX	7/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080087	BETAGEN	MEP	MEDPHARMI	12	42.26	507.12	J18	J18-C02	8/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080012	MICONOS	MEP	MEDPHARMI	271	4.58	1241.18	J19	J19-F02	8/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080020	MICONOS	MEP	MEDPHARMI	60	5.33	319.8	J19	J19-D01R(	7/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360601	ANIMAX O	DEC	DECHRA VE	2383	1.89	4503.87	J19	J19-G01	3/16/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	76501670	ZUBRIN T/	SCH	SCHERING P	65	24.75	1581.25	J19	J19-D02	9/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78068551	PROIN LIC	PRN	PRN PHARM.	0	5.25	0	J20	J20-D01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074542	MOMETAM	SCH	SCHERING P	129	71.97	9284.13	J20	J20-G01	6/27/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78060258	TRI OTIC I	MEP	MEDPHARMI	25	34.58	864	J20	J20-D02D(	7/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466761	POTASSIL	PHO	PHOENIX PH	8	6.72	28.6	J20	J20-E02	10/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080251	TRI OTIC I	MEP	MEDPHARMI	74	47.62	3516.46	J21	J21-G01	6/10/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78540233	BETAGEN	MEP	MEDPHARMI	605	4.09	2474.45	J21	J21-D01	7/7/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78350643	BETAGEN	MEP	MEDPHARMI	116	3.96	481.68	J21	J21-C01	4/27/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78384708	MICOTIL 3	ELN	ELANCO ANI	2	120	240	J23	J23-B02	8/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78501854	ZUBRIN 7/	SCH	SCHERING P	99	38.89	3850.11	J23	J23-D01	10/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78583779	MOMETAS	SCH	SCHERING P	128	103.36	13078.44	J25	J25-G01	11/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447268	RIMADYL 1	PFI	PFIZER	158	78.37	11813.72	J25	J25-D01	4/13/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78501843	ZUBRIN 7/	SCH	SCHERING P	13	93.7	1780.3	J25	J25-E02,E	6/7/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014936	VIOKASE '	FTD	FORT DODG	12	60.82	682.04	J27	J27-F01	1/24/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78081673	METHIO F	LLO	LLOYD LABO	6	33.87	246.96	J27	J27-C01	11/24/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78081681	METHIO F	LLO	LLOYD LABO	90	3.5	315	J27	J27-C02	6/9/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78501850	ZUBRIN 7/	SCH	SCHERING P	6	172.56	1034.26	J27	J27-F02	12/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78389642	GASTROG	MRK	MERIAL LTD	145	24.72	3609.12	J28	J28-E01	3/1/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78069683	CICYTOCI	PHO	PHOENIX PH	170	2.84	482.6	J29	J29-E01	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78501868	ZUBRIN 7/	SCH	SCHERING P	10	205.09	2050.9	J29	J29-B03	10/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391202	THYROID	PAA	PALA-TECH I	47	10.43	490.21	J30	J30-F02	8/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360688	ANIMAX O	DEC	DECHRA VE	634	2.36	1260.24	K01	K01-E01	4/20/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447243	RIMADYL 1	PFI	PFIZER	173	25.71	4447.83	K02	K02-F01	11/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78068707	VITAMIN A	NEO	NEOGEN CO	18	8.15	146.7	K07	K07-D02,R	1/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78068319	VITAMIN B	PHO	PHOENIX PH	283	2.43	687.69	K12	K12-D01	2/2/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78403502	ANTHELCI	PFI	PFIZER	12	208.94	2507.28	K12	K12-G01	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062907	RECOVR I	FTD	FORT DODG	14	20.15	282.1	K13	K13-E03	8/12/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360693	ANIMAX O	DEC	DECHRA VE	609	3.93	2393.37	K13	K13-F01	3/16/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78389004	THYRO TA	LLO	LLOYD LABO	7	59.38	416.62	K13	K13-E05	10/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78068335	VITAMIN B	PHO	PHOENIX PH	119	10.75	1279.25	K14	K14-E02	8/15/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78464787	GASTROG	MRK	MERIAL LTD	4	1779.8	7119.36	K14	K14-F01	3/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78085517	VITAMIN K	NEO	NEOGEN CO	82	6.06	680.1	K15	K15-E02	10/13/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447468	RIMADYL 1	PFI	PFIZER	21	56.2	1180.2	K15	K15-D01	5/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78339081	CLINTABS	VIR	VIRBAC AN I	23	88.94	2045.62	K17	K17-G02	3/15/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447367	RIMADYL 1	PFI	PFIZER	199	19.36	3853.62	K17	K17-F01	6/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073831	OTOMAX 1	SCH	SCHERING P	87	76.26	7337.22	K18	K18-C01	12/11/2003	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78086478	UNIFRIM F	MCL	MAC LEOD P	294	2.6	764.4	K18	K18-G01	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78086552	PREDNISC	LLO	LLOYD LABO	60	20.35	1221	K18	K18-E01	6/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78371570	HETACIN I	FTD	FORT DODG	6	20.52	123.12	K19	K19-B01	2/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391210	EQUINE T	PAA	PALA-TECH I	0	10.17	0	K21	K21-C01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074534	MOMETAS	SCH	SCHERING P	130	103.64	13473.2	K24	K24-F01	6/27/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78447284	RIMADYL I	PFI	PFIZER	81	16.81	1280.61	K25	K25-E01	12/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78483371	POLYGLYI	ART	ARTHRODYI	763	50	38150	K27	K27-F01	1/16/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78352677	PREDNISC	LLO	LLOYD LABO	30	35.43	1062.9	K30	K30-D01	8/3/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78088103	DEXTROS	PHO	PHOENIX PH	327	2.05	670.35	L01	L01-F02	9/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78588838	THYRO TA	LLO	LLOYD LABO	1	10.22	10.22	L01	L01-C05	1/7/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78551883	IVERHART	VIR	VIRBAC AN I	214	112.73	24124.22	L01	L01-E01	3/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78000606	PROPOFL	ABB	ABBOTT LAB	4063	6.9	27995.7	L02	L02-D02	8/11/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066589	PROIN CH	PRN	PRN PHARM	0	8.27	0	L02	L02-D03		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365544	ISOFLURA	WVP	WEBSTER PI	1102	7.26	8424.6	L02	L02-E03G	8/5/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78006601	GENTAMA	PHO	PHOENIX PH	17	24.2	411.4	L06	L06-F01	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78549890	UNIPRIM F	MCL	MAC LEOD P	266	9.5	2527	L05	L05-E01	12/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78097850	TRIENAMI	PHO	PHOENIX PH	5	18.15	90.75	L07	L07-C01	12/2/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78088202	LIDOCAIN	PHO	PHOENIX PH	1123	1.42	1593.24	L07	L07-F02	12/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78305619	ANIMAX O	DEC	DECHRA VET	3029	3.36	10177.44	L07	L07-F01	12/7/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78345280	URIKARE	NEO	NEOGEN CO	1	16.77	16.77	L09	L09-C02	4/17/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78345322	URIKARE I	NEO	NEOGEN CO	1	8.81	8.81	L09	L09-C05	10/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074200	BANAMINI	SCH	SCHERING P	1275	16.92	21538.15	L10	L10-D02	2/15/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78088194	DEXAMET	PHO	PHOENIX PH	973	3.2	3113.6	L10	L10-D01	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78551772	IVERHART	VIR	VIRBAC AN I	209	50.25	10502.25	L10	L10-C01	10/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78006563	GENTAMA	PHO	PHOENIX PH	919	10.7	9833.3	L11	L11-F01	6/5/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78038538	FLUNIXIN	FTD	FORT DODG	58	30.5	1769	L11	L11-F02	3/18/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78560235	RECONCII	ELN548	ELANCO ANI	285	23.08	7077.05	L12	L12-C01	3/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073815	GENTOCII	SCH	SCHERING P	60	72.85	4372.8	M01	M01-F02	11/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78088723	WATER S	PHO	PHOENIX PH	669	1.71	1178.19	M01	M01-E05	11/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391533	DEXOLYTI	PHO	PHOENIX PH	0	2.37	0	M01	M01-D02		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78551939	TRI HEART	SCH	SCHERING P	359	101	36259	M01	M01-B05	4/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78560201	RECONCII	ELN548	ELANCO ANI	6	15.90	95.04	M01	M01-D05	3/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78020331	MICONAZI	EVS	VETOQUINO	0	10.87	0	M03	M03-B07		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78020349	MICONAZI	EVS	VETOQUINO	0	6.52	0	M03	M03-B08		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78088475	PHENYLBI	PHO	PHOENIX PH	2518	7.9	19892.6	M03	M03-E02	8/2/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414550	SALINE 0.I	PHO	PHOENIX PH	0	5	0	M03	M03-C03		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78477612	GENESIB	VIR	VIRBAC AN I	232	6.7	1554.4	M03	M03-C04	10/21/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78594128	CLAVAMO	PFI	PFIZER	314	90.4	28385.6	M03	M03-B10	4/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78063089	PANOLOG	FTD	FORT DODG	10	472.82	4728.2	M04	M04-B02	4/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplanOK	Updated	Created	On Restricted List?	Val Label?
883	78056935	PROIN CH	PRN	PRN PHARM	0	18.77	0	M05	M05-D01		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056544	PANACUR	IVT	INTERVET IN	135	81.5	11004	M07	M07-C07	8/19/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056459	PHENYLEI	PHO	PHOENIX PH	420	9.97	4187.4	M07	M07-D02	1/23/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056957	PROIN CH	PRN	PRN PHARM	12	4.87	58.44	M09	M09-C04	3/13/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78053204	ISOFLO 2	ABB	ABBOTT LAB	41	25.83	1059.03	M09	M09-C06G	11/22/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056286	SYNANTH	FTD	FORT DODG	1	178.5	178.5	M10	M10-C05	7/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057932	CLINDADI	PHO	PHOENIX PH	2834	2.67	7568.78	M11	M11-E02	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78053186	ISOFLO 1	ABB	ABBOTT LAB	153	12.2	1868.6	M11	M11-C03G	3/19/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073864	OTOMAX I	SCH	SCHERING P	234	86.8	20304.4	M11	M11-B03	8/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78001671	THYRO L I	WVG	WEBSTER G	142	12.81	1818.02	M11	M11-E06	3/11/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78397729	GENESIS '	VIR	VIRBAC AN	416	9.84	3968.64	M11	M11-D04	8/2/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391921	DEXAMET	WVG	WEBSTER G	339	9.05	3067.95	M11	M11-C03	10/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447300	RIMADYL I	PFI	PFIZER	445	31.82	14120.36	M11	M11-B04	4/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447409	RIMADYL I	PFI	PFIZER	270	116.11	31349.7	M11	M11-D01	4/20/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78439660	METACAM	BID	BOEHRINGE	889	37.71	33524.19	M11	M11-C06	5/24/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78564144	CLAVAMO	PFI	PFIZER	122	213.14	26003.08	M11	M11-B02	4/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056577	REGUMAT	IVT	INTERVET IN	426	179.5	76509.5	M13	M13-E04	9/15/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414527	SALINE PI	PHO	PHOENIX PH	192	1.88	342.16	M13	M13-B01	8/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414635	DEXOLYTI	PHO	PHOENIX PH	424	3.65	1547.6	M13	M13-E03	1/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447383	RIMADYL I	PFI	PFIZER	430	38.03	16350.9	M13	M13-C02	4/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78580227	RECONCII	ELN546	ELANCO ANI	152	21.39	3497.58	M13	M13-C04	3/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78564186	CLAVAMO	PFI	PFIZER	150	149.75	22312.5	M13	M13-E06	4/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057017	CEFA DRC	FTD	FORT DODG	2078	11.43	23068.02	M15	M15-C03	3/31/2000	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78060046	BETADEN	MEP	MEDPHARMI	2120	7.17	15200.4	M15	M15-C02R	3/5/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447329	RIMADYL I	PFI	PFIZER	135	94.85	12807.7	M15	M15-B04	4/20/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78551621	TRI HEAR	SCH	SCHERING P	1314	62.6	82256.4	M15	M15-D02	4/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78531947	TRI HEAR	SCH	SCHERING P	505	138.8	82643	M15	M15-D05	4/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78069859	SALINE PI	PHO	PHOENIX PH	252	1.71	430.92	M17	M17-B01	2/21/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78564110	CLAVAMO	PFI	PFIZER	299	48.68	14816.12	M17	M17-B02	4/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78030207	FLUNIXAN	FTD	FORT DODG	1026	14	28964	N05	N05-E03	4/5/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058606	ACEPROM	PHO	PHOENIX PH	1263	8.6	10861.8	N05	N05-E04	3/25/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78415113	SODIUM B	PHO	PHOENIX PH	105	5.15	540.75	N07	N07-D01	3/23/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78398598	THYRO TA	LLO	LLOYD LABO	2	36.75	73.5	NW	B01	10/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78356851	ISOFLURA	WVP	WEBSTER PI	1471	17	25007	P11	P11-D01G	10/21/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78351585	IVERHART	VIR	VIRBAC AN	203	79.28	16083.84	R07	R07-C01	3/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444936	PRIBUTAZ	FIR	FIRST PRIOF	288	8.95	2577.6	R10	R10-A01	12/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78349207	OTOMAX	SCH	SCHERING P	225	88.0	19455	R12	R12-D03	3/2/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391590	WATER S	PHO	PHOENIX PH	0	8.2	0	R12	R12-C02		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78071953	TRIBRISSI	SCH	SCHERING P	784	8.75	6860	R14	R14-D03	4/5/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78553357	MURICIN (	DEC	DECHRA VET	800	46.5	37200	R14	R14-C01	7/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074529	MOMETAS	SCH	SCHERING P	451	115.33	52013.83	R15	R15-E01	6/27/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78582735	COMFORT	ELN548	ELANCO ANI	445	328.22	146057.9	R15	R15-D03	10/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78582745	COMFORT	ELN548	ELANCO ANI	494	334.07	165030.6	R15	R15-D02	10/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78582753	COMFORT	ELN548	ELANCO ANI	532	345.77	183948.6	R15	R15-D01	10/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78582712	COMFORT	ELN548	ELANCO ANI	370	310.57	114867.9	R16	R16-D02	10/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78582720	COMFORT	ELN548	ELANCO ANI	337	315.52	106867.2	R16	R16-D01	10/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78377628	BIO MYCI	BIO	BOEHRINGE	12	17.5	210	R16	R16-D05	12/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058558	DISAL TAE	BIO	BOEHRINGE	33	43.69	1440.37	RF	A03-E05	9/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78388963	THYRO TA	LLO	LLOYD LABO	5	50.02	150.06	RF	A01-A00.A	10/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78388228	THYROZIN	PHO	PHOENIX PH	1	76	76	RF	A07-D05	9/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78417824	AMINO AC	PHO	PHOENIX PH	13	1.68	21.59	RF	A03-B09	12/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444904	LEVOXINE	PHO	PHOENIX PH	1	76	76	RF	A05-B06	3/26/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78543718	SOLOXINE	VIR	VIRBAC AN	12	57.72	612.64	RF	A03-B04	12/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78581671	IVERHART	VIR	VIRBAC AN	253	145.85	36925.35	S03	S03-E02	2/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78564102	CLAVAMO	PFI	PFIZER	634	81.8	51734.4	S11	S11-G02	4/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78551798	IVERHART	VIR	VIRBAC AN	70	121.65	8515.5	S12	S12-A02	10/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78551798	IVERHART	VIR	VIRBAC AN	151	121.65	18369.15	S12	S12-E03	10/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78091853	THYRO L I	WVG	WEBSTER G	20	110.99	2219.8	S14	S14-C01	11/15/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78551048	IVERHART	VIR	VIRBAC AN	172	78.83	13555.76	S15	S15-F02	2/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78404677	PHENYLBI	PHO	PHOENIX PH	0	14.25	0	S17	S17-F02		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78551772	IVERHART	VIR	VIRBAC AN	25	50.25	1256.25	SL	QUARANT	10/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014959	TELAZOL	FTD	FORT DODG	4	34.51	138.04	VAULT	QUARANT	1/16/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014959	TELAZOL	FTD	FORT DODG	3	34.51	104.73	VAULT	RETURN	11/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014959	TELAZOL	FTD	FORT DODG	2628	34.51	88147.75	VAULT	SL3-B10RI	3/26/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036579	TORBUTR	FTD	FORT DODG	1	58.98	58.98	VAULT	RETURN	2/26/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036579	TORBUTR	FTD	FORT DODG	22	58.98	1297.56	VAULT	SL1-A20RI	11/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036587	TORBUTR	FTD	FORT DODG	2	135.25	270.5	VAULT	QUARANT	10/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036587	TORBUTR	FTD	FORT DODG	203	135.25	27455.75	VAULT	SL1-B10RI	4/5/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DO Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplanOK	Updated	Created	On Restricted List?	Vet Label?
883	78038686	TORBUTR	FTD	FORT DODG	107	221.81	23733.67	VAULT	SL1-A40RI	2/10/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036637	KETASET	FTD	FORT DODG	12	6.05	72.6	VAULT	RETURN	11/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036637	KETASET	FTD	FORT DODG	1135	6.05	6868.75	VAULT	SL3-C10RI	7/5/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037082	TORBUGE	FTD	FORT DODG	3	48.37	145.11	VAULT	QUARANT	10/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037082	TORBUGE	FTD	FORT DODG	2	48.37	96.74	VAULT	RETURN	11/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037082	TORBUGE	FTD	FORT DODG	145	48.37	7013.65	VAULT	SL1-B20RI	7/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037090	TORBUGE	FTD	FORT DODG	1	156.06	156.06	VAULT	QUARANT	2/20/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037090	TORBUGE	FTD	FORT DODG	175	156.06	27310.50	VAULT	SL1-D10RI	1/7/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037108	TORBUGE	FTD	FORT DODG	63	21.97	1384.11	VAULT	SL1-B30RI	11/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058551	DOLOREX	IVT	INTERVET I	20	124	2480	VAULT	SL1-E30RI	1/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058197	KETAJECT	PHO	PHOENIX PH	413	4.25	1755.25	VAULT	SL1-D40RI	5/11/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059296	EUTHASO	VIR	VIRBAC AN	239	22.13	5289.07	VAULT	SL1-D20RI	6/16/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062756	SOLUPOIS	FTD	FORT DODG	24	132.15	3171.52	VAULT	SL1-E10RI	1/7/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073983	BEUTHAN	SCH	SCHERING P	607	32.71	19854.97	VAULT	SL1-C30RI	6/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78082673	TRI HIST (	NEO	NEOGEN CO	0	16.76	0	VAULT	SLS-C10		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78082681	TRI HIST (	NEO	NEOGEN CO	0	50.56	0	VAULT	SLS-C20		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346017	BUTORJE	PHO	PHOENIX PH	1	33.2	33.2	VAULT	QUARANT	2/11/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346017	BUTORJE	PHO	PHOENIX PH	81	33.2	2689.2	VAULT	SL1-A30RI	7/24/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346026	BUTORJE	PHO	PHOENIX PH	175	109.85	19223.75	VAULT	SL1-C20RI	11/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78671003	VETAKET	LLO	LLOYD LABO	435	4.56	1983.6	VAULT	SL1-B40RI	5/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78020240	BENZOYL	EVS	VETOQUINO	1	6.32	6.32	94	RETURN	2/14/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360277	ANTITOX	NUS	NOVARTIS A	24	4.26	102	94	RETURN		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78412681	CYSTORE	MRK	MERIAL LTD	2	8.55	17.1	94	RETURN	9/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78474547	BPO 3 SH	VES	VET SOLUTI	3	4.37	13.11	94	RETURN	11/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78336117	CYSTOLAI	VEL	VETERINARI	9	9.62	86.58	500	CHEMICAL	10/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78336125	CYSTOLAI	VEL	VETERINARI	14	61.11	855.54	500	CHEMICAL	10/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78417758	PANCREZ	VIR	VIRBAC AN	8	12.48	99.84	B04	B04-D03	9/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78403635	GRANULE	PFI	PFIZER	18	4.25	63	B07	B07-J02	7/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78403817	GRANULE	PFI	PFIZER	53	9.54	505.62	B09	B09-E05RI	5/16/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78413022	TETRADU	MRK	MERIAL LTD	8	49.5	396	B10	B10-J04	10/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78418659	METHIO-F	LLO	LLOYD LABO	6	9.65	59.28	B15	B15-E04	6/9/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78413030	TETRADU	MRK	MERIAL LTD	11	69.1	980.1	B22	B22-J01	9/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78336125	CYSTOLAI	VEL	VETERINARI	0	61.11	0	B23	B23-C01		TRUE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78336117	CYSTOLAI	VEL	VETERINARI	88	9.62	346.32	C13	C13-B06	2/22/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Extended Cost	Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78413014	TETRADU	MRK	MERIAL LTD	2	22.5	45	C22	C22-C01	3/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78390580	EQUINE C	NUS	NOVARTIS A	2	16.84	33.68	CF2	A10-F20D	7/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78390715	PARVO SI	NUS	NOVARTIS A	11	19.1	210.1	CF2	A10-E30D	9/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78412681	CYSTORE	MRK	MERIAL LTD	21	8.55	179.55	CF2	A02-F40	5/3/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78600878	VIRASHIEI	NUS	NOVARTIS A	3	100.5	301.5	CF2	A02-G50	6/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414907	TUCOPRI	PFI	PFIZER	18	91.91	1470.56	D09	D09-H01	6/9/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414303	STRONGII	PFI	PFIZER	10	58.32	583.2	E22	E22-E01	6/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414840	PREDEF 2	PFI	PFIZER	157	22.65	3003.15	E28	E28-E01	11/10/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78415022	CARBOCA	PFI	PFIZER	153	7.25	1101.75	F06	F06-D01	6/30/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78335976	PANACUR	IVT	INTERVET IN	8	301	2408	G23	G23-G01	11/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78377200	ALPHATR/	ABB	ABBOTT LAB	16	110.39	1655.85	H01	H01-G02	12/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78377688	MICRO VE	BIO	BOEHRINGE	17	16.65	283.49	H04	H04-E01	8/15/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78567995	SEBOZOL	VES	VET SOLUTI	8	68.36	178.68	J04	J04-G01	9/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78403536	DERMA CI	PFI	PFIZER	6	15.09	90.48	J22	J22-F02	12/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78020287	BENZOYL	EVS	VETOQUINO	8	81.35	410.8	K06	K06-G01	8/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78475788	TUCOPRI	PFI	PFIZER	152	19.84	2870.08	L03	L03-E01	1/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78474547	BPO 3 SH	VES	VET SOLUTI	159	4.37	694.83	M03	M03-D03	9/22/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78474564	BPO 3 SH	VES	VET SOLUTI	6	29.18	175.08	M03	M03-F06	6/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78020240	BENZOYL	EVS	VETOQUINO	545	6.32	2160.4	M07	M07-E04	10/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78567967	SEBOZOL	VES	VET SOLUTI	218	9.46	2063.04	M09	M09-B03	9/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78567979	SEBOZOL	VES	VET SOLUTI	100	5.83	583	M17	M17-B05	9/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78373090	GENTOCII	SCH	SCHERING P	6	71.34	428.04	D22	D22-G05	6/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	NA
883	78546534	VETRO M/	WVG	WEBSTER G	138	14.1	1945.8	D27	D27-G01	11/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	NA
883	78011373	FLUORES	AKO	AKORN INC	96	11.4	1117.2	D29	D29-D01	4/5/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	NA
883	78546542	VETBO M/	WVG	WEBSTER G	328	21.9	7139.4	D29	D29-G01	11/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	NA
883	78373708	GENTOCII	SCH	SCHERING P	12	31.98	383.76	H13	H13-F02	12/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	NA
883	78546559	VETRO M/	WVG	WEBSTER G	54	36.45	1958.3	RF	A07-E02	11/9/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	NA
883	78437671	ALUMINUI	WVG	WEBSTER G	1	2.64	2.64	05	NOPAPER	3/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	NA
883	78437671	ALUMINUI	WVG	WEBSTER G	8	2.64	17.04	B02	B02-F01	12/31/2037	TRUE	FALSE	3/18/2008 4:31	3/18/2008	YES	NA

Deals:

883	78008853	GENTAMA	PHO	PHOENIX PH	168	10.7	1778.2	MS	EE10A2	5/5/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78008861	GENTAMA	PHO	PHOENIX PH	144	24.2	3484.8	MS	EE10B2	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78009378	LACTATEI	ABB	ABBOTT LAB	14	15.5	217	MS	H02B2	10/18/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78008387	LACTATEI	ABB	ABBOTT LAB	112	16.8	1881.6	MS	H04B1	6/17/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009382	NORMOSC	ABB	ABBOTT LAB	6	15.5	93	MS	H02B1	3/7/2003	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009405	NORMOSC	ABB	ABBOTT LAB	95	17.94	1704.3	MS	H03D1	12/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78009788	SALINE 0.1	ABB	ABBOTT LAB	22	21.98	483.56	MS	H01B1	3/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026331	ECSTIM 3	NEO	NEOGEN CO	59	112.09	6613.31	MS	EE10C2	12/4/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026364	ECSTIM 5	NEO	NEOGEN CO	9	21.48	193.32	MS	EE10C1	3/7/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78026497	CHONDRC	NEO	NEOGEN CO	224	32.76	7338.24	MS	EE11B1	9/12/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036169	CENTRINE	FTD	FORT DODG	5	36.21	181.05	MS	BB02A3	4/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78033207	FLUNIXAN	FTD	FORT DODG	288	14	4032	MS	GG13D1	4/5/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036470	PROM ACI	FTD	FORT DODG	29	13.35	387.15	MS	II05A3	4/20/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036876	AMIGLYDE	FTD	FORT DODG	61	150.22	9163.42	MS	II05A2	12/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037017	CEFA DRC	FTD	FORT DODG	2	11.48	22.96	MS	TEMP	3/31/2003	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037298	POLYFLEX	FTD	FORT DODG	8	32.62	260.96	MS	II05A4	8/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037388	KETOFEN	FTD	FORT DODG	2	63.43	126.86	MS	II04C2	6/29/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037397	KETOFEN	FTD	FORT DODG	67	103.26	6918.42	MS	II04C3	4/5/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037439	SEDAZINE	FTD	FORT DODG	32	25.58	818.56	MS	II04B1	1/17/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036041	ETOGESIC	FTD	FORT DODG	24	75.42	1810.08	MS	II02B4	8/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036538	FLUNIXAN	FTD	FORT DODG	93	30.5	2836.5	MS	GG14D1	3/18/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78047743	DOMOSO	FTD	FORT DODG	12	15.93	191.16	MS	II04B3	12/7/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78047760	DOMOSO	FTD	FORT DODG	17	33.44	568.48	MS	II04B4	6/23/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78054689	DEXAMET	PHO	PHOENIX PH	17	4	68	MS	EE07C1	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056446	SALIX INJ	INT	INTERVET IN	176	9.33	1642.08	MS	EE11E3	3/8/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056544	PANACUR	INT	INTERVET IN	19	81.5	1548.5	MS	CC11B3	9/19/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78056577	REGUMAT	INT	INTERVET IN	207	178.6	51646.2	MS	H20B1	9/15/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057353	IVERCIDE	PHO	PHOENIX PH	47	9.85	448.95	MS	GC10B1	7/28/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057361	IVERCIDE	PHO	PHOENIX PH	28	18.2	509.6	MS	CC10B2	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057429	ANIKACIN	PHO	PHOENIX PH	60	99.05	6776.2	MS	EE11B2	3/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057635	GUAIFENE	PHO	PHOENIX PH	12	9.22	110.64	MS	GG03D2	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057643	TRIENAMI	PHO	PHOENIX PH	3	11.8	35.4	MS	EE08B4	11/21/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057734	PERTAGYI	INT	INTERVET IN	4	16.83	65.52	MS	AA09C6	4/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057742	FLUMEGU	PHO	PHOENIX PH	77	12.76	984.08	MS	GG13B1	7/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057759	FLUMEGU	PHO	PHOENIX PH	47	29.25	1374.75	MS	GG13B2	8/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057874	CHLORAN	BIM	BIMEDA INC	24	27.55	661.2	MS	DD08A1	1/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List	Vet Label?
883	78057832	CLINDADF	PHO	PHOENIX PH	9	2.07	18.62	MS	FF03C2	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057865	VITAMIN C	PHO	PHOENIX PH	53	1.72	56.76	MS	EE09A1	12/15/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057873	VITAMIN C	PHO	PHOENIX PH	68	3.3	224.4	MS	EE09A2	1/28/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78057881	VITAMIN B	NEO	NEOGEN CO	47	5	235	MS	AA02C2	5/12/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058098	THIAMINE	NEO	NEOGEN CO	14	2.47	34.58	MS	EE08B3	8/10/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058114	FUROSEM	PHO	PHOENIX PH	2	22.7	45.4	MS	EE11B4	12/12/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058437	THYROZIN	PHO	PHOENIX PH	1	29.45	29.45	MS	DD07A2	2/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058452	XYLA JEC	PHO	PHOENIX PH	220	13.26	3036.54	MS	EE10B1	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058877	THYROZIN	PHO	PHOENIX PH	1	8	8	MS	DD10A4	5/18/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058760	PEN G 25	PHO	PHOENIX PH	184	9.8	1748	MS	AA00	6/14/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058787	PEN G 10	PHO	PHOENIX PH	37	5.75	212.75	MS	AA02E1	1/19/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058957	PROIN CH	PRN	PRN PHARM	0	4.87	0	MS	II03A5		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058965	PROIN CH	PRN	PRN PHARM	0	10.77	0	MS	II03A4		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059049	LACTATEI	PHO	PHOENIX PH	16	33	528	MS	H17B2	5/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059312	HYPERTO	PHO	PHOENIX PH	58	2.76	161.24	MS	GG03C1	5/23/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059718	MAXIM 20	PHO	PHOENIX PH	4	5.65	22.6	MS	EE06A1	9/5/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059726	MAXIM-20	PHO	PHOENIX PH	5	13.05	65.25	MS	EE06D1	3/9/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062493	HYALOVE	FTD	FORT DODG	98	29.98	2678.06	MS	AA10B3	5/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062501	HYALOVE	FTD	FORT DODG	1	31.99	31.99	MS	AA10B4	3/15/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062699	RECOVR I	FTD	FORT DODG	2	12.63	25.26	MS	II05C6	6/4/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062949	VETALOG	FTD	FORT DODG	3	29.06	87.18	MS	II04A4	4/13/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062956	VETALOG	FTD	FORT DODG	14	80.26	1123.64	MS	II04A1	7/7/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062964	VETALOG	FTD	FORT DODG	4	16.56	66.24	MS	II04A2	7/26/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062972	VETALOG	FTD	FORT DODG	3	67.82	203.46	MS	II04A5	9/1/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78063007	PANOLOG	FTD	FORT DODG	1	134.04	134.04	MS	FF02C5	7/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78063182	PEN G WS	PHO	PHOENIX PH	3	5.87	17.61	MS	AA09C3	5/14/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78063188	ISOFLO 1	ABB	ABBOTT LAB	6	12.2	73.2	MS	FF12A1	5/18/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78063204	ISOFLO 2	ABB	ABBOTT LAB	7	28.63	160.01	MS	FF12A2	11/22/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78064184	DEPO MEI	PFI	PFIZER	25	28.96	724.5	MS	A04C1	2/7/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78064192	DEPO MEI	PFI	PFIZER	228	14.82	3308.56	MS	A04B2	8/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78064196	SOLU DEL	PFI	PFIZER	105	10.17	1098.36	MS	A04B1	6/30/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78064204	SOLU DEL	PFI	PFIZER	48	24.29	1170.72	MS	A04D3	9/13/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78064253	HYLARTIN	PFI	PFIZER	115	45.07	5183.06	MS	AA03D1	6/4/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78065838	ATROPINE	NEO	NEOGEN CO	11	1.81	19.91	MS	EE07A2	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78069565	CHORION NT		INTERVET IN	122	14.13	1723.86	MS	GG14A1	4/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78069558	SALINE PI	PHO	PHOENIX PH	4	1.71	6.84	MS	GG03A1	8/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78069368	OXYTOCI	PHO	PHOENIX PH	52	2.84	147.68	MS	EE09C1	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78071963	TRIBRISSI	SCH	SCHERING P	252	8.76	2206	MS	GG12C1	4/5/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78071909	PHENYLZI	SCH	SCHERING P	16	6.2	99.2	MS	GG12B3	7/27/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78071997	PHENYLZI	SCH	SCHERING P	74	9	666	MS	GG12B1	2/17/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073732	OPTIMMU	SCH	SCHERING P	2	96.15	192.3	MS	FF01A7	6/1/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073849	OTOMAX I	SCH	SCHERING P	1	54.13	54.13	MS	FF03D2	3/30/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073884	OTOMAX I	SCH	SCHERING P	6	68.6	618.6	MS	FF03C7	2/24/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074229	BANAMIN	SCH	SCHERING P	61	17.16	1046.16	MS	GG12C2	9/6/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074237	BANAMIN	SCH	SCHERING P	13	35.2	457.6	MS	GG12C3	6/5/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074250	BANAMINE	SCH	SCHERING P	429	16.92	7258.68	MS	GG11D1	6/15/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074401	E-SE INJE	SCH	SCHERING P	34	61.93	2105.62	MS	EE11C4	6/16/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074419	BO-SE 10	SCH	SCHERING P	4	11.5	46	MS	EE10D4	10/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074478	NUFLOR	SCH	SCHERING P	13	46.5	604.5	MS	II01B2	4/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78074494	NUFLOR	SCH	SCHERING P	6	112	672	MS	II02A4	6/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78076953	VETRO SI	WVG	WEBSTER G	1	12.72	12.72	MS	FF01B6	3/30/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079591	HYDROCC	WVG	WEBSTER G	4	7.14	28.56	MS	BB00A2	2/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78079706	ANIMAX O	DEC	DECHRA VE	74	38	2812	MS	FF01C6	3/15/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080020	MICONOS	MEP	MEDPHARMI	1	5.33	5.33	MS	FF03C4	7/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080033	MICONOS	MEP	MEDPHARMI	2	7.99	15.98	MS	FF03C5	6/30/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080046	BETAGEN	MEP	MEDPHARMI	12	7.17	86.04	MS	FF02A2	2/9/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080053	BETAGEN	MEP	MEDPHARMI	20	12.19	243.8	MS	FF02A3	1/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080251	TRI OTIC	MEP	MEDPHARMI	2	47.52	95.04	MS	BB08A1	6/10/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78080277	TRI OTIC	MEP	MEDPHARMI	3	43.56	130.68	MS	BB09B	12/27/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78081553	THYRO LI	WVG	WEBSTER G	24	110.09	2663.76	MS	DD07C1	11/16/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78081871	THYRO LI	WVG	WEBSTER G	185	12.81	3497.85	MS	DD07B1	3/11/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78081939	ANASED 1	LLO	LLOYD LABO	158	14.9	2354.2	MS	FF04B3	4/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78081954	YOBINE IA	LLO	LLOYD LABO	3	37.19	111.57	MS	FF04B2	2/2/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78081962	TOLAZINE	LLO	LLOYD LABO	8	53.96	431.8	MS	EE11C3	8/17/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78086475	UNIPRIM I	MCL	MAC LEOD P	50	2.6	130	MS	CC07C1	8/23/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78086817	VITAMIN K	NEO	NEOGEN CO	6	8.05	48.3	MS	EE10D1	10/13/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78088103	DEXTROS	PHO	PHOENIX PH	83	2.05	160.65	MS	GG03C2	9/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78088194	DEXAMET	PHO	PHOENIX PH	161	3.2	483.2	MS	EE10A1	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

CC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78066202	LIDOCAIN	PHO	PHOENIX PH	201	1.42	285.42	MB	EE10C5	4/26/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066228	MANNITOL	NEO	NEOGEN CO	34	4.1	139.4	MS	EE09C2	6/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066301	EPINEPHF	PHO	PHOENIX PH	11	2.03	22.33	MS	AA09C1	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066319	VITAMIN E	PHO	PHOENIX PH	67	3.43	211.41	MS	EE09B4	2/2/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066327	VITAMIN B	PHO	PHOENIX PH	58	6.2	223.2	MS	EE09B3	7/20/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066335	VITAMIN B	PHO	PHOENIX PH	45	10.75	483.75	MS	EE09C1	8/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066442	SODIUM B	PHO	PHOENIX PH	46	3.92	180.32	MS	EE09B1	7/19/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066459	PHENYLBI	PHO	PHOENIX PH	160	0.97	1555.02	MS	DD06B1	1/28/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066467	PHENYLBI	PHO	PHOENIX PH	348	5.75	2001	MS	AA10D1	6/6/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066475	PHENYLBI	PHO	PHOENIX PH	836	7.9	6604.4	MS	DD06C1	6/2/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066707	VITAMIN A	NEO	NEOGEN CO	2	8.15	16.3	MS	EE03D1	1/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066723	WATER S	PHO	PHOENIX PH	144	1.71	246.24	MS	GG03B1	11/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066806	ACEPROM	PHO	PHOENIX PH	370	8.6	3182	MS	GG14B1	3/25/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066814	ACEPROM	PHO	PHOENIX PH	6	12.1	60.5	MS	GG14C1	9/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066822	ACEPROM	PHO	PHOENIX PH	6	48.8	292.8	MS	GG14C2	10/3/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066830	ACEPROM	PHO	PHOENIX PH	89	19.2	1738.8	MS	GG14C3	10/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78066848	ACEPROM	PHO	PHOENIX PH	11	.79	869	MS	GG14C4	9/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78328050	CLINDAM	PHO	PHOENIX PH	1	82.4	82.4	MS	FF03C1	3/14/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78346223	BETAGEN	MED	MEDPHARM	11	4.09	44.99	MS	FF02A1	7/7/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78352448	PROSTAN	PHO	PHOENIX PH	6	9.87	59.22	MS	GG14A3	2/27/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78352677	PREDNIS	LLO	LLOYD LABO	31	35.43	1098.33	MB	GG14C6	8/3/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78353811	FLUCORT	FTD	FORT DODG	10	26.75	267.5	MB	II04B2	9/3/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360465	CAL PHOS	PHO	PHOENIX PH	12	2.97	35.04	MS	GG02A2	9/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360593	ANIMAX O	DEC	DECHRA VET	18	3.93	70.74	MS	FF01C2	8/18/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360601	ANIMAX O	DEC	DECHRA VET	9	1.89	17.01	MS	FF01C3	8/16/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360619	ANIMAX O	DEC	DECHRA VET	18	3.36	60.4	MS	FF01C4	12/7/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78360627	ANIMAX O	DEC	DECHRA VET	55	5.46	300.3	MS	FF01C5	2/1/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365568	LACTATE	BAX	BAXTER CEN	197	15.6	3073.2	MB	H16B1	4/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78365700	PLASMAL'	BAX	BAXTER CEN	18	18.6	234	MS	H21B2	2/11/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78366544	ISOFLURA	WVP	WEBSTER PI	39	7.25	282.75	MB	FF12A4	8/6/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78366551	ISOFLURA	WVP	WEBSTER PI	30	17	510	MB	BB07B2	10/21/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78371576	HETACIN	FTD	FORT DODG	12	20.62	246.24	MB	II04C5	2/14/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78385294	DOMOSO	FTD	FORT DODG	1	238.74	238.74	MB	EE05C5	1/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78389542	GASTROG	MRK	MERIAL LTD	16	24.72	395.52	MB	FF03A1	3/1/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78391210	EQUINE T	PALA	PALA-TECH I	3	10.17	30.51	MS	DD07A1	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391633	DEXOLYTI	PHO	PHOENIX PH	15	2.37	35.55	MS	GG02B2	1/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391682	LIDOCAIN	PHO	PHOENIX PH	19	2.97	56.43	MS	EE10D3	4/26/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391690	WATER S	PHO	PHOENIX PH	3	3.2	9.6	MS	GG03B2	7/5/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391699	THIAMINE	NEO	NEOGEN CO	35	6.31	227.16	MS	EE08B2	6/22/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391716	PEN G PR	WVG	WEBSTER G	12	5.4	64.8	MS	AA09D2	8/14/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391830	OVACYST	PHO	PHOENIX PH	6	10.28	82.24	MS	GG14A4	9/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391853	MAXIM-20	PHO	PHOENIX PH	27	9.22	248.94	MS	EE06C3	10/18/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391921	DEXAMET	WVG	WEBSTER G	133	9.06	1203.65	MS	EE07C2	10/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78391947	PHOS P 2	PHO	PHOENIX PH	11	13.35	146.85	MS	EE07C3	8/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78392269	HYCOAT II	NEO	NEOGEN CO	27	30.52	824.04	MS	EE12C2	8/22/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78393061	LUTALYSE	PFI	PFIZER	48	11	528	MS	A04A2	6/30/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78393210	NAXCEL 1	PFI	PFIZER	108	17.41	1828.05	MS	A04C2	8/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78393814	NAXCEL 4	PFI	PFIZER	130	44.83	5827.9	MS	A04C5	12/13/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78396715	DERMA VI	MEP	MEDPHARMI	1	2.3	2.3	MS	FF02C1	10/16/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78396749	DERMA VI	MEP	MEDPHARMI	6	3.85	19.25	MS	FF02C2	8/16/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78396760	DERMA VI	MEP	MEDPHARMI	13	5.85	75.18	MS	FF02C3	8/16/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78397111	DERMA VI	MEP	MEDPHARMI	31	40.95	1268.45	MS	FF02C4	8/16/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78399202	PEN G PR	WVG	WEBSTER G	86	8.8	783.2	MS	AA08D1	1/18/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78403502	ANTHELCI	PFI	PFIZER	6	208.84	1283.84	MS	CC08C4	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78403825	DORMOSI	PFI	PFIZER	77	55.56	4279.56	MS	EE11C1	6/30/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78403918	DORMOSI	PFI	PFIZER	160	200.3	32048	MS	EE11C2	11/18/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78413873	WATER S	PHO	PHOENIX PH	16	1.06	31.66	MS	GG02B1	5/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414519	DUAL CLI	PHO	PHOENIX PH	9	13	117	MS	AA09D1	8/22/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414527	SALINE FI	PHO	PHOENIX PH	96	1.06	180.48	MS	GG01C2	9/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414535	DEXOLYTI	PHO	PHOENIX PH	15	3.65	65.7	MS	GG02C1	1/27/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414550	SALINE 0	PHO	PHOENIX PH	84	3	252	MS	GG01D1	9/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414642	D PANTHE	PHO	PHOENIX PH	6	5.3	31.8	MS	EE07A3	10/25/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78415105	FUROSEM	PHO	PHOENIX PH	40	10.4	416.4	MS	EE11B5	12/12/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78415113	SODIUM N	PHO	PHOENIX PH	56	5.15	288.7	MS	GG02A1	9/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78416287	CAL PHOS	PHO	PHOENIX PH	31	2.61	87.11	MS	GG02A3	8/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78420070	SPEC TUS	NEO	NEOGEN CO	7	7	49	MS	II02A3	9/20/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78420085	LIVER 7 IN	NEO	NEOGEN CO	9	9.21	82.89	MS	AA10B2	8/15/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78441235	VETSULIN	IVT	INTERVET IN	1	38.11	38.11	MS	AA09C4	7/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Vet Label?
883	78461243	VETSULIN IVT		INTERVET IN	10	14.16	141.6	MB	AA09C6	12/19/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78443201	P BLOC 1 STL		CEVA ANIMA	43	27.5	1182.5	MB	EE08B1	11/7/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444573	VETRACH WVG		WEBSTER G	37	1.83	67.71	MS	FF01A2	2/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444686	VETROPO WVG		WEBSTER G	20	1.81	62.49	MS	FF01B3	2/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444694	VETROPO WVG		WEBSTER G	2	2.09	4.18	MS	FF01B4	1/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444696	LEVOXINE PHO		PHOENIX PH	12	9	108	MB	DD07A3	3/29/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78444939	PROBUTAZ FIR		FIRST PROF	43	8.95	384.85	MS	DC06A2	11/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447103	RIMADYL I PFI		PFIZER	1	39.91	39.91	MB	II03B1	12/18/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447201	RIMADYL I PFI		PFIZER	2	118.62	237.24	MS	II03B2	4/20/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447227	RIMADYL I PFI		PFIZER	1	12.79	12.79	MB	II03B3	6/30/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447269	RIMADYL I PFI		PFIZER	2	76.37	152.74	MS	II03C1	4/19/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447284	RIMADYL I PFI		PFIZER	2	18.61	31.62	MB	II03B4	7/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447300	RIMADYL I PFI		PFIZER	1	31.68	31.68	MS	II03B5	3/29/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447328	RIMADYL I PFI		PFIZER	2	94.86	189.72	MB	II03B6	4/20/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447387	RIMADYL I PFI		PFIZER	4	19.38	77.52	MB	II03B8	6/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447383	RIMADYL I PFI		PFIZER	2	38.83	77.66	MB	TEMP	4/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78447409	RIMADYL I PFI		PFIZER	3	116.11	348.33	MB	II03B7	4/20/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78451861	SEDIVET BID		BOEHRINGE	70	43.87	3036.9	MB	EE11A2	6/13/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78456860	METACAM BID		BOEHRINGE	11	37.71	414.81	MS	II03A9	5/24/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78459846	HY-50 3ML BEX		HYDREX PH	118	28.9	3410.2	MS	AA01B1	9/8/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78464753	EQVALAN MRK		MERIAL LTD	43	23.38	1005.34	MS	CC11A3	9/13/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78464761	GASTROG MRK		MERIAL LTD	9	356.18	3205.44	MB	FF06A1	8/18/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78464779	GASTROG MRK		MERIAL LTD	5	712.32	3561.6	MS	FF06A2	9/26/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78464787	GASTROG MRK		MERIAL LTD	5	1779.5	8899.2	MS	FF06A3	3/22/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78465571	VITAMIN B PHO		PHOENIX PH	13	4.55	59.15	MS	EE08C2	3/14/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466039	VITAMIN B PHO		PHOENIX PH	16	13	208	MS	EE07B1	8/25/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466134	GENTOZE SCH		SCHERING P	45	13.86	623.7	MS	EE07B3	1/27/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78477497	VETROGE WVG		WEBSTER G	63	4.5	283.5	MS	FF01C1	9/19/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78478802	VETALOG FTD		FORT DODG	26	85.3	2338.4	MS	II04A8	10/11/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78483971	POLYGLYAART		ARTHRODYN	288	50	14300	MS	EE12B1	1/10/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78488267	LUTALYSE PFI		PFIZER	6	34.95	209.7	MB	EE10D2	1/16/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78494577	PHENYLBI PHO		PHOENIX PH	92	14.25	883.5	MB	DD06B1	10/16/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78549690	UNIPRIM S MCL		MAG LEOD P	67	0.8	921.5	MS	DD08C1	12/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	70530350	RESPIRA MOD		MODERN VE	6	40	240	MB	II01B3	2/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Val Label?
883	78584110	CLAVAMO	PFI	PFIZER	2	48.88	97.76	MS	TEMP	4/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78559003	UNIPRIM	MCL	MAC LEOD P	24	18	432	MS	DD08C2	4/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78573276	EQUIOXX	MRK	MERIAL LTD	272	5.28	1436.16	MS	DD08A1	5/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78335978	PANACUR	IVT	INTERVET IN	4	301	1204	MS	CC11D2		FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78412681	CYSTORE	MRK	MERIAL LTD	15	8.55	128.25	MS	AA09C3	3/3/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414303	STRONGI	PFI	PFIZER	13	58.32	758.16	MS	CC11D2	6/20/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414640	PREDEF 2	PFI	PFIZER	39	22.95	895.05	MS	A04A3	11/10/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78414907	TUCOPRI	PFI	PFIZER	12	91.91	1102.92	MS	A04D1	6/9/2005	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78416022	CARBOCA	PFI	PFIZER	66	7.25	493	MS	A04A1	8/30/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78476786	TUCOPRI	PFI	PFIZER	38	19.54	742.52	MS	A04C2	1/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78466142	GENTOZE	SCH	SCHERING P	14	34.67	485.38	MS	EE07B4	12/29/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplenOK	Updated	Created	On Restricted List?	Control?	Attachment
883	78014308	DIAZEPAM	WVG	WEBSTER	1	17.9	17.9	VAULT	PENDING	9/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78014308	DIAZEPAM	WVG	WEBSTER	6	17.9	107.4	VAULT	SL2-D50	11/21/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78014316	DIAZEPAM	WVG	WEBSTER	6	33.74	202.44	VAULT	SL2-D60RI	8/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78014324	PHENOBA	WVG	WEBSTER	135	4.01	541.35	VAULT	SL2-A30RI	9/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78014951	DIAZEPAM	ABB	ABBOTT L	4048	0.99	4007.52	VAULT	SL4-B10RI	3/17/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78025012	PHENOBA	WVG	WEBSTER	1	3.8	3.8	VAULT	PENDING	12/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78025512	PHENOBA	WVG	WEBSTER	155	3.8	592.8	VAULT	SL2-B10RI	9/24/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78025520	PHENOBA	WVG	WEBSTER	1	4.2	4.2	VAULT	PENDING	11/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78025520	PHENOBA	WVG	WEBSTER	1	4.2	4.2	VAULT	QUARANT	1/18/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78025520	PHENOBA	WVG	WEBSTER	97	4.2	407.4	VAULT	SL2-D20RI	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78025538	PHENOBA	WVG	WEBSTER	3	7.75	23.25	VAULT	PENDING	7/19/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78025538	PHENOBA	WVG	WEBSTER	87	7.75	674.25	VAULT	SL2-E20RI	6/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78025546	PHENOBA	WVG	WEBSTER	5	1.71	8.55	VAULT	PENDING	7/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78025546	PHENOBA	WVG	WEBSTER	5	1.71	8.55	VAULT	SL2-E10RI	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78025546	PHENOBA	WVG	WEBSTER	42	1.71	73.53	VAULT	SL5-B10DI	7/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78025553	PHENOBA	WVG	WEBSTER	34	11.09	377.06	VAULT	SL2-E40RI	7/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78057320	DIAZEPAM	WVG	WEBSTER	12	9.48	113.76	VAULT	SL2-D30RI	8/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78057336	DIAZEPAM	WVG	WEBSTER	5	9.16	45.8	VAULT	PENDING	9/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78057336	DIAZEPAM	WVG	WEBSTER	7	9.16	64.12	VAULT	SL2-D40RI	9/11/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78166271	BELLADO	WVG	WEBSTER	3	6.83	20.49	VAULT	SL2-A20RI	6/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78335647	PENTOTH	ABB	ABBOTT L	414	8.94	3701.16	VAULT	SL4-C10RI	9/13/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78342686	DIAZEPAM	WVG	WEBSTER	34	2.21	75.14	VAULT	SL2-C30RI	7/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78342702	DIPHENO	WVG	WEBSTER	105	4.69	492.45	VAULT	SL2-C40RI	12/5/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78357701	DIAZEPAM	WVG	WEBSTER	1	1.9	1.9	VAULT	PENDING	11/12/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78357701	DIAZEPAM	WVG	WEBSTER	64	1.9	121.6	VAULT	SL2-B30RI	10/4/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78357719	DIAZEPAM	WVG	WEBSTER	22	2.1	46.2	VAULT	SL2-B20RI	10/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78370964	PHENOBA	WVG	WEBSTER	3	37.75	113.25	VAULT	PENDING	11/1/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78370964	PHENOBA	WVG	WEBSTER	1	37.75	37.75	VAULT	QUARANT	1/18/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78370964	PHENOBA	WVG	WEBSTER	9	37.75	339.75	VAULT	SL2-C10RI	3/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78379578	PHENOBA	WVG	WEBSTER	20	3.63	72.6	VAULT	SL2-E30RI	5/10/2006	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	
883	78380377	DIAZEPAM	WVG	WEBSTER	3	11.53	34.59	VAULT	PENDING	10/24/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES	

DC Identity	Item Number	Item Description	Vendor Abbreviation	Vendor Name	Quantity	Cost	Extended Cost	Zone	Location	Placement Date	PickOK	ReplanOK	Updated	Created	On Restricted List?	Control?
883	78390377	DIAZEPAM	WVG	WEBSTER	9	11.53	103.77	VAULT	SL2-D10RI	9/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78390834	ALPRAZOL	WVG	WEBSTER	9	13.49	121.41	VAULT	SL2-A40RI	8/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78398012	ALPRAZOL	WVG	WEBSTER	21	3	63	VAULT	SL2-A10RI	7/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78429884	ALPRAZOL	WVG	WEBSTER	139	4.02	558.78	VAULT	SL2-A50RI	10/29/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78433285	ALPRAZOL	WVG	WEBSTER	9	7.81	70.29	VAULT	SL2-C60RI	7/31/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78437251	MIDAZOLA	WVG	WEBSTER	13	15.7	204.1	VAULT	SL2-A60RI	7/30/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78558003	DIPHENOX	WVG	WEBSTER	1	7.42	7.42	VAULT	PENDING	10/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78576598	PHENOBA	WVG	WEBSTER	108	3.68	384.48	VAULT	SL5-B20RI	7/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78575606	PHENOBA	WVG	WEBSTER	1	7.05	7.05	VAULT	PENDING	9/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78575606	PHENOBA	WVG	WEBSTER	1	7.05	7.05	VAULT	QUARANT	2/11/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78575606	PHENOBA	WVG	WEBSTER	95	7.96	755.25	VAULT	SL5-B30RI	7/18/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014969	TELAZOL	FTD	FORT DOI	4	34.91	139.64	VAULT	QUARANT	1/18/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014969	TELAZOL	FTD	FORT DOI	3	34.91	104.73	VAULT	RETURN	11/20/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78014969	TELAZOL	FTD	FORT DOI	2535	34.91	88147.75	VAULT	SL3-B10RI	3/26/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036579	TORBUTR	FTD	FORT DOI	1	58.98	58.98	VAULT	RETURN	2/28/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036579	TORBUTR	FTD	FORT DOI	22	58.98	1297.56	VAULT	SL1-A20RI	11/28/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036587	TORBUTR	FTD	FORT DOI	2	135.25	270.5	VAULT	QUARANT	10/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036587	TORBUTR	FTD	FORT DOI	203	135.25	27455.75	VAULT	SL1-B10RI	4/8/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036595	TORBUTR	FTD	FORT DOI	107	221.81	23735.67	VAULT	SL1-A40RI	2/10/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036837	KETASET	FTD	FORT DOI	12	6.05	72.6	VAULT	RETURN	11/6/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78036837	KETASET	FTD	FORT DOI	1135	6.05	6866.75	VAULT	SL3-C10RI	7/5/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037082	TORBUGE	FTD	FORT DOI	3	48.37	145.11	VAULT	QUARANT	10/8/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037082	TORBUGE	FTD	FORT DOI	2	48.37	96.74	VAULT	RETURN	11/13/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037082	TORBUGE	FTD	FORT DOI	145	48.37	7013.65	VAULT	SL1-B20RI	7/2/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037090	TORBUGE	FTD	FORT DOI	1	158.06	158.06	VAULT	QUARANT	2/25/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037090	TORBUGE	FTD	FORT DOI	176	158.06	27810.56	VAULT	SL1-D10RI	1/7/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78037108	TORBUGE	FTD	FORT DOI	63	21.97	1384.11	VAULT	SL1-B30RI	11/10/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78055551	DOLOREX	IVT	INTERVET	20	124	2480	VAULT	SL1-E30RI	1/25/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78058197	KETAJECT	PHO	PHOENIX	413	4.25	1754.28	VAULT	SL1-D40RI	3/17/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78059296	EUTHASO	VIR	VIRBAC AI	259	22.13	6280.07	VAULT	SL1-D20RI	8/18/2004	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78062758	EQUIPOIS	FTD	FORT DOI	24	132.16	3172.32	VAULT	SL1-E10RI	1/7/2008	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES
883	78073963	BEUTHAN	SCH	SCHERING	607	32.71	19854.97	VAULT	SL1-C30RI	9/26/2007	FALSE	FALSE	3/18/2008 4:31	3/18/2008	YES	YES

controlled substances pursuant to Registration [redacted], for further distribution for veterinary use only.

Except as amended herein, all other terms and conditions of the Settlement Agreement for Final Order shall remain in full force and effect.

FOR PATTERSON LOGISTICS SERVICES, INC., AND WEBSTER VETERINARY SUPPLY, INC.

Signature

R. STEPHEN ARMSTRONG, VP
Printed Name and Title

Dated: 2/21/09

ATTORNEYS FOR PATTERSON LOGISTICS SERVICES, INC., AND WEBSTER VETERINARY SUPPLY, INC.

Shannon B. Hartsfield, Esquire
Florida Bar No. 0055130
Pamela Anne Thomas, Esquire
Florida Bar No. 376914
HOLLAND & KNIGHT LLP
Post Office Drawer 810
Tallahassee, Florida 32302-0810
Telephone: 850-224-7000
Facsimile: 850-224-8832

Dated: 2/25/09

FOR THE DEPARTMENT OF HEALTH
Drugs, Devices and Cosmetics Program
4052 Bald Cypress Way, Bin C04
Tallahassee, Florida 32399

Rebecca R. Poston
Rebecca Poston, R. Ph.

Dated: 3/4/09

ATTORNEY FOR THE DEPARTMENT

Gary L. Asbell, Esquire
Assistant General Counsel
Florida Bar No. 0853615
Department of Health
4052 Bald Cypress Way, BIN #A02
Tallahassee, Florida 32399-1703
Telephone: 850-245-4444, Ext. 3930
Facsimile: 850-413-8743

Dated: 3-3-09

6082461_v1

STATE OF MAINE
BOARD OF PHARMACY

In re: Webster Veterinary Supply, Inc. Complaint No. 2012-PHA-8543	)))	CONSENT AGREEMENT

PARTIES

This document is a Consent Agreement ("the Consent Agreement") regarding the pending Wholesaler license for Webster Veterinary Supply, Inc. The parties to the Consent Agreement are Webster Veterinary Supply, Inc., now known as Patterson Veterinary Supply, Inc. ("Webster"), the Maine Board of Pharmacy ("the Board"), and the State of Maine Office of Attorney General ("the Attorney General"). The Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A)(C).

STATEMENT OF FACTS

1. Webster applied on or about July 9, 2010 for initial licensure due to a change in location (the "July 2010 Application").

2. Webster's July 2010 Application enclosed a copy of a March 9, 2005 Agreed Order in which Webster was disciplined by the Kentucky Board of Pharmacy.

3. The "Violation Disclosures" section of the July 2010 Application did not include a reference to the 2005 Kentucky Pharmacy Board Agreed Order.

4. On or about November 30, 2005, Webster submitted an application for renewal of license number WH70000847 (the "2005 Renewal Application") without disclosing the disciplinary action that occurred in Kentucky.

5. At its meeting on August 2, 2012, the Board reviewed the above mentioned information. Based on this information, the Board voted to preliminarily deny Webster's initial application for licensure as a Wholesaler.

6. In lieu of the denial, the Board voted at its June 6, 2013 meeting to offer Webster this Consent Agreement. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Kelly McLaughlin, Senior Consumer Assistant, Board of Pharmacy, 35 State House Station, Augusta, Maine 04333 by July 5, 2013, the Board will set this matter for an adjudicatory hearing.

COVENANTS

7. Webster admits the facts stated above and the submission of the 2005 Renewal Application constitutes grounds for discipline pursuant to 10 M.R.S. § 8003(5-A)(A)(5) for violation of a Board Rule, specifically Chapter 12 § (2)(7-A).

8. As discipline for the violation of the Board Rule cited in paragraph 7, Webster agrees to:

A. Accept a REPRIMAND from the Board; and

B. Pay within 30 days of the Effective Date of this Consent Agreement a CIVIL PENALTY in the amount of one thousand dollars ($1,000.00).

9. Upon receipt of this executed Consent Agreement, the Board shall deem the issue of disclosure of the 2005 Kentucky Board discipline to be resolved and shall not deny Webster's applications filed between March 9, 2005 and the date of this Consent Agreement for any issue related to such disclosure. The Board shall approve the initial application consistent with the provisions of Board Rules chapter 12.

10. The Attorney General and the Board agree that no further agency or legal action will be taken against Webster's licenses based on the conduct related to this Consent Agreement, except in the event that Webster does not comply fully with the terms of the Consent Agreement. Any violation of the Consent Agreement will be a ground for discipline by the Board.

11. The Consent Agreement is not subject to appeal.

12. The Consent Agreement is not subject to amendment except by written agreement of all parties.

13. The Consent Agreement is a public document within the meaning of 1 M.R.S. § 402, et seq.

14. Webster understands that the execution of the Consent Agreement is completely voluntary and that it has the right to consult with an attorney before signing the Consent Agreement.

15. Webster acknowledges by signature hereto of an authorized representative that it has read this Consent Agreement, that it has had an opportunity to consult with an attorney before executing this

Consent Agreement, that it executed this Consent Agreement of its own free will, and that it agrees to abide by all terms and conditions set forth herein.

16. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

Dated: 2013.06.06

PATTERSON VETERINARY SUPPLY, INC.
(formerly known as WEBSTER VETERINARY SUPPLY, INC.)

Signature of Authorized Representative

Assoc. General Counsel
Print Name and Title

Dated: June 6, 2013

Kenneth W. Lehman, Esq., Maine Bar No. 3283
Bernstein Shur
Counsel for Patterson Veterinary Supply, Inc.

Dated: 6/6/2013

JOSEPH BRUNO, R.Ph., President
Maine Board of Pharmacy

Dated: June 6, 2013

MICHAEL MILLER
Assistant Attorney General

EFFECTIVE DATE: June 6, 2013

FILED
Department of Business and Professional Regulation
Deputy Agency Clerk
CLERK Brandon Nichols
Date 2/16/2018
File # 2018-01155

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATI

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner,

v. **Case No.: 2016-028926**

PATTERSON VETERINARY SUPPLY, INC.,

Respondent.
_____/

FINAL ORDER

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (Department), in accordance with the provisions of Section 120.57(4), Florida Statutes, hereby enters this Final Order incorporating and adopting, *in toto*, the Settlement Agreement entered into between Patterson Veterinary Supply, Inc. (Respondent) and the Department, attached hereto and incorporated by reference. This Final Order resolves alleged violations of Section 499.005(15), Florida Statutes (2012-2015), distributing prescription drugs to unauthorized persons; Section 499.005(2), Florida Statutes (2012-2015), adulterating prescription drugs; and Section 499.005(6)(a), Florida Statutes (2016), and Section 499.005.(18), Florida Statutes (2012-2015), failing to provide records for inspection, and to maintain records as required by Chapter 499, Florida Statutes, and the administrative rules adopted pursuant thereto.

This Final Order is effective on the date it is filed with the Agency Clerk of the Department of Business & Professional Regulation as indicated on this Final Order.

DONE and ORDERED this 15th day of February, 2018 in Tallahassee, Florida.

JONATHAN ZACHEM, SECRETARY

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

By: _____
Drew F. Winters
Division Director
Drugs, Devices, and Cosmetics

Prepared by:

Kathryn E. Price
Chief Attorney
Division of Drugs, Devices, and Cosmetics

NOTICE OF RIGHT TO APPEAL

Unless expressly waived, any party adversely affected by this Final Order may seek judicial review by filing an original Notice of Appeal with the Clerk of the Department of Business & Professional Regulation, and a copy of the notice, accompanied by the filing fees prescribed by law, with the clerk of the appropriate District Court of Appeal within 30 days of the effective date of this order, in accordance with Florida Rule of Appellate Procedure 9.110, and Section 120.68, Florida Statutes.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of this Final Order has been provided by United States Mail to: Shannon Hartsfield, Esquire, Holland & Knight, LLP, 315 South Calhoun Street, Suite 600, Tallahassee, Florida 32301 this 16th day of February, 2018.

By: Brandon M. Nichols
Agency Clerk's Office

RECEIVED
FEB 14 2018
Drugs, Devices and Cosmetics

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner, **Case No.: 2016-028926**

v.

PATTERSON VETERINARY SUPPLY, INC.,

Respondent.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above-named parties hereby enter into this Settlement Agreement (this "Agreement") as disposition of the alleged violations described in the Notice of Violation dated December 21, 2017, in case number 2016-028926 (the "Allegations"). The terms herein become effective upon rendition of the final order, which shall incorporate this Agreement.

The State of Florida, Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereafter, "Department") is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.165 and Chapter 499, Florida Statutes.

STIPULATED FACTS

1. Patterson Veterinary Supply, Inc. (hereafter, "Respondent") is permitted as a prescription drug wholesale distributor by the Department, having been issued permit number 22:1462. Respondent holds additional permits with the Department that are not the subject of this settlement agreement.

2. Respondent's address of record for permit number 22:1462 is 300 N.W. 52nd Avenue, Ocala, Florida 34482.

3. Respondent was issued a Notice of Violation on December 21, 2017, on Case No. 2016-028926, alleging that it committed certain violations of Chapter 499, Florida Statutes, and the administrative rules adopted pursuant thereto.

CONCLUSIONS OF LAW

4. Respondent by and through its undersigned agent, admits that it is subject to the applicable provisions of Chapter 499, Florida Statutes, and the relevant jurisdiction of the Department.

5. Respondent neither admits nor denies the Allegations. The parties are entering into this settlement to resolve the issues raised by the Department, and any alleged or potential violations, whether known or reasonably discoverable by the Department that could be raised by the Department up through the date this Agreement is executed by the parties.

SETTLEMENT TERMS

6. Respondent agrees to immediately cease any practices mentioned in the Allegations that are in violation of Chapter 499, Florida Statutes.

7. Respondent agrees to pay a settlement amount of **Twenty Four Thousand Five Hundred Dollars ($24,500). Payment of the settlement amount shall be made only by corporate check, cashier's check, or money order to the Professional Regulation Trust Fund, and shall be remitted to The Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, Florida, 32399-1047, Attention: Tammy Shaw, Senior Legal Assistant.** Respondent acknowledges that payment is enclosed with this Agreement. The payment and execution of this Agreement by Respondent are absolute conditions precedent to Petitioner's execution of this Agreement.

8. Respondent affirms that it is not in violation of any of the statutes referenced in the Notice of Violation letter issued in case number 2016-028926.

9. The Department agrees to issue a renewal of permit 22:1462 to operate as a prescription drug wholesale distributor to Respondent upon Respondent's submission of a completed application, and within thirty days of entry of the final order in this matter.

10. The Department agrees that this Agreement will not be deemed to constitute discipline against Respondent, within the meaning of Section 499.066, Florida Statutes, and Rule 61N-1.024, Florida Administrative Code, and that this Agreement will not be considered in any future claim, action or proceeding against Respondent by the Department. The Department will not deny or seek to deny any application for a permit of Respondent based on the Allegations. Nothing herein shall be construed to limit, restrict or otherwise affect the Department's rights to (i) inspect under Section 499.051, Florida Statutes, (ii) examine, sample, test, embargo, seize, detain, condemn or destroy any drug, device, or cosmetic in accordance with Sections 499.06, 499.0632, and 499.065, Florida Statutes, or (iii) seek injunctions and take any other action authorized by Section 499.066 and 499.0661, Florida Statutes, in the event of a public health emergency or any immediate and substantial threat, hazard or danger to public health.

STANDARD PROVISIONS

11. It is expressly understood that a violation of the terms of this Agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary action may be taken.

12. The parties agree that this Agreement will be incorporated into a final order that will be filed with the Department agency clerk and will be a public document. The final order will contain no material terms other than those in this Agreement. The final order shall

operate to close Case Number 2016-028926. The final order shall be the final disposition in this proceeding and shall constitute final agency action with respect thereto.

13. Respondent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of this Agreement and the final order in which the Agreement is incorporated, provided the final order does not conflict with this Agreement.

14. Each party waives the right to seek any attorney's fees or costs from the other party in connection with this proceeding.

15. This Agreement may be executed in any number of counterparts including, without limitation, telecopies, and facsimile transmission copies, all of which together shall constitute a single document.

16. The parties agree that this Agreement represents a fair, appropriate and reasonable resolution to, and final disposition of, all disputes and matters made subject hereof.

17. The terms and provisions of this Agreement are severable, and if any term or provision is declared or deemed void, invalid, illegal or otherwise unenforceable, then all remaining terms and provisions shall remain in full force and effect.

18. It is expressly understood that this Agreement is subject to approval of the Division of Drugs, Devices, and Cosmetics, and has no force or effect until the Division accepts the settlement and adopts it in a final order.

19. The signatories hereto are vested with the authority to execute this Agreement on behalf of their respective principals, and as duly designated representatives, to fully bind such principals.

(Remainder of page Blank)

PATTERSON VETERINARY SUPPLY, INC.,

By: AARON RODRIGUEZ

Name:

Title: VP, Regulatory Affairs

Date: Feb. 12, 2018

FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION DIVISION OF DRUGS, DEVICES, AND COSMETICS,

By:

Name: DEEN F. WATTERS

Title: DIVISION DIRECTOR

Date: 2/15/2018

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

Case Nos. **A-2020-0112**
A-2020-0114
A-2020-0512
A-2021-0190

Patterson Veterinary Supply, Inc. (Grove City)
1031 Mendota Heights Road
Saint Paul, MN 55120

License No. **01-2037250**

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Patterson Veterinary Supply, Inc. (Patterson Grove City), for the purpose of resolving all issues between the parties relating to the Board investigation of sales of dangerous drugs, including controlled substances, to entities that did not possess active Terminal Distributor of Dangerous Drugs licenses at the time of the sales, and a change in Responsible Person. Together, the Board and Patterson Grove City are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Patterson Grove City is a licensed Wholesaler Distributor of Dangerous Drug, License No. 01-2037250.

FACTS

1. The Board initiated an investigation of Patterson Grove City's Wholesale Distributor of Dangerous Drugs License No. 01-2037250, related to Patterson Grove City's sales of dangerous drugs, including controlled substances, to entities that did not possess an active Ohio Terminal Distributor of Dangerous Drugs license at the time of the sales, and a change in Responsible Person.

2. On or about March 3, 2021, March 10, 2021, and June 21, 2021, the Board sent Notices of Opportunity for Hearing to Patterson Grove City related to the above-listed matters, which

outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Patterson Grove City neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letters dated March 3, 2021, March 10, 2021, and June 21, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notices, and hereby adjudicates the same.

3. The Board disciplines Patterson Grove City with a written reprimand for its failure to change its Responsible Person in compliance with Ohio law.

4. Patterson Grove City agrees to pay to the Board a monetary penalty in the amount of $3,125.00 to resolve the above-listed matters. This fine will be attached to the license record and must be paid no later than 6 months from the effective date of this Order. To pay this fine, login to www.elicense.ohio.gov and process the items in the cart.

5. Patterson Grove City agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. Patterson Grove City agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Patterson Grove City of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Patterson Grove City by the Board and will NOT discharge Patterson Grove City from any obligation under the terms of this Agreement.

7. Patterson Grove City agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Patterson Grove City understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Patterson Grove City will operate.

10. Patterson Grove City waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Les Korsh Vice President, General Counsel
And Secretary, on behalf of,
Patterson Veterinary Supply, Inc. (Phoenix), Respondent

December 21, 2021
Date of Signature

Alex Cooper, Attorney for Respondent

December 31, 2021
Date of Signature

Rich Miller, RPh, President,
State of Ohio Board of Pharmacy

January 5, 2022
Date of Signature

Henry G. Appel, Ohio Assistant Attorney General

January 5, 2022
Date of Signature

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor
Columbus, Ohio 43215-6108
Tel: (614) 466-4143
www.pharmacy.ohio.gov
1/7/2022 6:08 PM

Your payment was successful.

Order Status	Successful
Applied Payment	$3125.00
Contact	Kelley Karau
Operator	CBOSS Integration
Process Date	1/7/2022 6:02 PM
Receipt Number	[redacted]
Payment	[redacted]
Reference Number	[redacted]
Card Number	[redacted]
Amount	$3,125.00
Settlement Date	1/11/2022

Fee Payments

Licensee Name	License Number	Endorsement	State/Province	Type	Amount	Amount Outstanding	Payment Amount
				PRX - Settlement Agreement (4K90)	$3,125.00	$0.00	$3,125.00

Thank you for your transaction.

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

Case Nos. **A-2021-0197**
A-2021-0206
A-2021-0217

Patterson Veterinary Supply, Inc. (Phoenix)
1031 Mendota Heights Road
Saint Paul, MN 55120

License No. **01-1988450**

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Patterson Veterinary Supply, Inc. (Patterson Phoenix), for the purpose of resolving all issues between the parties relating to the Board investigation of sales of dangerous drugs, including controlled substances, to entities that did not possess active Terminal Distributor of Dangerous Drugs licenses at the time of the sales. Together, the Board and Patterson Phoenix are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Patterson Phoenix is a licensed Wholesaler Distributor of Dangerous Drug, License No. 01-1988450.

FACTS

1. The Board initiated an investigation of Patterson Phoenix's Wholesale Distributor of Dangerous Drugs License No. 01-1988450, related to Patterson Phoenix's sales of dangerous drugs, including controlled substances, to entities that did not possess an active Ohio Terminal Distributor of Dangerous Drugs license at the time of the sales.

2. On or about June 21, 2021, the Board sent Notices of Opportunity for Hearing to Patterson Phoenix related to the above-listed matters, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Patterson Phoenix neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letters dated June 21, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notices, and hereby adjudicates the same.

3. Patterson Phoenix agrees to pay to the Board a monetary penalty in the amount of $6,500.00 to resolve the above-listed matters. This fine will be attached to the license record and must be paid no later than 6 months from the effective date of this Order. To pay this fine, login to www.elicense.ohio.gov and process the items in the cart.

4. Patterson Phoenix agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. Patterson Phoenix agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Patterson Phoenix of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Patterson Phoenix by the Board and will NOT discharge Patterson Phoenix from any obligation under the terms of this Agreement.

6. Patterson Phoenix agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. Patterson Phoenix understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Patterson Phoenix will operate.

9. Patterson Phoenix waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Les Korsh Vice President, General Counsel
And Secretary, on behalf of,
Patterson Veterinary Supply, Inc. (Phoenix), Respondent

December 21, 2021
Date of Signature

Alex Cooper, Attorney for Respondent

December 31, 2021
Date of Signature

Rich Miller, RPh, President,
State of Ohio Board of Pharmacy

January 5, 2022
Date of Signature

Henry G. Appel, Ohio Assistant Attorney General

January 5, 2022
Date of Signature

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor
Columbus, Ohio 43215-6108
Tel: (614) 466-4143
www.pharmacy.ohio.gov
1/7/2022 5:29 PM

Your payment was successful.

Order Status	Successful
Applied Payment	$6500.00
Contact	Kelley Karau
Operator	CBOSS Integration
Process Date	1/7/2022 5:28 PM
Receipt Number	[redacted]
Payment Reference Number	
Card Number	
Amount	$6,500.00
Settlement Date	1/11/2022

Fee Payments

Licensee Name	License Number	Endorsement	State/Province	Type	Amount	Amount Outstanding	Payment Amount
				PRX - Settlement Agreement (4K90)	$6,500.00	$0.00	$6,500.00

Thank you for your transaction.

State of Utah
Department of Commerce
Division of Occupational and Professional Licensing
ATTN: Citation Coordinator
160 East 300 South
P.O. Box 146741
Salt Lake City, Utah 84114-6741

Telephone: (801) 530-6628
Fax: (801) 530-6511
Website: www.dopl.utah.gov

101919

CITATION

ISSUED TO: Patterson Veterinary Supply, Inc.		
PROFESSION: Class C Pharmacy	LICENSE #: 11651073-1710	CASE #: 133347
DOB: / /N/A	DL #: N/A	SSN/EIN #:
BUSINESS ADDRESS: 5000A Dahlia Street Unit A	CITY: Denver	STATE: CO ZIP: 80216
BUSINESS PHONE: 303-377-2418	BUSINESS EMAIL: pattersonlicensing@pattersoncompanies.com	
HOME ADDRESS: N/A	CITY: N/A	STATE: N/A ZIP: N/A
HOME PHONE: N/A	HOME EMAIL: N/A	
LOCATION OF OFFENSE: Patterson Veterinary Supply, Inc. 5000A Dahlia Street Unit A Denver, CO 80216		
	DATE OF OFFENSE: 02 /10 /2022	DATE ISSUED: 06 /23 /2022

OFFENSE CODE	DESCRIPTION
58-1-501(2)(a)	"unprofessional conduct" means conduct, by a licensee or applicant, that is defined as unprofessional conduct under this title or under any rule adopted under this title and includes: (a) violating
R156-17b-502(22)	any statute, rule, or order regulating an occupation or profession under this title; 22) failing to provide consulting pharmacist, designated representative, responsible party, PIC, RDPIC, or DMPIC information to the Division within 30 days of a change in consulting pharmacist, designated representative, responsible party, PIC,RDPIC or DMPIC

REMARKS: On 2/11/2022 the Division received notification of a change in Designated Representative with the form being dated 02/10/2022 and the designated representative association date of 5/01/2021.

Fine Pursuant to R156-17b-502(22)

PERSON SERVED: Certified Mail 70161370000001859402 SERVED BY: Alicia Moran VIA certified mail

☑ FINE $ 1,250.00 ☑ CEASE AND DESIST ORDER

I ACKNOWLEDGE RECEIPT OF THIS CITATION AND CERTIFY THAT I HAVE READ AND UNDERSTAND THE RIGHTS ADVISEMENT CONTAINED BELOW AND HAVE BEEN PROVIDED A NOTICE OF RESPONSE.

RECIPIENT'S SIGNATURE — DATE: 7/08/2022

I CERTIFY THAT THE INFORMATION IN THIS CITATION IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF.

INVESTIGATOR'S SIGNATURE

READ CAREFULLY

1. If you wish to contest this citation at a hearing, you must notify the Division in writing within 20 calendar days of receipt. The hearing will be conducted according to Title 63 G, Chapter 4.
2. If you do not contest the citation within 20 calendar days of receipt, the citation will become a final order of the Division and is not subject to further agency review.
3. Failure to comply with a final order of the Division is a Class A misdemeanor. The Division may refuse to issue or renew or may suspend, revoke, or place on probation a license you hold or apply for.

DIVISION COPY

NOTICE OF RESPONSE

DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING

Heber M. Wells Building
160 E 300 S
PO Box 146741
Salt Lake City, UT 84114-6741

Phone: 801-530-6088
Fax: 801-530-6511
Email: fines@utah.gov

You can pay your fine online at www.dopl.utah.gov
Scroll down and click on the RED triangle, then click on $Pay Fine
or mail payment to the PO Box listed above

Citation #: 1333417	Date of Citation: 6/23/2022	
Name: Patterson Veterinary Supply, Inc.	Phone: (303) 377-2418	
Address: 5000A Dahlia St. Unit A		
City: Denver	State: CO	Zip: 80216

You must respond within 20 calendar days to your citation as outlined below:

If you fail to timely respond, the citation will become the final order of the Division and may result in denial of future licensure or disciplinary action against a license you currently hold.

Select only one of the following:

☒	1. I admit committing the offense, choose not to contest the citation, and hereby submit the fine imposed (if applicable). By doing so, I hereby waive any and all affirmative defenses I may have to this citation.
☐	2. I admit committing the offense, hereby submit the fine imposed (if applicable) with a written explanation of the circumstances of the offense and request that the fine be reduced or the sanction be modified.
☐	3. I admit committing the offense, but I request a pre-citation hearing conference to explain the circumstances of the offense. *(On the back of this form please submit a brief written explanation of the circumstances of the offense.)*
☐	4. I deny committing the offense and request a hearing to contest the citation. *(On the back of this form please provide a written response to the alleged citation.)*

I certify that I have knowingly and voluntarily made the above election of rights. I understand that if I request a hearing the Division will notify me in writing of the hearing date and that if I fail to appear at the hearing a default judgment will be entered against me.

Signature: [signature]	Date of Signature: 7/08/2022

Updated: 05/05/2021

NABP ACCREDITED

DRUG DISTRIBUTOR

Patterson Veterinary Supply, Inc

located at

1031 Mendota Hts Rd Ste 100, Mendota Heights , MN 55120

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.



Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

0923

PATTERSON

1031 Mendota Heights Road
Saint Paul, MN 55120
800.328.5536

Parent Company:	Patterson Companies, Inc.
Address:	1031 Mendota Heights Road Saint Paul, MN 55120
Ownership:	100%
FEIN:	[redacted]
State of Incorporation:	Minnesota

PATTERSON VETERINARY SUPPLY, INC. – Officer List

Corporate address:	1031 Mendota Heights Road, St. Paul, MN 55120
Phone Number:	651-686-1600
FEIN:	[redacted]
State of Incorporation:	Minnesota - #11R-993 (6/18/2001)

Robert J. Rajalingam **Chief Executive Officer**
Business Address: 1031 Mendota Heights Road
St. Paul, MN 55120
Business Phone: 651-686-1600
Email: Facilitylicensing@pattersoncompanies.com

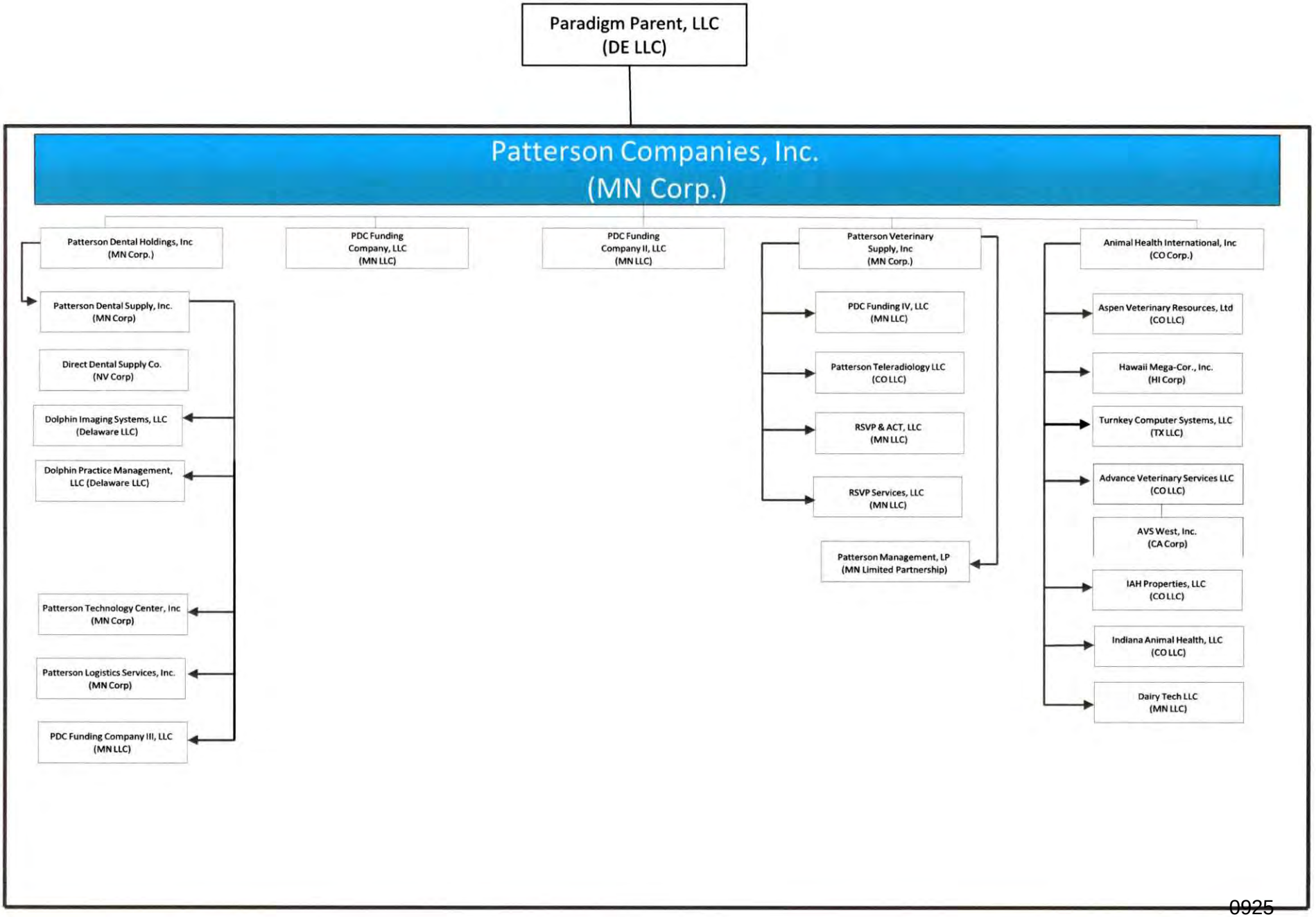
George L. Henriques **President**
Business Address: 2915 Rocky Mountain Ave., Suite 400
Loveland, CO 80538
Business Phone: 970-353-2000
Email: Facilitylicensing@pattersoncompanies.com

Kevin M. Barry **Chief Financial Officer**
Business Address: 1031 Mendota Heights Road
St. Paul, MN 55120
Business Phone: 651-686-1600
Email: Facilitylicensing@pattersoncompanies.com

Leslie B. Korsh **Corporate Secretary**
Business Address: 1031 Mendota Heights Road
St. Paul, MN 55120
Business Phone: 651-686-1600
Email: Facilitylicensing@pattersoncompanies.com

Effective 4/22/2025

Organizational Chart



Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	PATTERSON VETERINARY SUPPLY, INC.
Date Filed:	06/18/2001
File Number:	11R-993
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota
This certificate has been issued on:	07/22/2025



Steve Simon
Secretary of State
State of Minnesota

State of Minnesota

Minnesota Board of Pharmacy
St. Paul, MN 55102

HAS ISSUED
Wholesaler/Distributor
License Number 381984

To: Patterson Veterinary Supply, Inc.
1031 Mendota Heights Road, Suite 100
Saint Paul, MN 55120

EFFECTIVE DATE
4/18/25

EXPIRATION DATE
5/31/26

State of Minnesota

Minnesota Board of Pharmacy
St. Paul, MN 55102

HAS ISSUED
Wholesaler/Distributor
License Number 381984

To: Patterson Veterinary Supply, Inc.

EFFECTIVE DATE

EXPIRATION DATE

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES INC
925 CAROLINA PINES BLVD
STE B
BLYTHEWOOD, SC 290167926

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES INC
925 CAROLINA PINES BLVD
STE B
BLYTHEWOOD, SC 290167926

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	03-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-10-2025

PATTERSON LOGISTICS SERVICES INC
925 CAROLINA PINES BLVD
STE B
BLYTHEWOOD, SC 290167926

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K42165931

Application/License No._____

Patterson Veterinary Supply, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1031 Mendota Heights Rd., Suite 100, St. Paul, MN 55120 (Address of Applicant/Principal), as PRINCIPAL, and Federal Insurance Company (Surety Company), a corporation organized under the laws of the state of Indiana (Stete of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 202B Hall's Mill Road, Whitehouse Station, NJ 08889-3454 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on January 12, 2026 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 12th day of January, 20 26.

APPLICANT/PRINCIPAL
Patterson Veterinary Supply, Inc.

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY
Federal Insurance Company

Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact
print name
NV Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness Brittany D. Stuckel

Witness JoAnn R. Frank

Countersigned by:

N/A
Nevada Resident Agent

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Delaware corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint

Cynthia L. Choren

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **19th** day of **July, 2024.**

Rupert HD Swindells, Assistant Secretary

Warren Eichhorn, Vice President

STATE OF NEW JERSEY
County of Hunterdon SS.

On this **19th** day of **July, 2024** before me, a Notary Public of New Jersey, personally came Rupert HD Swindells and Warren Eichhorn, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Rupert HD Swindells and Warren Eichhorn, being by me duly sworn, severally and each for himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22,2027

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Rupert HD Swindells, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this January 12, 2026

Rupert HD Swindells, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903- 3493 Fax (908) 903- 3656 e-mail: surety@chubb.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Patterson Veterinary Supply, Inc. MDEG License # (if applicable): _____

Physical Address: 1031 Mendota Heights Road, Suite 100

City: Saint Paul State: MN Zip: 55120

Mailing Address (if different from physical address): Attn: Regulatory Licensing - 1031 Mendota Heights Road, Suite 100

City: Saint Paul State: MN Zip: 55120

Telephone: 651-686-1600 Website: https://www.pattersonvet.com/

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Ernest Middle: _____ Last: Pasillas III

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: Attn: Regulatory Licensing - 1031 Mendota Heights Road, Suite 100

City: Saint Paul State: MN Zip: 55120

Telephone: 651-686-1600 Email: facilitylicensing@pattersoncompanies.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Dinuba Union Highschool		9/90 - 5/94	
Address	**City**	**State**	**Zip**
340 E Kern St	Dinuba	CA	93618
Diploma/Degree obtained, if any			
Graduation Diploma			

School Name		From - To (MM/YY – MM/YY)	
College of the Sequoias		Not Completed	
Address	**City**	**State**	**Zip**
915 S Mooney Blvd	Visalia	CA	93277
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/18 - Present	[redacted]	Apple Valley	MN	[redacted]
8/18 - 11/18		Eagan	MN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Patterson Veterinary Supply, Inc.			10/23 - Present	
Business Address		City	State	Zip
1031 Mendota Heights Road		Saint Paul	MN	55120
Phone	Title		Number of Employed Hours	
817-235-1764	VP of Continuous Improvement		approx. 4150	
Description of Duties				
Please see attached work experience description.				

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			01/18 - 10/23	
Business Address		City	State	Zip
1031 Mendota Heights Road		Saint Paul	MN	55120
Phone	Title		Number of Employed Hours	
817-235-1764	Senior Director of Distribution		approx. 12,000	
Description of Duties				
Director of Distribution Network - Provide direction for fulfillment centers for stategy, objectives and procedures and compliance.				

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			05/10 - 01/18	
Business Address		City	State	Zip
1031 Mendota Heights Road		Saint Paul	MN	55120
Phone	Title		Number of Employed Hours	
817-235-1764	Regional Logistics Manager		15,000 +	
Description of Duties				
Regional oversight and direction regarding goals, procedures, and compliance.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case # N/A		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/29/25
Date

I, Ernest Pasillas III, **certify that as the MDEG Administrator for**

Patterson Veterinary Supply, Inc.,

that I (initial that you have read and meet the following requirements):

1. EP Have a high school diploma or its equivalent;
2. EP Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. EP Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. EP Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ernest Pasillas III
Print Name (First, Last)

Ernest Pasillas III
Original Signature (electronic, copies or stamps not accepted)

10/29/25
Date

Board Use Only	Date Received: 11/20/25

ERNEST PASILLAS III

[redacted]

PROFILE

Detail oriented, dependable professional with twenty four years of pharmaceutical distribution experience and fifteen plus years of management experience.

HIGHLIGHTS OF QUALIFICATIONS

Management Skills

- Has had the opportunity of managing for Patterson Logistics in various capacities and has a solid understanding of "Patterson" goals,
- Has participated in numerous Project Travel teams that have afforded me the opportunity to learn from other Managers and key Fulfillment Center personnel.
- Strong communicator that is able to motivate other people to achieve company strategies and objectives.

Computer Skills

- Microsoft Word, Excel, Access, Power Point, Lawson, Lotus Notes, and Patterson Warehouse Management applications

PROFESSIONAL EXPERIENCE

Patterson Logistic Services – Eagan, MN — October 2023 – Present
Vice President of Continuous Improvement

- Responsible for building internal capabilities that support continuous improvement methodology and a culture of process excellence that aligns with our company values.
- Identifying, prioritizing and leading enterprise continuous improvement projects.

Patterson Logistic Services – Eagan, MN — May 2018 – October 2023
Director of Distribution Network/ Sr. Director of Distribution

- Responsible for providing direction for the Fulfillment Centers with regards to company strategy, objectives and procedures. Works with VP and finance to set budgetary goals for total distribution network.
- Responsible to ensure that the Fulfillment Centers are in compliance with Regulatory bodies, 3rd party auditors, etc.

Patterson Logistic Services - Kent, WA — January 2010 – May 2018
Regional Logistics Manager

- Responsible for providing direction for the Distribution Centers in the Western Region with regards to company goals, procedures, and initiatives.
- Responsible for all P&L aspects for the Distribution Centers in the Western Region.
- Responsible to ensure that the Distribution Centers in the Western Region is in compliance with Regulatory bodies, 3rd party auditors, etc.

Patterson Logistic Services - Kent, WA — February 2005 - December 2009
Distribution Center Manager

- Responsible to manage all aspects of the daily operation of the Distribution Center. Including providing direction for Northwest Distribution Center with regards to company goals, procedures, and initiatives.
- Responsible for all P&L aspects for the Northwest D.C.
- Responsible to ensure that the Northwest DC is in compliance with Regulatory bodies, 3rd party auditors, etc.

Patterson Logistic Services – Fort Worth, TX — February 2002 - February 2005
Production Team leader

- Managed two line supervisors and 30 employees in a high paced production environment.
- Responsible for hiring, training, reviewing, and terminating all shipping employees.
- Assisted DC manager with preparation for audits from Regulatory bodies and 3rd party auditors.

EDUCATION

College of Sequoias – Visalia, CA — 1994-2000
Major Course of Study: Business Administration
Minor Course of Study: Accounting

Attachment to Work Experience

Mr. Pasillas has held and currently holds executive leadership roles at Patterson Companies, Inc., the parent company of Patterson Veterinary Supply, Inc. His responsibilities include providing oversight and strategic direction for:

- **Patterson Veterinary Supply, Inc.** – a licensed wholesale distributor
- **Patterson Logistics Services, Inc.** – a licensed third-party logistics provider

Patterson Veterinary Supply, Inc., currently employs Mr. Pasillas. Please refer to the attached *Explanation of Work Experience* and details of relevant facilities.

Veterinary Supply, Inc., 1031 Mendota Heights Road, Mendota Heights, MN 55120, operates as a virtual distributor. This location functions exclusively as a sales office and **does not** possess, store, or ship prescription drug products.

Licensed Facilities

Patterson Veterinary Supply, Inc. operates the following licensed wholesale facilities:

- Charlotte, NC (California License: OSD 8277)
- Phoenix, AZ (California License: OSD 5491)

Mr. Pasillas previously held a Certified Wholesale Distributor License for Patterson's Dinuba, California facility under License TPL 1084 when the State of California licensed Third-Party Logistics Providers as Wholesale Distributors. His license number was EXC 19704. This license was relinquished, and Mr. Pasillas transitioned to the Third-Party Logistics Provider (DR) license DRL 40296 in accordance with California Business & Professions Code § 4161.

Patterson Logistics Services, Inc. operates under:

- Dinuba, CA License: TPL 1084

Explanation of Work Experience

Work Experience (Past 3 Years)

I have worked at Patterson Companies, Inc. and its subsidiaries for many years, including the past three. I have had direct oversight of operations involving the distribution of dangerous drugs and devices., at and for many licensed wholesale facilities. My responsibilities span regulatory compliance, operational execution, and strategic development across a national logistics network.

Regulatory and Compliance Oversight

- Ensure all distribution centers-maintained compliance with DEA, FDA, and state pharmacy board regulations related to the handling and distribution of dangerous drugs and devices.
- Conduct 24+ site visits annually to perform internal audits, assess regulatory readiness, and support local teams in implementing corrective actions.
- Partner with regulatory affairs and legal teams to interpret and operationalize new or updated regulations, ensuring SOPs and training materials were current and enforced.
- Act as the central point of contact for regulatory inspections and customer audits involving controlled substances or dangerous devices.

Operational Leadership

- Direct a team of over 1,400 employees through a structured leadership hierarchy, including 3 Regional Directors and 6 Area Operations Managers.
- Oversee daily operations at licensed facilities, ensuring secure storage, accurate order fulfillment, and compliant transportation of regulated products.
- Support the development and implementation of diversion prevention protocols, chain-of-custody documentation, and temperature-sensitive handling procedures.

Continuous Improvement and SOP Governance

- As VP of Continuous Improvement, lead the team responsible for creating, reviewing, and updating SOPs specific to logistics and regulatory compliance.
- Conduct root cause analyses for compliance deviations and operational failures, implementing sustainable corrective actions.

- Lead enterprise-wide initiatives to improve cost-to-serve, inventory accuracy, and regulatory preparedness, including the development of a continuity playbook for potential UPS strikes and cybersecurity events.

Customer and Stakeholder Engagement

- Serve as the escalation point for customer issues involving dangerous drugs or devices, coordinating cross-functional responses to resolve concerns quickly and compliantly.
- Support onboarding of new customers requiring access to controlled substances, including licensing verification and process alignment.
- Collaborate with sales, legal, and compliance teams to adapt distribution processes in response to policy or regulatory changes.

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
11/04/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA LLC 333 South 7th Street, Suite 1400 Minneapolis, MN 55402-2400 CN102114303-Stnd-GAWU-25-26	**CONTACT NAME:** Marsh	U.S. Operations & Technology **PHONE (A/C, No, Ext):** 866-966-4664 **FAX (A/C, No):** **E-MAIL ADDRESS:** Minneapolis.CertRequest@marsh.com	
	INSURER(S) AFFORDING COVERAGE		**NAIC #**
	INSURER A : Starr Indemnity & Liability Company		38318
INSURED Patterson Companies, Inc. and its subsidiaries and affiliates 1031 Mendota Heights Road St. Paul, MN 55120	**INSURER B :** N/A		N/A
	INSURER C :		
	INSURER D :		
	INSURER E :		
	INSURER F :		

COVERAGES **CERTIFICATE NUMBER:** CHI-010950096-05 **REVISION NUMBER:** 6

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X **COMMERCIAL GENERAL LIABILITY** CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC OTHER:			1000100137251	11/01/2025	11/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 2,000,000 $ 1,000,000 $ 0 $ 2,000,000 $ 10,000,000 $ 4,000,000
A A	**AUTOMOBILE LIABILITY** X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			1000198195251 (AOS) 1000198196251 (MA)	11/01/2025 11/01/2025	11/01/2026 11/01/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
	UMBRELLA LIAB OCCUR **EXCESS LIAB** CLAIMS-MADE DED RETENTION $						EACH OCCURRENCE AGGREGATE	$ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N [ ] N/A **(Mandatory in NH)** If yes, describe under DESCRIPTION OF OPERATIONS below						PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence only.

CERTIFICATE HOLDER

Patterson Companies
1031 Mendota Heights Road
St. Paul, MN 55120

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA LLC

Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Patterson Veterinary Supply, Inc.

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 1031 Mendota Heights Road, Suite 100

City: Saint Paul State: MN Zip: 55120

Mailing Address (if different from physical address): Attn: Regulatory Licensing - 1031 Mendota Heights Road, Suite 100

City: Saint Paul State: MN Zip: 55120

Telephone: 651-686-1600 Website: https://www.pattersonvet.com/

Licensing Company Email: facilitylicensing@pattersoncompanies.com

Section 2: Personal Information

First: Ernest Middle: Last: Pasillas III

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: Attn: Regulatory Licensing - 1031 Mendota Heights Road, Suite 100

City: Saint Paul State: MN Zip: 55120

Telephone: 651-686-1600 Email: facilitylicensing@pattersoncompanies.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Dinuba Union Highschool		9/90 - 5/94	
Address	**City**	**State**	**Zip**
340 E Kern St	Dinuba	CA	93618
Diploma/Degree obtained, if any			
Graduation Diploma			

School Name		From - To (MM/YY – MM/YY)	
College of the Sequoias		Not Completed	
Address	**City**	**State**	**Zip**
915 S Mooney Blvd	Visalia	CA	93277
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/18 - Present	[redacted]	Apple Valley	MN	[redacted]
8/18 - 11/18		Eagan	MN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Patterson Veterinary Supply, Inc.			10/23 - Present	
Business Address	**City**		**State**	**Zip**
1031 Mendota Heights Road	Saint Paul		MN	55120
Phone	**Title**		**Number of Employed Hours**	
817-235-1764	VP, Strategic Business Operations and Transformation		approx. 4160	
Description of Duties				
Please see attached work experience description				

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			01/21 - 10/23	
Business Address	**City**		**State**	**Zip**
1031 Mendota Heights Road	Saint Paul		MN	55120
Phone	**Title**		**Number of Employed Hours**	
817-235-1764	Senior Director of Distribution		approx. 12,165	
Description of Duties				
Director of Distribution Network - Provide direction for fulfillment centers for stategy, objectives and procedures and compliance.				

Business Name			From - To (MM/YY – MM/YY)	
Patterson Logistics Services, Inc.			05/18 - 01/21	
Business Address	**City**		**State**	**Zip**
1031 Mendota Heights Road	Saint Paul		MN	55120
Phone	**Title**		**Number of Employed Hours**	
817-235-1764	Director of Distribution			
Description of Duties				
Regional oversight and direction regarding goals, procedures, and compliance.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N/A	

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/29/25
Date

I, Ernest Pasillas III, **certify that as the designated representative for**

Patterson Veterinary Supply, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. EP I am at least 21 years of age;
3. EP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. EP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. EP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. EP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. EP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ernest Pasillas III

Print Name (First, Last)

E Pasillas

Original Signature (electronic, copies or stamps not accepted)

10/29/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ernest Pasillas III

Print Name (First, Last)

Ernest Pasillas III — 10/29/25

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Minnesota, ss. County of Dakota

I, Ernest Pasillas III, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Ernest Pasillas III — 10/29/25

Original Signature — **Date**

Subscribed and Sworn to before me this 29th day of October 2025.

Notary Public Signature

ANNE M FROISTAD
Notary Public
State of Minnesota
My Commission Expires
01/31/2029

(Seal)

PATTERSON VETERINARY

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.225.7911

Patterson Veterinary Supply, Inc.
1031 Mendota Heights Road, Suite 100
Saint Paul, MN 55120

Employee List

Employee Names
Ernest Pasillas III
Alyssa Rathsabandith

4S

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: AOSS Medical Supply, LLC

Physical Address: 2700 Shiloh Road

City: Richardson State: TX Zip: 75082

Mailing Address (if different from physical address): c/o State License Servicing, 225 Dolson Ave, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: aossmedicalsupply.com

Name of Designated Representative (DR): Curlee Don Hudson

Licensing Company Email: AOS@slsny.com DR Email: curlee_hudson@aossmedical.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☒ Others: Drugs (Human OTC), Devices (OTC)	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Distribution sites within organization, US Government & Sister-sites		☒ Others: Distributor - Wholesaler

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A - No discipline to report

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: JMS North America Corp.
Address: 22320 Foothill Blvd. City: Hayward State: CA Zip: 94541
Name: Becton, Dickinson, & Company
Address: 21588 Network Place City: Chicago State: IL Zip: 60673
Name: Dynarex Corp.
Address: 155 Chestnut Ridge Rd. City: Montvale State: NJ Zip: 07645
Name: American Healthcare Products Inc.
Address: 1028 Westminster Ave. City: Alhambra State: CA Zip: 91803

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:
Date of SEC Registration: SEC Registration Number: Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: LA
Parent Company (if any): N/A - Personal Owners
Corporation/Organization Name: AOSS Medical Supply, LLC
Mailing Address: c/o State License Servicing 225 Dolson Ave, 4th Floor
City: Middletown State: NY Zip: 10940
Telephone: (845) 544-2482 Email: AOS@slsny.com
Contact Person Name: Christine Cannon

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		X
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

AOSS Medical Supply, LLC

Facility Name

Linda P Liew

Print Name of Authorized Person Submitting Application

Linda P. Liew

Original signature of Authorized Person (copies or stamps not accepted)

2/24/2026

Date

Board Use Only	Date Received: 3/5/26	Amount: $1000 ck 40105

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
AOSS MEDICAL SUPPLY, INC.
2700 Shiloh Road
Richardson, TX 75082
Registration Number: 2319162
FEI Number*: 1000112500
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2026

Owner/Operator:
AOSS MEDICAL SUPPLY, INC.[6]
2700 Shiloh Road
Richardson, TX US 75082
Owner/Operator Number: 9005297[7]

Official Correspondent:
Eric Liew
2700 Shiloh Road
Richardson, TX 75082
Phone: 318-3258290

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 03/09/2026

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

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start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9005297&OwnerOperator

AOSS Medical Supply, L.L.C.

Corporate Address: 4971 Central Avenue, Monroe, LA 71203 USA
FEIN: 72-0864272
aossmedicalsupply.com

Drug Labeler Code: N/A
Incorporation State: LA
Incorporation Date: 1/31/1991

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
SHI	2700 Shiloh Road Richardson, TX 75082 County: Dallas	N/A	N/A - No CS	119296816	No	(318) 325-8290	(318) 632-7859

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Linda P. Liew	[redacted]	Manager	No	[redacted]		
Nicholas Hon Liew		Designated Representative	No			
Curlee Don Hudson		RS Logistics Director	No			

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Linda P. Liew	[redacted]	Manager	45	No	[redacted]		
Hon Keong Liew		Manager	55	No			

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Linda P. Liew	[redacted]	Manager	No	[redacted]		
Hon Keong Liew		Manager	No			

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
AOSS Medical Supply, LLC			
Corporation Service Company			
Savannah Liew Siu			

Company Particulars

AOSS Medical Supply, L.L.C.
Louisiana | Utah | Texas
(800) 462-8310
www.aossmedicalsupply.com

AOSS Medical Supply, L.L.C. – Ownership Organizational Chart

Hon Keong Liew,
Manager
55%

Linda Liew
Manager
45%

AOSS Medical Supply, L.L.C.
FEIN: 72-0864272
Headquarters and Distribution Center:
2700 Shiloh Rd, Richardson TX 75082



AOSS Medical Supply, L.L.C.
Office & Distribution Center
(Louisiana):
4971 Central Avenue
Monroe, LA 71203



AOSS Medical Supply, L.L.C.
Office & Distribution Center
(Utah):
130 South 5100 West
Salt Lake City, UT 84104



Incorp Good Standing

UNITED STATES OF AMERICA

State of Louisiana

Nancy Landry

SECRETARY OF STATE

As Secretary of State of the State of Louisiana, I do hereby Certify that

AOSS MEDICAL SUPPLY, L.L.C.

A limited liability company domiciled in MONROE, LOUISIANA,

Filed charter and qualified to do business in this State on January 30, 1991,

I further certify that the records of this Office indicate the company has paid all fees due the Secretary of State, and so far as the Office of the Secretary of State is concerned, is in good standing and is authorized to do business in this State.

I further certify that this certificate is not intended to reflect the financial condition of this company since this information is not available from the records of this Office.

In testimony whereof, I have hereunto set my hand and caused the Seal of my Office to be affixed at the City of Baton Rouge on,

January 16, 2026

Nancy Landry

Secretary of State

Web 34372656K

STATE OF LOUISIANA · UNION · JUSTICE · CONFIDENCE · SECRETARY OF STATE

Certificate ID: 12139328#2NJ62

To validate this certificate, visit the following web site, go to **Business Services**, **Search for Louisiana Business Filings**, **Validate a Certificate**, then follow the instructions displayed.
www.sos.la.gov

official VOL for HSL (TX)

TEXAS
Health and Human Services

Texas Department of State Health Services

Jennifer A. Shuford, M.D., M.P.H.
Commissioner

November 17, 2025

Kaleysha Reyes
State License Servicing
kreyes@slsny.com

CFN: 2105988
Lic.: 1003611
Type: 2501
File: 6619

Re: License Verification

Dear Kaleysha Reyes:

This letter shall serve as a verification of licensure for the following firm:
AOSS MEDICAL SUPPLY LLC
2700 SHILOH RD
RICHARDSON, TX 75082

License No.	1003611
Type of license:	Prescription Drug Distributor
Status of license:	Current
Date license issued:	03/20/2024
Date license expires:	05/15/2026
Disciplinary action:	None

The firm is in good standing as of the date of this letter.

If you have questions or need additional information, please contact me at 512-834-4503, via fax at (512) 834-6759, or email me at Justin.Arnold@dshs.texas.gov.

Sincerely,

Justin Arnold, MBA, RS
Medical Research Specialist
Drugs and Medical Devices Unit
Consumer Protection Division

Mailing address:
Justin Arnold
Drugs and Medical Devices Unit, MC 1987
PO Box 149347
Austin, TX 78714-9347

Verification of Home State License (TX)

License Number: 1003611 ***Current Date: 02/27/2026 10:13 AM***

Name:	**AOSS MEDICAL SUPPLY LLC**
License Type:	**Prescription Drug Distributor**
License Status:	**Current**
Expiry Date:	**05/15/2026**
Effective Rank Date:	**04/11/2023**
Modifier(s):	**Wholesales Distributor**
	Own Label Dist
	Prescription
	Non Prescript

Addresses

Physical Loc	Address	AOSS MEDICAL SUPPLY LLC 2700 SHILOH RD RICHARDSON , TX DALLAS 75082 US
Mailing Address	Address	AOSS MEDICAL SUPPLY LLC C/O STATE LICENSE SERVICING MIDDLETOWN , NY OUT OF STATE/UNKNOWN 10940

Food & Drug Owner

Licensee's Role:	**Food & Drug License**
Related Party Role:	**Food & Drug Owner**

Related Party Name	**License**	**Owner #**	**Address**
AOSS MEDICAL SUPPLY LLC	**Status:** **Current** **Expiration Date:**		MONROE , LA OUT OF STATE/UNKNOWN 71203

Limited liability cert

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/03/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Nowell Agency
1500 Old Fannin Road
Brandon MS 39047

CONTACT NAME: Wendy Palato
PHONE (A/C, No, Ext): (601) 992-4444 **FAX (A/C, No):**
E-MAIL ADDRESS: GPalato@hilbgroup.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A: Benchmark Insurance Company	
INSURER B: Travelers Indemnity Co of America	25666
INSURER C: The Travelers Companies, Inc.	COMTTI
INSURER D:	
INSURER E:	
INSURER F:	

INSURED
Alpha Omega Systems & Services, Inc.
4971 Central Avenue
Monroe LA 71203

COVERAGES **CERTIFICATE NUMBER:** CL2511309735 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [ ] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			R1025 G1163-10	11/01/2025	11/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG Employee Benefits	$ 1,000,000 $ 100,000 $ 10,000 $ 1,000,000 $ 3,000,000 $ 3,000,000 $ 1,000,000
B	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] HIRED AUTOS ONLY [X] SCHEDULED AUTOS [ ] NON-OWNED AUTOS ONLY			BA 8L797097	11/01/2025	11/01/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) Uninsured motorist	$ 1,000,000 $ $ $ $ 1,000,000
A	[X] UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $			UM1025 1164-10	11/01/2025	11/01/2026	EACH OCCURRENCE AGGREGATE	$ 5,000,000 $ 5,000,000 $
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [N] If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		UB 7J920424	11/01/2025	11/01/2026	[X] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1000000 $ 1000000 $ 1000000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER
Alpha Omega Systems and Services Inc.
4971 Central Ave
Monroe LA 71203

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Rebecca Chandler

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Additional Named Insureds

Other Named Insureds	
AOSS Medical Supply, LLC	Limited Liability Company, Other
Club 100, LLC	Limited Liability Company, Other
Liew Properties, LLC	Limited Liability Company, Other
NES, LLC	Limited Liability Company, Other

COPYRIGHT 2007, AMS SERVICES INC

THE HARTFORD

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy STE 206
Reno, NV 89521

RIDER

Attached to and forming part of Bond # 43BSBJI2875 ,
on behalf of AOSS Medical Supply, LLC
of 2700 Shiloh Road, Richardson, TX 75082
in favor of Nevada State Board of Pharmacy
and in the amount of One Hundred Thousand ($100,000.00) Dollars.

It is understood and agreed that effective December 4, 2025
The Principals Address shall be changed
from 4971 Central Ave, Monroe, LA 71203
to 2700 Shiloh Road, Richardson, TX 75082

All other conditions and terms remain as originally written.

Signed, Sealed, and Dated January, 22nd , 2026

Hartford Fire Insurance Company

By: _____

Hieneka Harrington , Attorney-in-Fact

HARTFORD FIRE INSURANCE CO. INCORPORATED 1810

Form GENCNG-A (Rev. 07/01/22)

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: THE HILB GROUP CENTRAL LLC
Agency Code: 43-230174

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Hieneka Harrington
of Lake Mary, Florida,
its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by, and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 43BSBJI2875
Naming AOSS Medical Supply, LLC as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of January 22, 2026.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

Revised: July 31, 2024

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 43BSBJI2875

Application/License No. _____

Alpha Omega Systems and Services, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2700 Shiloh Road, Richardson, TX 75082 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is _____ (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 28, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 28th day of February, 2025.

APPLICANT/PRINCIPAL

Alpha Omega Systems and Services, LLC

Erika Liew

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Becky Chandler, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: NOWELL AGENCY
Agency Code: 43-230174

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Becky Chandler

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by, and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 43BSBJI2875
Naming Alpha Omega Systems and Services, LLC as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of February 28, 2025.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

Revised: July 31, 2024

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG AOSS Medical Supply, LLC MDEG License # (if applicable) N/A

Physical Address 2700 Shiloh Road

City Richardson State TX Zip 75082

Mailing Address (if different from physical address) c/o State License Servicing, 225 Dolson Ave, 4th Floor

City Middletown State NY Zip 10940

Telephone (845) 544-2482 Website aossmedicalsupply.com

Licensing Company Email AOS@slsny.com

Section 2: Personal Information

First Curlee Middle Don Last Hudson

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Richardson State TX Zip [redacted]

Telephone [redacted] Email curlee_hudson@aossmedical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Howard College		08/1967 - 05/1970	
Address	City	State	Zip
1001 Birdwell Lane	Big Spring	TX	79720
Diploma/Degree obtained, if any			
Associates			
School Name		From - To (MM/YY – MM/YY)	
Fred Douglass		09/1963 - 06/1967	
Address	City	State	Zip
505 E College St	Sherman	TX	75090
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2003 - Present	[redacted]	Richardson	TX	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
AOSS Medical Supply, LLC			11/2022 - Present
Business Address	**City**	**State**	**Zip**
2700 Shiloh Road	Richardson	TX	75082
Phone	**Title**	**Number of Employed Hours**	
(214) 763-3511	RS Logistics Director	~ 6,586 hrs	
Description of Duties			
This highly visible position comes with the responsibility to provide results drive focused leadership. Directs and oversees the inventory, pick pack, shipping activities of personnel and section budget. Proactively lead the team to continuously improve processes, analysis data measurements to identify opportunities for improvement.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A - No discipline to report

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Curlee Don Hudson, **certify that as the MDEG Administrator for**

AOSS Medical Supply, LLC,

that I (initial that you have read and meet the following requirements):

1. CDH Have a high school diploma or its equivalent;
2. CDH Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CDH Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CDH Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Curlee Don Hudson
Print Name (First, Last)

Curlee Don Hudson
Original Signature (electronic, copies or stamps not accepted)

02/24/2026
Date

Board Use Only	Date Received: 3/5/26

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler AOSS Medical Supply, LLC

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 2700 Shiloh Road

City Richardson State TX Zip 75082

Mailing Address (if different from physical address) c/o State License Servicing, 225 Dolson Ave, 4th Floor

City Middletown State NY Zip 10940

Telephone (845) 544-2482 Website aossmedicalsupply.com

Licensing Company Email AOS@slsny.com

Section 2: Personal Information

First Curlee Middle Don Last Hudson

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City Richardson State TX Zip [redacted]

Telephone [redacted] Email curlee_hudson@aossmedical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Howard College		08/1967 - 05/1970	
Address	City	State	Zip
1001 Birdwell Lane	Big Spring	TX	79720
Diploma/Degree obtained, if any			
Associates			

School Name		From - To (MM/YY – MM/YY)	
Fred Douglass		09/1963 - 06/1967	
Address	City	State	Zip
505 E College St	Sherman	TX	75090
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2003 - Present	[redacted]	Richardson	TX	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
AOSS Medical Supply, LLC			11/2022 - Present	
Business Address		**City**	**State**	**Zip**
2700 Shiloh Road		Richardson	TX	75082
Phone	**Title**		**Number of Employed Hours**	
(318) 325-8290	RS Logistics Director		~ 6,586 hrs	

Description of Duties

This highly visible position comes with the responsibility to provide results drive focused leadership. Directs and oversees the inventory, pick pack, shipping activities of personnel and section budget. Proactively lead the team to continuously improve processes, analysis data measurements to identify opportunities for improvement.

Business Name			From - To (MM/YY – MM/YY)	
Fossil Group Inc			08/1995 - 03/2019	
Business Address		**City**	**State**	**Zip**
901 S Central Expy		Richardson	TX	75080
Phone	**Title**		**Number of Employed Hours**	
(972) 234-2525	Sr. Manager of DC Operations		~ 49,920 hrs	

Description of Duties

Driving order fulfillment, compliance, staffing, training, and quality control. Ensured fulfillment of over 10 million units annually over retail, wholesale, and e-commerce. Governed annual labor budget. Manged shipping orders.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A - No discipline to report

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Curlee Don Hudson, **certify that as the designated representative for**

AOSS Medical Supply, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CDH I am at least 21 years of age;
3. CDH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CDH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CDH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CDH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CDH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Curlee Don Hudson

Print Name (First, Last)

Curlee Don Hudson

Original Signature (electronic, copies or stamps not accepted)

02/24/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Curlee Don Hudson

Print Name (First, Last)

Curlee Don Hudson — 02/24/2026

Original Signature (electronic, copies or stamps not accepted) — Date

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Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Collin

I, Curlee Don Hudson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Curlee Don Hudson — 02/24/2026

Original Signature Curlee Don Hudson **Date**

Subscribed and Sworn to before me this 24 day of February 2026

Amy Patterson

Notary Public Signature

AMY PATTERSON
Notary ID #133032378
My Commission Expires
April 7, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: AOSS Medical Supply, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 2700 Shiloh Road

City: Richardson State: TX Zip: 75082

Mailing Address (if different from physical address): c/o State License Servicing 225 Dolson Ave, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: aossmedicalsupply.com

Licensing Company Email: AOS@slsny.com

Section 2: Personal Information

First: Linda Middle: P Last: Liew

Alias(es, nicknames, name changes, etc.): Linda Kay Liew, Linda Kay Pruett

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted]

City: Frisco State: TX Zip: [redacted]

Telephone: [redacted] Email: linda@aossmedical.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Louisiana at Monroe		08/1981- 05/1984	
Address	**City**	**State**	**Zip**
700 University Ave	Monroe	LA	71209
Diploma/Degree obtained, if any			
Acounting / Associates of Art			

School Name		From - To (MM/YY – MM/YY)	
Florence High School		09/1977 - 06/1981	
Address	**City**	**State**	**Zip**
232 MS-469	Florence	MS	39073
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2023- Present	[redacted]	Frisco	TX	[redacted]
2008 - Present		Monroe	LA	
2003 - 2008		Monroe	LA	

Personal History Application (Applicant's Initials LR) 2 of 7

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
AOSS Medical Supply, LLC			1993 - Present	
Business Address		**City**	**State**	**Zip**
2700 Shiloh Road		Richardson	TX	75082
Phone	**Title**			
(318) 325-8290	COO, Owner (45%)			

Description of Duties

Developing, creating and procuring AOSS Private Label Brand Products. Training, directing, and developing AOSS team and key leaders in all departments and locations. Overseeing operations as a whole and leading procurement department; ensuing quality products through the supply chain. Oversee all areas of AOSS including Accounting, Human Resources, Procurement, Marketing, Warehouse management, inventory control, order fulfillment, payroll, taxation and vendor management.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A - No discipline to report

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Linda P. Liew

Print Name (First, Last)

Linda P. Liew — 2/24/2026

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Collin

I, Linda P. Liew, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Linda P. Liew — 2/24/2026

Original Signature Linda P. Liew — **Date**

Subscribed and Sworn to before me this 24 day of February 2026.

Amy Patterson

Notary Public Signature

NOTARY PUBLIC STATE OF TEXAS
AMY PATTERSON
Notary ID #133032378
My Commission Expires
April 7, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site AOSS Medical Supply, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) N/A

Physical Address 2700 Shiloh Road

City Richardson State TX Zip 75082

Mailing Address (if different from physical address) c/o State License Servicing, 225 Dolson Ave, 4th Floor

City Middletown State NY Zip 10940

Telephone (845) 544-2482 Website aossmedicalsupply.com

Licensing Company Email AOS@slsny.com

Section 2: Personal Information

First Hon Middle Keong Last Liew

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Frisco State TX Zip [redacted]

Telephone [redacted] Email eric@aossmedical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northeast Louisiana University		01/1985 - 12/1989	
Address	**City**	**State**	**Zip**
700 University Ave	Monroe	LA	71209
Diploma/Degree obtained, if any			
Bachelor of Science, Business Economics			

School Name		From - To (MM/YY – MM/YY)	
SMK Taman Sea		01/1976 -12/1981	
Address	**City**	**State**	**Zip**
Sekolah Menengah Kebangsaan Taman Sea, Jalan 21/37, SS2, 46300 Petaling Jaya,	Selangor, Malaysia		
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2023 - Present	[redacted]	Frisco	TX	[redacted]
From - To (MM/YY – MM/YY)		City	State	
2008 - Present		Monroe	LA	
From - To (MM/YY – MM/YY)		City	State	
2003 - 2008		Monroe	LA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
AOSS Medical Supply			1988 - Present	
Business Address		**City**	**State**	**Zip**
2700 Shiloh Road		Richardson	TX	75082
Phone	**Title**			
(318) 325-8290	CEO, Owner (55%)			
Description of Duties				
Developing, creating, and procuring AOSS Private Label Brand Products. Overseeing operations as a whole and leading procurement department; ensuring quality products through the supply chain; experience in developing, planning and implementing successful strategies. In-depth knowledge of corporate governance, financeand performance management principles.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/24/2026.
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hon Keong Liew

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/24/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Collin

I, Hon Keong Liew, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature Hon Keong Liew

Date 2/24/2026

Subscribed and Sworn to before me this 24 day of February 2026

Notary Public Signature

AMY PATTERSON
Notary ID #133032378
My Commission Expires
April 7, 2029

AMY PATTERSON
Notary ID #1330323
My Commission Expi
April 7, 2029

(Seal)

Employee List

AOSS Medical Supply, LLC
4971 Central Ave, Monroe, LA 71203
318.325.8290

List of AOSS Employees on site

1. Linda L.
2. Erika L.
3. Rosmery M.
4. Jessie S.
5. Hannah T.
6. Aakanksha S.
7. Brendan M.
8. Kimberly D.
9. Leia E.
10. Linda Paulette C.
11. Nicholas L.
12. Eric L.
13. Curlee H.
14. Kevin T.
15. Johnny P.
16. Gaylon H.
17. Jose G.
18. Sedric S.
19. Terrance J.
20. Brenden W.
21. Cadman J.
22. Walter T.
23. Doris S.
24. Dora G.
25. Hang P.
26. Blanca Q.

4T

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ■ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03058	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: VGYAAN Pharmaceuticals LLC (Name changes to: Aryeh Pharma Corp)

Physical Address: 23 Orchard Road, Ste 180

City: Skillman State: NJ Zip: 08558

Mailing Address (if different from physical address): Same as Above

City: State: Zip:

Telephone: 201-633-3604 Website: www.aryehpharma.com

Name of Designated Representative (DR): Carol Chao

Licensing Company Email: compliance@aryehpharma.com DR Email: carolchao@aryehpharma.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

01/22/2026
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NJ

Parent Company (if any): Aryeh Pharma Corp

Corporation/Organization Name: VGYAAN Pharmaceuticals LLC (Name changes to: Aryeh Pharma Corp)

Mailing Address: 185 Hudson St, Ste 2500

City: Jersey City State: NJ Zip: 07311

Telephone: 201-633-3604 Email: compliance@aryehpharma.com

Contact Person Name: Anilkumar Amin

Section 6: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

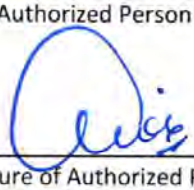
I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Aryeh Pharma Corp

Facility Name

Anilkumar Amin

Print Name of Authorized Person Submitting Application



Original signature of Authorized Person (copies or stamps not accepted)

01/22/2026

Date

Board Use Only	Date Received: 2/3/26	Amount: CC $1000 1767

Labeler - ARYEH PHARMA CORP. (136950666) **NDC Labeler Code:** 85957

Contact	Address	Telephone Number	Email Address
Carol Chao	Address: 35-2006 Hudson St. City, State, Zip: Jersey City, NJ, 07302-6556 Country: USA	+1-646-491-2103	carolchao@aryehpharma.com

Labeler Detail

Name	Address	ID/FEI	Business Operations
ARYEH PHARMA CORP.	Address: 35-2006 Hudson St. City, State, Zip: Jersey City, NJ, 07302-6556 Country: USA	136950666	distributes drug products under own private label(Distributes human prescription drug products), (Distributes human over-the-counter drug products)

Revised: 10/2025

ARYEH PHAR

verified M.H 2/4/26

ARYEH
PHARMACEUTICALS

Aryeh Pharma Corp.

Officers and Directors

Name: Anilkumar Amin
Title: Chairman of Board

inquiries@aryehpharma.com

(201) 633-3604

Aryeh Pharmaceuticals
185 Hudson Street
Suite 2500
Jersey City, NJ 07311

ARYEH
PHARMACEUTICALS

Aryeh Pharma Corp.

Owners

Name: Anilkumar Amin

Title: Chairman of Board

Percentage: 100%

inquiries@aryehpharma.com

(201) 633-3604

Aryeh Pharmaceuticals
185 Hudson Street
Suite 2500
Jersey City, NJ 07311

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

ARYEH PHARMA CORP.
0451246760

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on February 24, 2025.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

JUSTYN VOLESKO
35-2006 HUDSON STREET
JERSEY CITY, NJ 07302

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 8th day of December, 2025

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6171366982

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0024285

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written noticeprior to the change of the address of such new location and the name and address of the individual to be in charge thereof.A fee of $20.00 shall accompanying such notification."

Registered as ☐ Manufacturer ☑ Distributor which conducts business at the following locations:

Reg. No.:
7202721

Aryeh Pharma Corp
185 Hudson ST STE 2500
JERSEY CITY, NJ 07311

ISSUED PURSUANT TO:
N.J.S.A. 24:6B
EXPIRES: January 31, 2027

Establishment Copy

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RS0280153	02-28-2027	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	12-30-2025

SADDLE RIVER MARKETING
600 VALLEY HEALTH PLAZA
PARAMUS, NJ 076523607

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RS0280153	02-28-2027	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	12-30-2025

SADDLE RIVER MARKETING
600 VALLEY HEALTH PLAZA
PARAMUS, NJ 076523607

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RS0280153	02-28-2027	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	12-30-2025

SADDLE RIVER MARKETING
600 VALLEY HEALTH PLAZA
PARAMUS, NJ 076523607

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

WESTFIELD

Westfield Insurance Company
One Park Circle, P.O.Box 5001
Westfield Center, OH 44251-5001

SURETY RIDER

Bond Number 502538F
License Number _____

To be attached to and form a part of Pharmaceutical Wholesaler ($25,000) Bond
Bond Type

In favor of Nevada State Board of Pharmacy
Obligee

On behalf of ARYEH PHARMA CORP.
Principal

Surety hereby gives the consent to amend Address, Add Secondary Location to read:

To:
Principal Address:
185 Hudson St Suite 2500 Jersey City NJ 07311

Secondary Location:
23 Orchard Road, Ste 180, Skillman, NJ 08558

Effective: March 10, 2026

Signed and sealed this 10th day of March, 2026.

WESTFIELD INSURANCE COMPANY SEAL

Westfield Insurance Company

Joshua Kayser ,Attorney in Fact

Agent:
Brooklyn Ventures LLC dba SuretyBonds.com
803 E. Walnut Street, 5th Floor
Columbia, Missouri 65201

Obligee:
Nevada State Board of Pharmacy
431 W. Plumb Lane
Reno, NV 89509

THIS POWER OF ATTORNEY SUPERCEDES ANY PREVIOUS POWER BEARING THIS SAME POWER # AND ISSUED PRIOR TO 08/21/25, FOR ANY PERSON OR PERSONS NAMED BELOW.

General Power of Attorney

CERTIFIED COPY

POWER NO. **2400012 01**

Westfield Insurance Co.
Westfield National Insurance Co.
Ohio Farmers Insurance Co.

Westfield Center, Ohio

Know All Men by These Presents, That WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY and OHIO FARMERS INSURANCE COMPANY, corporations, hereinafter referred to individually as a "Company" and collectively as "Companies," duly organized and existing under the laws of the State of Ohio, and having its principal office in Westfield Center, Medina County, Ohio, do by these presents make, constitute and appoint

MATTHEW BOCKLAGE, BRAD BULLERDIECK, SEDA GULER, BERNARDO C. SCORZA GASPAR, ROBERT J. WOLF, BLAKE OLIVER, MARK KARR, JOSHUA KAYSER, LIAM COLEMAN, JOINTLY OR SEVERALLY

of **COLUMBIA** and State of **MO** its true and lawful Attorney(s)-in-Fact, with full power and authority hereby conferred in its name, place and stead, to execute, acknowledge and deliver **any and all bonds, recognizances, undertakings, consents of surety, or other instruments or contracts of suretyship in any penal limit,** and to bind any of the Companies thereby as fully and to the same extent as if such bonds were signed by the President, sealed with the corporate seal of the applicable Company and duly attested by its Secretary, hereby ratifying and confirming all that the said Attorney(s)-in-Fact may do in the premises. Said appointment is made under and by authority of the following resolution adopted by the Board of Directors of each of the WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY and OHIO FARMERS INSURANCE COMPANY:

"Be It Resolved, that the President, any Senior Executive, any Secretary or any Fidelity & Surety Operations Executive or other Executive shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

The Attorney-in-Fact may be given full power and authority for and in the name of and on behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements of indemnity and other conditional or obligatory undertakings and any and all notices and documents canceling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed by the President and sealed and attested by the Corporate Secretary."

"Be it Further Resolved, that the signature of any such designated person and the seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signatures or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached." (Each adopted at a meeting held on February 8, 2000).

In Witness Whereof, WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY and OHIO FARMERS INSURANCE COMPANY have caused these presents to be signed by their **Vice President, Surety** and their corporate seals to be hereto affixed this **21st** day of **AUGUST** A.D., **2025** .

Corporate Seals Affixed

WESTFIELD INSURANCE COMPANY
WESTFIELD NATIONAL INSURANCE COMPANY
OHIO FARMERS INSURANCE COMPANY

By: **Gary W. Stumper,** *Vice President, Surety*

State of Ohio
County of Medina ss.:

On this **21st** day of **AUGUST** A.D., **2025** , before me personally came **Gary W. Stumper** to me known, who, being by me duly sworn, did depose and say, that he resides in **Medina, OH;** that he is **Vice President, Surety** of WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY and OHIO FARMERS INSURANCE COMPANY, the companies described in and which executed the above instrument; that he knows the seals of said Companies; that the seals affixed to said instrument are such corporate seals; that they were so affixed by order of the Boards of Directors of said Companies; and that he signed his name thereto by like order.

Notarial Seal Affixed

David A. Kotnik, Attorney at Law, *Notary Public*
My Commission Does Not Expire (Sec. 147.03 Ohio Revised Code)

State of Ohio
County of Medina ss.:

I, **Kathleen Golovan, Chief Administrative Officer & Corporate Secretary** of WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY and OHIO FARMERS INSURANCE COMPANY, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney, executed by said Companies, which is still in full force and effect; and furthermore, the resolutions of the Boards of Directors, set out in the Power of Attorney are in full force and effect.

In Witness Whereof, I have hereunto set my hand and affixed the seals of said Companies at Westfield Center, Ohio, this 10th day of March A.D., 2026

Kathleen Golovan, *Chief Administrative Officer & Corporate Secretary*

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 502538F

Application/License No. _____

ARYEH PHARMA CORP, doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
185 Hudson Street, Suite 2500, Jersey City NJ 07311 as
(Address of Applicant/Principal)
PRINCIPAL, and Westfield Insurance Company, a
(Surety Company)
corporation organized under the laws of the state of Ohio
(State of Incorporation)
and authorized to transact a general surety business in the State of
Nevada, whose address for purposes of service is
One Park Circle, Westfield Center, OH 44251-5001 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 9/18/25.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions.

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 18th day of September, 20 25.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Surety Company's Representative

Joshua Kayser, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A Retaliatory
Nevada Resident Agent

POWER NO. 2400012 01
General Power of Attorney

CERTIFIED COPY

Westfield Insurance Co.
Westfield National Insurance Co.
Ohio Farmers Insurance Co.
Westfield Center, Ohio

Know All Men by These Presents, That WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY and OHIO FARMERS INSURANCE COMPANY, corporations, hereinafter referred to individually as a "Company" and collectively as "Companies", duly organized and existing under the laws of the State of Ohio, and having their principal offices in Westfield Center, Medina County, Ohio, do by these presents make, constitute and appoint **MATTHEW BOCKLAGE, JAMIE BRIGGS, BRAD BUTTERFIELD, SEDA GUTER, BRIAN D. RUSSELL, JR., BERNARDO C. SCORZA GASPAR, ROBERT J. WOLF, BLAKE OLIVER, MARK KARR, JOSHUA KAYSER, ZACK LENZ, JOINTLY OR SEVERALLY,** of **COLUMBIA** and State of **MO** their true and lawful Attorney(s)-in-Fact, with full power and authority hereby conferred in their name(s) place and stead, to execute, acknowledge and deliver any and all bonds, recognizances, undertakings, or other instruments or contracts of suretyship **in any penal limit -**

LIMITATION: THIS POWER OF ATTORNEY CANNOT BE USED TO EXECUTE NOTE GUARANTEE, MORTGAGE DEFICIENCY, MORTGAGE GUARANTEE, OR BANK DEPOSITORY BONDS.

and to bind any of the Companies thereby as fully and to the same extent as if such bonds were signed by the President, sealed with the corporate seal of the applicable Company and duly attested by its Secretary, hereby ratifying and confirming all that the said Attorney(s)-in-Fact may do in the premises. Said appointment is made under and by authority of the following resolution adopted by the Board of Directors of each of the WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY and OHIO FARMERS INSURANCE COMPANY:

BE IT RESOLVED, that the President, any Senior Executive, any Secretary or any Fidelity & Surety Operations Executive or Assistant Vice President shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

The Attorney-in-Fact may be given full power and authority for and in the name of and on behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements of indemnity and other conditional or obligatory undertakings, and any and all notices and documents cancelling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be binding upon The Company as if signed by the President and sealed and attested by the Corporate Secretary.

"BE IT FURTHER RESOLVED, that the signature of any such designated person and the seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signatures or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached. (Each adopted at a meeting held on February 8, 2000.)

In Witness Whereof, WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY and OHIO FARMERS INSURANCE COMPANY have caused these presents to be signed by their **National Surety Leader** and **Senior Executive** and their corporate seals to be hereto affixed this **27th** day of **July**, A.D., **2022**.

Corporate Seals Affixed

WESTFIELD INSURANCE COMPANY
WESTFIELD NATIONAL INSURANCE COMPANY
OHIO FARMERS INSURANCE COMPANY

By **Gary W. Stumper,**
National Surety Leader and *Senior Executive*

State of Ohio
County of Medina ss

On this **27th** day of **July**, A.D., **2022**, before me personally came **Gary W. Stumper,** to me known, who, being by me duly sworn, did depose and say that he resides in **Medina, Ohio**, that he is **National Surety Leader** and **Senior Executive** of WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, the companies described in and which executed the above instrument; that he knows the seals of said Companies; that the seals affixed to said instrument are such corporate seals; that they were so affixed by order of the Board of Directors of said Companies, and that he signed his name thereto by like order.

Notarial Seal Affixed

By

David A. Kotnik, Attorney at Law, *Notary Public*
My Commission Does Not Expire (Sec. 147.03 Ohio Revised Code)

State of Ohio
County of Medina ss

CERTIFICATE

I, **Frank Carrino**, Secretary of the WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney, executed by said Companies, which is still in full force and effect; and furthermore, the resolutions of the Board of Directors, set out in the Power of Attorney are in full force and effect.

In Witness Whereof, I have hereunto set my hand and affixed the seal of said Company at Westfield Center, Ohio, this 18 day of, September A.D., 2025

BPOAC (03-22)

By

Frank Carrino, *Secretary*

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Vgyaan Pharmaceuticals LLC (Name changes to "Aryeh Pharma Corp")

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 23 Orchard Rd, Ste 180

City: Skillman State: NJ Zip: 08558

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 201-633-3604 Website: www.aryehpharma.com

Licensing Company Email: compliance@aryehpharma.com

Section 2: Personal Information

First: Carol Middle: Jean Last: Chao

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted]

City: New York State: NY Zip: [redacted]

Telephone: [redacted] Email: carolchao@aryehpharma.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Harvard University			09/02 - 09/07
Address	**City**	**State**	**Zip**
Massachusetts Hall	Cambridge	MA	02138
Diploma/Degree obtained, if any			
PhD Chemistry & Chemical Biology			

School Name			From - To (MM/YY – MM/YY)
Cornell University			09/98 - 05/02
Address	**City**	**State**	**Zip**
410 Thurston Avenue	Ithaca	NY	14850
Diploma/Degree obtained, if any			
BA Biology			

School Name			From - To (MM/YY – MM/YY)
Newman Smith High School			08/94 - 05/98
Address	**City**	**State**	**Zip**
2335 N Josey Ln	Carrollton	TX	75006
Diploma/Degree obtained, if any			
High School			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/19 - Present	[redacted]	New York	NY	[redacted]
03/14 - 12/19		New York	NY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Aryeh Pharma Corp			01/26 - Present	
Business Address		**City**	**State**	**Zip**
23 Orchard Road, Ste 180		Skillman	NJ	08558
Phone	**Title**		**Number of Employed Hours**	
201-633-3604	Operations Lead		180	
Description of Duties				
Leading and managing operations for Aryeh Pharma in Skillman office in preparation for distributing generic prescription pharmaceutical products in the US.				

Business Name			From - To (MM/YY – MM/YY)	
Aryeh Pharma Corp			06/25 - 01/26	
Business Address		**City**	**State**	**Zip**
185 Hudson St Ste 2500		Jersey City	NJ	07311
Phone	**Title**		**Number of Employed Hours**	
646-491-2103	Operations Lead		1400	
Description of Duties				
Leading and managing operations for Aryeh Pharma in Jersey City office in preparation for distributing generic prescription pharmaceutical products in the US.				

Business Name			From - To (MM/YY – MM/YY)	
Mylan			08/10 - 11/20	
Business Address		**City**	**State**	**Zip**
405 Lexington Ave #52		New York	NY	10174
Phone	**Title**		**Number of Employed Hours**	
917-262-2950	Director, Portfolio		20,000	
Description of Duties				
Worked at Viatris, a global pharmaceutical wholesaler, within the portfolio strategy team to support decision on which generic prescription products should be sold and distributed in the US and worldwide.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name N/A			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Carol Chao, **certify that as the designated representative for**

Aryeh Pharma Corp,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Carol Chao

Print Name (First, Last)

Carol Chao

Original Signature (electronic, copies or stamps not accepted)

01/22/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Carol Chao

Print Name (First, Last)

Carol Chao

Original Signature (electronic, copies or stamps not accepted)

1/23/2026

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of New York

I, Carol Chao, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Carol Chao

Original Signature

1/23/2026

Date

Subscribed and Sworn to before me this 23 day of JANUARY 2026

Notary Public Signature

Nafiu Zahid Shoisob
Notary Public State of New York
01SH0022453
Qualified in Bronx County
Commission Expires March 18, 20 28

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Vgyaan Pharmaceuticals LLC(Name changes "Aryeh Pharma Corp")

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 23 Orchard Rd, Ste 180

City: Skillman State: NJ Zip: 08558

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 2016333604 Website: www.aryehpharma.com

Licensing Company Email: compliance@aryehpharma.com

Section 2: Personal Information

First: Anilkumar Middle: Last: Amin

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Princeton Junction State: NJ Zip: [redacted]

Telephone: [redacted] Email: anilamin@aryehpharma.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
New Jersey Institute of Technology		09/01 - 05/03	
Address	City	State	Zip
323 Dr Martin Luther King Jr Blvd	Newark	NJ	07102
Diploma/Degree obtained, if any			
Master's Degree, Technology Management			
School Name		From - To (MM/YY – MM/YY)	
Bhavans College		05/83 - 06/88	
Address	City	State	Zip
India Munshi Nagar, Andheri West,	Mumbai	MH	400062
Diploma/Degree obtained, if any			
Bachlors in Science			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/09 - Present	[redacted]	Princeton Junction	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Aryeh Pharma Corp			06/25 - Present
Business Address	**City**	**State**	**Zip**
185 Hudson St, Ste 2500	Jersey City	NJ	07311
Phone	**Title**		
201-633-3604	Chaiman of Board		
Description of Duties			
Provides executive leadership and strategic direction for Aryeh's US generic business.			

Business Name			From - To (MM/YY – MM/YY)
Viatris (formerly Mylan)			11/20 - 09/24
Business Address	**City**	**State**	**Zip**
405 Lexington Ave #52	New York	NY	10174
Phone	**Title**		
917-262-2950	Chief Business Development Officer / Head of Global Business Development		
Description of Duties			
Lead company's efforts to identify and execute opportunities, strategic partnerships, joint ventures, alliances and acquisitions			

Business Name			From - To (MM/YY – MM/YY)
Mylan			12/13 - 11/20
Business Address	**City**	**State**	**Zip**
405 Lexington Ave #52	New York	NY	10174
Phone	**Title**		
917-262-2950	Head of Global Business Development / VP, Global Portfolio Business Development		
Description of Duties			
Identify and execute BD opportunities to accelerate Mylans's business growth			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Anilkumar Amin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/23/2026

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Mercer

I, ANILKUMAR AMIN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/23/26

Date

Subscribed and Sworn to before me this 23 day of January 2026

Notary Public Signature

TIMOTHY MCOMAW
NOTARY PUBLIC
STATE OF NEW JERSEY
ID [redacted]
MY COMMISSION EXPIRES 06/08/2027

(Seal)

ARYEH
PHARMACEUTICALS

Aryeh Pharma Corp.

Employees

1. Name: Anilkumar Amin
   Title: Chairman of Board
2. Name: Carol Chao
   Title: Operations Lead

inquiries@aryehpharma.com

(201) 633-3604

Aryeh Pharmaceuticals
185 Hudson Street
Suite 2500
Jersey City, NJ 07311

4U

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Aurora Pharmaceutical, Inc.

Physical Address: 1196 Hwy 3 South

City: Northfield State: MN Zip: 55057

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 507-645-3225 Website: www.aurorapharmaceutical.com

Name of Designated Representative (DR): Michael Strobel

Licensing Company Email: license@aurorapharmaceutical.com DR Email: mstrobel@aurorapharmaceutical.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Midwest Vet Supply
Address: 2835 Coleman St City: Las Vegas State: NV Zip: 89032

Name: MWI Animal Health
Address: PO Box 247 City: Thorofare State: NJ Zip: 08086

Name: Veterinary Provisions
Address: 11910 Hwy 3 S City: Northfield State: MN Zip: 55057

Name: Precision Logistics
Address: PO Box 808 City: Loveland State: CO Zip: 80538

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota
Parent Company (if any): n/a
Corporation/Organization Name: Aurora Pharmaceutical, Inc.
Mailing Address: 11910 Hwy 3 S
City: Northfield State: MN Zip: 55057
Telephone: 507-645-3225 Email: license@auroraphramaceutical.com
Contact Person Name: Deryl Kukacka

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Aurora Pharmaceutical, Inc.

Facility Name

Deryl Kukacka

Print Name of Authorized Person Submitting Application

Deryl Kukacka

Original signature of Authorized Person (copies or stamps not accepted)

9-30-25

Date

Board Use Only	Date Received: _____	Amount: _____

Drug Establishments Current Registration Site

New Search (index.cfm)

Search Results for **Aurora Pharmaceutical, Inc.**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Aurora Pharmaceutical, Inc., DBA Jefferson Labs	3008276347	832848639	MANUFACTURE;	1196 Hwy 3 South, Northfield, Minnesota (MN) 55057, United States (USA)	12/31/2026

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Monday, Feb 2, 2026

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Aurora Pharmaceutical, Inc
Ownership

Name	Title	Ownership	Work	Work	DOB
Michael A Strobel	President/CEO	50%	1196 Highway 3 S Northfield MN 55057	507-650-7309	[redacted]
Mark G Werner	Vice President	50%	1196 Highway 3 S Northfield MN 55057	507-650-7308	

Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Aurora Pharmaceutical, Inc.
Date Filed:	12/20/2018
File Number:	1056094600050
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota

This certificate has been issued on: 09/18/2025

Steve Simon
Secretary of State
State of Minnesota

State of Minnesota

Minnesota Board of Pharmacy
St. Paul, MN 55102

HAS ISSUED

Wholesaler/Distributor
License Number 364122

To: Aurora Pharmaceutical, Inc.
1196 Hwy 3 S
Northfield, MN 55057

EFFECTIVE DATE
6/1/25

EXPIRATION DATE
5/31/26

State of Minnesota

Minnesota Board of Pharmacy
St. Paul, MN 55102

HAS ISSUED

Wholesaler/Distributor
License Number 364122

To: Aurora Pharmaceutical, Inc.

EFFECTIVE DATE
6/1/25

EXPIRATION DATE
5/31/26

State of Minnesota

Minnesota Board of Pharmacy
St. Paul, MN 55102

HAS ISSUED

Manufacturer
License Number 461506

To: Aurora Pharmaceutical, Inc.
1196 Hwy 3 S
Northfield, MN 55057

EFFECTIVE DATE
6/1/25

EXPIRATION DATE
5/31/26

State of Minnesota

Minnesota Board of Pharmacy
St. Paul, MN 55102

HAS ISSUED

Manufacturer
License Number 461506

To: Aurora Pharmaceutical, Inc.

EFFECTIVE DATE
6/1/25

EXPIRATION DATE
5/31/26

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. CBE1063353

Application/License No. _____

Aurora Pharmaceutical Inc., doing or intending to do
Applicant/Principal
business as a pharmaceutical wholesaler, whose address for purposes of service is

1196 Highway 3 S, Northfield, MN 55057-3009, as
Address of Applicant/Principal
PRINCIPAL, and The Cincinnati Insurance Company, a
Surety Company
corporation organized under the laws of the state of Ohio
State of Incorporation
and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is

6200 S Gilmore Rd, Fairfield, OH 45014-5141 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ($ 100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on

September 24, 2025.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 29th day of September, 20 25.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Matthew M Sewich, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

THE CINCINNATI INSURANCE COMPANY
THE CINCINNATI CASUALTY COMPANY

Fairfield, Ohio CBE1063353

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That THE CINCINNATI INSURANCE COMPANY and THE CINCINNATI CASUALTY COMPANY, corporations organized under the laws of the State of Ohio, and having their principal offices in the City of Fairfield, Ohio (herein collectively called the "Companies"), do hereby constitute and appoint

Matthew M Sewich

of NORTHFIELD MN
their true and legal Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign, execute, seal and deliver on behalf of the Companies as Surety, any and all bonds, policies, undertakings or other like instruments, as follows:

One Hundred Thousand Dollars $ 100,000.00

This appointment is made under and by authority of the following resolutions adopted by the Boards of Directors of The Cincinnati Insurance Company and The Cincinnati Casualty Company, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the President or any Senior Vice President be hereby authorized, and empowered to appoint Attorneys-in-Fact of the Company to execute any and all bonds, policies, undertakings, or other like instruments on behalf of the Corporation, and may authorize any officer or any such Attorney-in-Fact to affix the corporate seal; and may with or without cause modify or revoke any such appointment or authority. Any such writings so executed by such Attorneys-in-Fact shall be binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company.

RESOLVED, that the signature of the President or any Senior Vice President and the seal of the Company may be affixed by facsimile on any power of attorney granted, and the signature of the Secretary or Assistant Vice-President and the Seal of the Company may be affixed by facsimile to any certificate of any such power and any such power of certificate bearing such facsimile signature and seal shall be valid and binding on the Company. Any such power so executed and sealed and certified by certificate so executed and sealed shall, with respect to any bond or undertaking to which it is attached, continue to be valid and binding on the Company.

IN WITNESS WHEREOF, the Companies have caused these presents to be sealed with their corporate seals, duly attested by their President or any Senior Vice President this 16th day of March, 2021.

THE CINCINNATI INSURANCE COMPANY
THE CINCINNATI CASUALTY COMPANY

Stephen A. Ventre

STATE OF OHIO)SS:
COUNTY OF BUTLER)

On this 16th day of March, 2021 before me came the above-named President or Senior Vice President of The Cincinnati Insurance Company and The Cincinnati Casualty Company, to me personally known to be the officer described herein, and acknowledged that the seals affixed to the preceding instrument are the corporate seals of said Companies and the corporate seals and the signature of the officer were duly affixed and subscribed to said instrument by the authority and direction of said corporations.

Keith Collett, Attorney at Law
Notary Public – State of Ohio
My commission has no expiration date.
Section 147.03 O.R.C.

I, the undersigned Secretary or Assistant Vice-President of The Cincinnati Insurance Company and The Cincinnati Casualty Company, hereby certify that the above is the Original Power of Attorney issued by said Companies, and do hereby further certify that the said Power of Attorney is still in full force and effect.

Given under my hand and seal of said Companies at Fairfield, Ohio, this 29th day of September, 2025

BN-1457 (3/21)

A OR B AND C MUST BE COMPLETED

A. FOR ACKNOWLEDGEMENT OF Individual, Partnership, Limited Liability Company or Limited Liability Partnership
(Note: If partnership all signatures are required to be notarized. Please copy the page if necessary.)

STATE OF _____)
) ss
COUNTY OF _____)

On this_____day of_____personally came _____

to me well known to be the identical person(s) described in and who executed the foregoing bond and he/she/they acknowledged the same to be his/her/their own free act and deed.

(SEAL)

Notary Public, _____ County, _____

My Commission Expires _____

B. FOR ACKNOWLEDGEMENT of Corporate Contractor

STATE OF MINNESOTA)
) ss
COUNTY OF RICE)

On this 3rd day of OCTOBER, 2025 personally came MICHAEL STROBEL

who being by me duly sworn, did say that he/she is PRESIDENT

of AURORA PHARMACEUTICAL, INC, a C-CORP

corporation; and that said instrument was executed in behalf of the corporation by authority of its Board of Directors; that he/she acknowledged said instrument to be the free act and deed of the corporation.

(SEAL)

Heather C Cole
Notary Public
Minnesota
My Commission Expires January 31, 2028

Heather C. Cole

Notary Public, RICE County, MN

My Commission Expires January 31, 2028

PART C MUST BE COMPLETED BY THE SURETY COMPANY

C. FOR ACKNOWLEDGEMENT of Corporate Surety

STATE OF MINNESOTA)
) ss
COUNTY OF RICE)

On this 2ND day of September, 2025 personally came MATTHEW SEWICH

and _____ to me personally known, who being by me duly sworn, did say that he/she is the attorney in fact of CINCINNATI INSURANCE, the corporation whose name is affixed to the foregoing instrument; that the seal affixed to the foregoing instrument is the corporate seal of the said corporation; and that said instrument was executed in behalf of said corporation by authority of its board of directors and said MATTHEW SEWICH acknowledged that he/she executed said instrument as attorney in fact as the free act and deed of said corporation.

(SEAL)

Heather C Cole
Notary Public
Minnesota
My Commission Expires January 31, 2028

Heather C. Cole

Notary Public, RICE County, MN

My Commission Expires January 31, 2028

This material can be made available in different forms, such as large print, Braille or on audio.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Aurora Pharmaceutical, Inc

Pharmacy/Wholesaler License # (if applicable) in process

Physical Address 1196 Hwy 3S

City Northfield State MN Zip 55057

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 507-645-3225 Website _____

Licensing Company Email license@auroraPharmaceutical.com

Section 2: Personal Information

First Michael Middle A Last Strobel

Alias(es, nicknames, name changes, etc.) n/a

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Northfield State MN Zip [redacted]

Telephone [redacted] Email MStrobel@auroraPharmaceutical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Minnesota		1976-1980	
Address	City	State	Zip
2053 Buford Ave	St. Paul	MN	55108
Diploma/Degree obtained, if any			
DVM			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1991- Curre	[redacted]	Northfield	MN	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Aurora Pharmaceutical, Inc			12/18 - Present
Business Address	**City**	**State**	**Zip**
1196 Hwy 3 South	Northfield	MN	55057
Phone	**Title**	**Number of Employed Hours**	
507-645-3225	President/CEO	Full-time, 6+ years	
Description of Duties			
oversee all operations of business			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	n/a	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

n/a

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Strobel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-8-26

Date

Please have this section completed in the presence of a Notary Public.

State of Minnesota, ss. County of Rice

I, Michael Strobel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-8-26

Date

Subscribed and Sworn to before me this 8th day of January 2026.

Dawn Miller

Notary Public Signature

Dawn Marie Miller
Notary Public
Minnesota
My Commission Expires January 31, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Aurora Pharmaceutical, Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) in process

Physical Address 1196 Hwy 3 South

City Northfield State MN Zip 55057

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 507-645-3225 Website _____

Licensing Company Email license@aurorapharmaceutical.com

Section 2: Personal Information

First Michael Middle A Last Strobel

Alias(es, nick[redacted]s, etc.) n/a

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Northfield State MN Zip [redacted]

Telephone _____ Email MStrobel@aurorapharmaceutical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of MN		1976 - 1980	
Address	City	State	Zip
2053 Buford Ave	St. Paul	MN	55108
Diploma/Degree obtained, if any			
DVM			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1991 - Curre	[redacted]	Northfield	MN	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Aurora Pharmaceutical, Inc			12/2018 - Current	
Business Address		City	State	Zip
11916 Hwy 3 S		Northfield	MN	55057
Phone	Title			
507-645-3225	President + CEO			
Description of Duties				
over see general operations				

Business Name			From - To (MM/YY – MM/YY)	
Aurora Pharmaceutical, LLC			6/2009 - 12/2018	
Business Address		City	State	Zip
11916 Hwy 3 S		Northfield	MN	55057
Phone	Title			
507-645-3225	President/CEO			
Description of Duties				
oversee general operations				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		n/a
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted) Date

I, Michael Strobel, **certify that as the designated representative for** Aurora Pharmaceutical, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Michael Strobel
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-8-2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Strobel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-8-2026

Date

Please have this section completed in the presence of a Notary Public.

State of Minnesota, ss. County of Rice

I, Michael Strobel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-8-26

Date

Subscribed and Sworn to before me this 8th day of January 2026

Notary Public Signature

Dawn Marie Miller
Notary Public
Minnesota
My Commission Expires January 31, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Aurora Pharmaceutical, Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) in process

Physical Address 1140 Hwy 3 S

City Northfield State MN Zip 55057

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 507-645-3225 Website _____

Licensing Company Email license@auroraPharmaceutical.com

Section 2: Personal Information

First Mark Middle L. Last Werner

Alias(es, nicknames, name changes, etc.) n/a

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Northfield State MN Zip [redacted]

Telephone _____ Email mwerner@auroraPharmaceutical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: University of Minnesota		From - To (MM/YY – MM/YY) 1972 - 1976	
Address: 2053 Buford Ave	City: St. Paul	State: MN	Zip: 55108
Diploma/Degree obtained, if any: DVM			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY) 1980 - Current	[redacted]	City: Northfield	State: MN	[redacted]
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Aurora Pharmaceutical, Inc			2018 - Current	
Business Address		**City**	**State**	**Zip**
1196 Hwy 3 S		Northfield	MN	55057
Phone	**Title**			
507-645-3225	Vice President / Secretary			
Description of Duties				
oversee general operations				

Business Name			From - To (MM/YY – MM/YY)	
Veterinary Provisions			1980 - Current	
Business Address		**City**	**State**	**Zip**
1200 Cannon Rd		Northfield	MN	55057
Phone	**Title**			
507-645 3225	Co-owner			
Description of Duties				
oversee general operations				

Business Name			From - To (MM/YY – MM/YY)	
Cannon Valley Vet			1980 – Current	
Business Address		**City**	**State**	**Zip**
1194 Hwy 3 S		Northfield	MN	55057
Phone	**Title**			
952-645-3225	Vet - retired, co-owner currently			
Description of Duties				
Retired				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

11/19/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Werner

Print Name (First, Last)

Mark G Werner

Original Signature (electronic, copies or stamps not accepted)

11/19/25

Date

Please have this section completed in the presence of a Notary Public.

State of Minnesota, ss. County of Rice

I, Mark Werner, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Mark G Werner

Original Signature

11-20-25

Date

Subscribed and Sworn to before me this 20 day of November 2025

Dawn Miller

Notary Public Signature

Dawn Marie Miller
Notary Public
Minnesota
My Commission Expires January 31, 2027

(Seal)

NAME	EXTENSION
AURORA Rev: 1/16/2026	
Alina Garbar	3221
Alli Eotvos (HR)	3261
Aurora Front Desk	7200
Aurora Shipping	3206
Brittany Peterson	7254
Chad Rossow	3216
Curtis Holland	3234
Dan Lauer	3231
Danielle Schultz	3222
Dave Oliver	3244
Dave Ostman	3238
Dave Skroch	3220
Dawn Miller	7313
Denyl Kukacka	3200
Don Sohre	3247
Edward Malnar	3218
Eric Randall	7203
Gracie Storch	3254
Haley Johnson	3255
Jared Olson	3232
Jay Paquette	3250
Kasey Hoey	3236
Katie Noland	3228
Kelsie Flanagan	7209
Kenzie Mjoen	3240
Kevin Bell	3219
Larry Bohlman	3227
Lori Happel-Jarratt	7207
Lori Westerhouse	3241
Mallory Fricke	3229
Melissa Lindsay	3233
Michelle Schumacher (HR)	3251
Mike Gill	3224
Mike Strobel	7309
Mike Trelstad	3217
Mike Wille	3248
Nick Warren	3260
Patrick Wadzinski	3243
Peggy Anne Hawkins	7205
Randy Ernste	7256
Rich Mihalik	7253
Ryan McNamara	3211
Sarah Trnka	3239
Sheila Peterson	7319
Warehouse/ Mike Marquardt	3206

4V

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03013	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Avadel CNS Pharmaceuticals, LLC

Physical Address: 16640 Chesterfield Grove Rd, Suite 200

City: Chesterfield State: MO Zip: 63005

Mailing Address (if different from physical address): 16640 Chesterfield Grove Rd., Suite 200

City: Chesterfield State: Missouri Zip: 63005

Telephone: 636-449-1830 Website: www.avadel.com

Name of Designated Representative (DR): Heather Kruchowski

Licensing Company Email: license@avadel.com DR Email: hkruchowski@avadel.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☒ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Pharmacies, Specialty Distributors		☒ Others: Virtual manufacturer

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See attached customer list

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Avadel US Holdings, LLC

Corporation/Organization Name: Avadel CNS Pharmaceuticals, LLC

Mailing Address: 16640 Chesterfield Grove Rd., Suite 200

City: Chesterfield State: Missouri Zip: 63005

Telephone: 636-449-1830 Email: license@avadel.com

Contact Person Name: Heather Kruchowski

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Avadel CNS Pharmaceuticals, LLC
Facility Name

Heather Kruchowski
Print Name of Authorized Person Submitting Application

Heather Kruchowski
Original signature of Authorized Person (copies or stamps not accepted)

17 Feb 2026
Date

Board Use Only	Date Received: 3/4/26	Amount: $1000 Ch 5365

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (index.cfm)

Search Results for **avadel cns**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Avadel CNS Pharmaceuticals, LLC	3012841301	117441358	MANUFACTURE;	16640 Chesterfield Grove Rd Ste 200, Chesterfield, Missouri (MO) 63005, United States (USA)	12/31/2026

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Sunday, Mar 1, 2026

Return to Drug Firm Annual Registration Status Home Page (default.cfm)



Description of Operations

Avadel CNS Pharmaceuticals, LLC ("Avadel") is a Virtual Manufacturer. Avadel's products are manufactured by a Contract Manufacturer and distributed to Specialty Distributors and Specialty Pharmacies by a 3PL, Eversana Life Sciences, who is licensed to distribute into the state.

Avadel's product is listed as a Schedule CIII Non-Narcotic. As a virtual manufacturer who does not handle pharmaceuticals at any time, either by physically manufacturing or distributing drugs, Avadel is exempt from obtaining a DEA registration.

Avadel CNS uses the following to produce their product:

Contract Manufacturers

Meribel Pharma Pessac
11 Avenue Gustave Eiffel Parc Industriel, Bersol 1
Pessac, France 33608
+46 8 602 52 00
FDA Establishment Identification Number: 3011269473

Catalant Pharma Solutions
1100 Enterprise Dr
Winchester, KY 40391-9668
859-745-2200
FDA Establishment Identification Number: 1000122400

Contract Packager

Sharp Corporation
7570 Industrial Park Way
Macungie, PA 18062
FDA Establishment Identification Number: 3009566827

At no time does the contract manufacturer own Avadel's products, contract with Avadel's customers, invoice or sell an Avadel product.



Third Party Logistics Information

For distribution into the commercial supply channels, Eversana Life Sciences, LLC acts as Avadel's Third Party Logistics (3PL) provider to manage the storage and distribution of Avadel's product to Specialty Pharmacies and Distributors throughout the United States. Eversana Life Sciences, LLC's address is:

Eversana Life Sciences, LLC
4580 Mendenhall Rd.
Memphis, TN 38141
(901) 795-7117
DEA: RD0205333

Labeler Code:

13551

Avadel's hours of operation are 8:00 am – 5:00pm CST, Monday through Friday

Ownership Information

Avadel CNS Pharmaceuticals, LLC ("Avadel CNS") is a limited liability company.
Avadel CNS is 100% owned by parent company Avadel US Holdings, LLC ("Avadel US").

Company Information

Avadel CNS Pharmaceuticals, LLC
16640 Chesterfield Grove Rd.#200
Chesterfield, MO 63005
(636) 449-1830
https://www.avadel.com/
license@avadel.com

FEIN: 84-4723949
State of Formation: Delaware
Date Incorporated: 12/4/2019
File Number: 7734658

Blair Jackson, President
16640 Chesterfield Grove Rd., Suite 200
Chesterfield, MO 63005
Ownership: 0%

Joshua Reed, Treasurer
16640 Chesterfield Grove Rd., Suite 200
Chesterfield, MO 63005
Ownership: 0%

Anne Giovanoni, Secretary
16640 Chesterfield Grove Rd., Suite 200
Chesterfield, MO 63005
Ownership: 0%

Designated Representative

Heather Kruchowski, Vice President, Quality
16640 Chesterfield Grove Rd., Suite 200
Chesterfield, MO 63005
Ownership: 0%

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THAT "AVADEL CNS PHARMACEUTICALS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE NOT HAVING BEEN CANCELLED OR REVOKED SO FAR AS THE RECORDS OF THIS OFFICE SHOW AND IS DULY AUTHORIZED TO TRANSACT BUSINESS.

THE FOLLOWING DOCUMENTS HAVE BEEN FILED:

CERTIFICATE OF FORMATION, FILED THE FOURTH DAY OF DECEMBER, A.D. 2019, AT 3:10 O`CLOCK P.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE AFORESAID CERTIFICATES ARE THE ONLY CERTIFICATES ON RECORD OF THE AFORESAID LIMITED LIABILITY COMPANY, "AVADEL CNS PHARMACEUTICALS, LLC".

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "AVADEL CNS PHARMACEUTICALS, LLC" WAS FORMED ON THE FOURTH DAY OF DECEMBER, A.D. 2019.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

7734658 8310

SR# 20260663798

Authentication: 203135315

Date: 02-19-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Missouri

Division of Professional Registration

Drug Distributor

Wholesale Drug Distributor

VALID THROUGH OCTOBER 31, 2027
ORIGINAL CERTIFICATE/LICENSE NO. 2021000490
AVADEL CNS PHARMACEUTICALS LLC
AVADEL CNS PHARMACEUTICALS LLC
16640 CHESTERFIELD GROVE RD STE200
CHESTERFIELD MO 63005
UNITED STATES

State of Missouri

Missouri Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy

Drug Distributor

Wholesale Drug Distributor

VALID THROUGH OCTOBER 31, 2027
ORIGINAL CERTIFICATE/LICENSE NO. 2021000490
Heather Kruchowski

AVADEL CNS PHARMACEUTICALS LLC
AVADEL CNS PHARMACEUTICALS LLC
16640 CHESTERFIELD GROVE RD STE200
CHESTERFIELD MO 63005
UNITED STATES

EXECUTIVE DIRECTOR

DIVISION DIRECTOR

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	08-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	08-07-2025

EVERSANA LIFE SCIENCE SERVICES, LLC
4580 S MENDENHALL RD
MEMPHIS, TN 381416700

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	08-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

Hartford Fire Insurance Company



Date: September 20, 2022 **Agency Code:** 83 553702

AON RISK SERVICES CENTRAL INC
200 E RANDOLPH ST 12TH FLR
CHICAGO IL, 60601

OBLIGEE:
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
RENO, NV 89521

Attn: Bond Department

Insured / Principal: AVADEL CNS PHARMACEUTICALS LLC
Policy / Bond #: 83BSBIP7624
Account Name/Number: AVADEL CNS 83M100772805
Policy Term: March 24, 2022 - March 24, 2023
Type of Policy: Surety - License & Permit
Billing Term: Annual
Billing Type: Agency Bill
Transaction Type: Reinstatement
Transaction Effective Date: March 24, 2022
Bond Limit: $100,000

Agent's Advice of Premium for Fidelity and Surety Bonds

Premium	Commission %	Commission Amount
$ 1,000	35.00 %	$ 350.00

COMMENTS:

Premium will be included in your usual Agency Accounting statement or Direct Bill notification.
If you have any questions regarding this transaction, please contact your Hartford Bond Center.

Date: September 20, 2022

Agency Code: 83 553702

Agency Information

AON RISK SERVICES CENTRAL INC
200 E RANDOLPH ST 12TH FLR
CHICAGO, IL 60601

Obligee Information

OBLIGEE:
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206 RENO, NV 89521

Insured / Principal: AVADEL CNS PHARMACEUTICALS LLC
Policy / Bond #: 83BSBIP7624
Account Name/Number: AVADEL CNS 83M100772805
Policy Term: March 24, 2022 - March 24, 2023
Type of Policy: Surety - License & Permit
Billing Term: Annual
Billing Type[1]: Agency Bill
Transaction Type: Reinstatement
Transaction Effective Date: March 24, 2022
Bond Limit: $100,000

Premium
$1,000

State Tax / Surcharge if applicable
$ /

This record is a billing advice only.

If you have any questions regarding this transaction, please contact your agent or The Hartford's Billing Department.

[1] **Billing Type:**

- Agency Bill – Premium will be billed through your Agent.
- Direct Bill – You will receive a billing statement directly from The Hartford.
    - Credit Card – Premium noted on this statement has been submitted to your Credit Card for this term only and it will be reflected in your Direct Bill notification you receive from The Hartford.

September 20, 2022

THE HARTFORD

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206

RENO, NV 89521

REINSTATEMENT NOTICE

Re: Bond Number: 83BSBIP7624

Principal: AVADEL CNS PHARMACEUTICALS LLC

Bond Type: Tax Payment - Other than specifically classified

On 8/19/22 **, we sent you Notice of Cancellation/Non-Renewal on the above bond to be effective**

☐ _____ **days following receipt**

☒ 9/28/22

Please disregard our Notice of Cancellation/Non-Renewal and consider this bond in full force and effect without interruption.

We are sorry for any inconvenience this may have caused your office.

Hartford Fire Insurance Company

By: Jessica Ciccone

Jessica Ciccone, Attorney-in-fact

HARTFORD FIRE INSURANCE CO. INCORPORATED 1810

CC: AVADEL CNS PHARMACEUTICALS LLC
16640 Chesterfield Grove Road, Suite 200

Chesterfield,MO 63005

CC: AON RISK SERVICES CENTRAL INC
200 E RANDOLPH ST 12TH FLR
CHICAGO, IL 60601

AGT: Please forward a copy of this reinstatement notice to the insured. Thank You.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 83BSBIP7624

Application/License No. _____

AVADEL CNS PHARMACEUTICALS LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 16640 Chesterfield Grove Road, Suite 200 Chesterfield, MO 63005 (Address of Applicant/Principal), as PRINCIPAL, and HARTFORD FIRE INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Hartford Plaza Hartford, CT 06155 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 24, 2021 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 24th day of March, 2021.

APPLICANT/PRINCIPAL
AVADEL CNS PHARMACEUTICALS LLC

COMPANY

SURETY
HARTFORD FIRE INSURANCE COMPANY

Authorized Representative

Surety Company's Representative

Derek J. Elston, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Paul M. Allen

Witness Rachel Fore

Countersigned by:

Nevada Resident Agent N/A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Avadel CNS Pharmaceuticals, LLC

Pharmacy/Wholesaler License # (if applicable) 03013

Physical Address 16640 Chesterfield Grove Rd, Suite 200

City Chesterfield State MO Zip 63005

Mailing Address (if different from physical address)

City 16640 Chesterfield Grove Rd., Suite 200 State Missouri Zip 63005

Telephone 636-449-1830 Website www.avadel.com

Licensing Company Email license@avadel.com

Section 2: Personal Information

First Heather Middle Rene Last Kruchowski

Alias(es, nicknames, name changes, etc.) Heather Rene Rulo, Heather Rene Wuebbels

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 16640 Chesterfield Grove Rd., Suite 200

City Chesterfield State Missouri Zip 63005

Telephone [redacted] Email hkruchowski@avadel.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Lindenwood University		09/04 - 12/05	
Address	**City**	**State**	**Zip**
209 S Kingshighway St	St. Charles	MO	63301
Diploma/Degree obtained, if any			
Masters of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Southern Illinois University		09/94 - 12/98	
Address	**City**	**State**	**Zip**
1 Hairpin Dr	Edwardsville	IL	62026
Diploma/Degree obtained, if any			
Bachelor of Science-Biology			

School Name		From - To (MM/YY – MM/YY)	
Civic Memorial High School		09/90 - 12/93	
Address	**City**	**State**	**Zip**
200 School Street	Bethalto	IL	62010
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/25 - Present	[redacted]	O'Fallon	MO	[redacted]
From - To (MM/YY – MM/YY)		City	State	
05/06 - 05/25		O'Fallon	MO	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Avadel CNS Pharmaceuticals, LLC			05/18 - Present	
Business Address		City	State	Zip
16640 Chesterfield Grove Rd, Suite 200		Charlestown	MO	63005
Phone	Title		Number of Employed Hours	
636-449-1839	Sr. Director, Quality		40 hours a week	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Avadel Pharmaceuticals			03/13 - 05/18	
Business Address		City	State	Zip
16640 Chesterfield Grove Rd, Suite 200		Charlestown	MO	63005
Phone	Title		Number of Employed Hours	
636-449-1839	Director, Quality Operations		40 hours a week	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Nesher Pharmaceuticals			08/11 - 03/13	
Business Address		City	State	Zip
13910 St Charles Rock Rd		Bridgeton	MO	63044
Phone	Title		Number of Employed Hours	
	Consent Decree Integrator/Product Planning		40 hours a week	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Heather R. Kruchowski, BS, MBA

[redacted]

An insightful and results driven leader accomplished at Project Management through initiating and implementing changes, building teams and developing processes and systems to benefit the company and shareholders while ensuring global compliance. Strong relationship builder who thinks strategically, communicates effectively, and works collaboratively across the organization to influence decisions. Works as a change agent to bring cohesive execution of company vision while providing the most productive and efficient processes without sacrificing quality or compliance.

- Led a global team inclusive of internal and third-party contributors to harmonize the corporate quality management system across all global sites to ensure compliance with both EU and US GMP standards.
- Implemented full suite of SAAS-based quality system implementation inclusive of all key systems across a global organization in four months.
- First Quality employee for a start-up pharmaceutical company with no commercialized products and grew that organization to include a full staff supporting multiple commercialized products, internal development work and external acquisition and due diligence.
- Experience working with vast variety of product lines inclusive of API manufacturing, solid and liquid oral dose drugs, ointments, parenteral injections, Class II medical device, and combination drug/device nasal spray.
- Full confidence and experience working with US FDA and other regulatory parties through inspection management and execution, response development and remediation follow-through. Experienced with significant compliance remediation for organizations with no systems to those with poor systems including work post 483 and Consent Decree.
- Excellent team management skills for direct reports and outside partners and contributors within a global setting bridging many time zone and cultural differences. Proven record in development of key contributors through mentoring and leadership through demonstration.

PROFESSIONAL EXPERIENCE

Senior Director, Quality US Operations – *May 2018 – Present*

Director, Quality Operations – *Mar 2013 – May 2018*

Avadel Pharmaceuticals (formerly Eclat Pharmaceuticals)

- Head of Quality responsible for the direction of all quality activities associated with US Operations; including establishing, implementing and maintaining systems and / or services to assure product quality and full compliance to cGMP and other regulatory requirements.
- Provide leadership in sustaining GMP compliance within all departments integrating risk- and scientific-based Quality Management Systems.
- Evaluate all systems, procedures, and metrics to drive consistency and promote best practices and integration within the organization and global partners.
- Host all third-party and regulatory audits, develop audit responses, and support timely completion of remediation or commitments.
- Directs the quality oversight of contract manufacturing/packaging facilities and service providers inclusive of decision making affecting routine production, validation, and product development.
- Ensures the system in place for non-conformances, deviations, customer complaints and other quality related issues is compliant, issues investigated in a timely manner and corrective/preventive actions are assigned and completed as required.
- Ensure that all issues (such as Field Alerts, Recalls, or other market actions) are reported to the agency as required within predefined time limits.
- Directs and manages all aspects of Quality Systems, Quality Operations, Validation, and Vendor Management.

Consent Decree Integrator & New Product Planning –*Aug 2011 – Mar 2013*
Nesher Pharmaceuticals (formerly KV Pharmaceuticals)

- Ensured all Consent Decree obligations and commitments are met according to specified deliverable timelines.
- Provided leadership in sustaining CD compliance within all departments integrating all CD and Quality Management Systems. Under my lead, we were successfully able to reduce the required amount of third party GMP oversight and auditing by 75% resulting in budgetary savings in excess of 10 million dollars.
- Led task teams for process simplification to strengthen compliance and increase efficiency.
- Fostered vertical and horizontal integration of systems, initiatives, and changes within the Nesher Organization.
- Developed and implemented plans for new products introduction.
- Assisted in evaluating systems, procedures to drive consistency and promote best practices and integration within the organization.
- Provided support during third-party/regulatory audits, assist in the development of audit responses, and support timely completion of third-party audit commitments.
- Direct Quality Oversight in the development of new and the reintroduction of pre-Consent Decree products.

Quality Assurance Manager – *Aug 2010 – Aug 2011*

- Responsible for the quality oversight of multiple manufacturing/packaging facilities including direct management of a multi-tiered organization supporting 24-hour operations involving 150 personnel.
- Oversight of and responsibility for Quality issues, decisions affecting routine production, and the coordination of cGMP training within the plant.
- Ensured Non-conformances, Deviations, Customer Complaints, and other quality related issues were investigated in a timely manner and corrective/preventative actions are assigned and completed as required.
- Ensured all batches released to market or for further processing complied with all internal and external requirements.

TrackWise Coordinator - *Dec 2008 – Jul 2009, Apr 2010 – Aug 2010*

- Managed projects in the TrackWise electronic process management system. Project types include Change Control, Nonconformance, Planned Deviation, Investigations and CAPA.
- Ensured timely completion of investigations and corrective actions.
- Performed final review of investigations and corrective actions to assess for complete identification of root cause and effective implementation of corrective actions.
- Developed and reported systemic metrics to executive management.
- Developed a Quality System Dashboard reporting quality system status as compared to defined cycle time targets.

Quality Assurance Supervisor – *Apr 2007 - Dec 2008, Jul 2009 – Apr 2010*

- Managed a group of four direct reports responsible for performing floor level quality assurance checks of compression start ups, packaging line start ups, in-process AQL analysis, Annual Product Inspections.
- Primary quality contact for the off-shift operations.
- Served as the quality representative for the SWAT team to improve line clearance practices during product changeover of packaging lines.
- Chaired the corporate objective project for FY07 to reduce the number of repeat NCRs.
- Served as the primary FDA inspection coordinator.

Senior Quality Assurance Specialist *Jun 2004 - Apr 2007*
Sigma-Aldrich Corporation (Currently Millipore-Sigma)

- Served as the primary FDA contact during on-site inspection.
- Designed and implemented a Management of Change program supporting ISO, cGMP, and PSM business units.
- Designed and implemented a CAPA program supporting ISO and cGMP business units.
- Served as the project manager in the implementation of a Business Process Management System. Led a cross-functional team consisting of operations, quality control, process development and quality assurance.
- Developed and implemented a departmental training program to ensure that all employees training requirements are documented and any deficiencies identified and addressed.

Quality Assurance Specialist – *Mar 2001 - Jun 2004*

- Hosted all customer audits including the management of the inspection process through the receipt, response and closure of any observations.
- Developed and conducted general cGMP training for all personnel directly and indirectly involved with cGMP operations. Presented training material in multiple formats from one-on-one, small groups, and large conference centers.
- Reviewed and releasee raw materials and components for use in cGMP processes.
- Wrote and reviewed technical documents describing company policy and department procedure.
- Reviewed and approved Certificates of Analysis for cGMP material prior to the release and distribution of product to the customer.
- Answered general quality questionnaires and animal origin and risk questionnaires.
- Led and participated in many process improvement exercises to increase the efficiency and productivity of the company, to ensure the safety and quality of the product, and to control systems and coordinate their activities to ensure a uniform, seamless interaction.

Chemist I – *Jan 1999 - Mar 2001*

- Analyzed samples for purity, functionality, and accuracy in the cGMP Tissue Culture and Microbiology quality control lab.
- Coordinated the evaluation of raw sera for use in cGMP manufacturing including: specification review, assignment of tests, review of results and vendor documents, and release of material for general plant use.
- Coordinated all testing performed by outside contract laboratories.
- Reviewed the work of coworkers to ensure proper cGMP compliance and product processes and specifications.
- Served as chairperson for facility Safety committee.

▪ EDUCATION

- **Master of Business Administration** – Lindenwood University, St. Charles, Missouri
- **Bachelors of Science, Biology** – Southern Illinois University, Edwardsville, Illinois

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
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Business Name			From - To (MM/YY – MM/YY)	
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Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		x
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A
AKL 17 Feb 2026

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Heather Kruchowski, **certify that as the designated representative for**

Avadel CNS Pharmaceuticals, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. HRK I am at least 21 years of age;
3. HRK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. HRK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. HRK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. HRK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. HRK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Heather Kruchowski
Print Name (First, Last)

Heather Kruchowski
Original Signature (electronic, copies or stamps not accepted)

17 Feb 2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Heather Kruchowski
Print Name (First, Last)

Heather Kruchowski
Original Signature (electronic, copies or stamps not accepted)

17 Feb 2026
Date

Please have this section completed in the presence of a Notary Public.

State of Missouri, ss. County of Saint Louis City

I, Heather Kruchowski, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Heather Kruchowski
Original Signature

2/17/2026
Date

Subscribed and Sworn to before me this 17 day of February.

Notary Public Signature

ERIN CLAY
Notary Public, Notary Seal
State of Missouri
St. Louis City
Commission # 23218370
My Commission Expires 07-26-2027

(Seal)



Confidential Information - Do Not Distribute

The content of this document is confidential and is not to be used beyond its intended use.

Blair Jackson
Joshua Reed
Anne Giovanoni
Heather Kruchowski
Scott Macke
Josalyn Moore
Julie Bray

4W

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH N/A	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Bayer Medical Care Inc.

Physical Address: 1 Bayer Drive

City: Indianola State: PA Zip: 15051

Mailing Address (if different from physical address): c/o State License Servicing, Inc., 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: radiology.bayer.com

Name of Designated Representative (DR): Heather G Tourre

Licensing Company Email: BMC@slsny.com DR Email: heather.tourre@bayer.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Clinics or Institutions, US Government		☒ Others: Manufacturer - Own Label

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A - No Discipline to report

Kathleen Ann Dunst
Original Signature (electronic, copies or stamps not accepted)

2/17/26
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A
Address: _____ City: _____ State: _____ Zip: _____
Name: N/A
Address: _____ City: _____ State: _____ Zip: _____
Name: N/A
Address: _____ City: _____ State: _____ Zip: _____
Name: N/A
Address: _____ City: _____ State: _____ Zip: _____

N/A **Section 4: Publicly Traded Corporation**

State of Incorporation: _____
Parent Company (if any): _____
Corporation Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): Schering Berlin Inc.
Corporation/Organization Name: Bayer Medical Care Inc.
Mailing Address: c/o State License Servicing, Inc. 225 Dolson Avenue, 4th Floor
City: Middletown State: NY Zip: 10940
Telephone: (845) 544-2482 Email: BMC@slsny.com
Contact Person Name: Christine Cannon

N/A **Section 6: Partnership**

Partnership Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

N/A **Section 7: Sole Owner**

Owner's Name: _____
Business Name: _____
Business Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: FDA #: 2520313	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Bayer Medical Care Inc.

Facility Name

Kathleen Ann Dunst

Print Name of Authorized Person Submitting Application

Kathleen Ann Dunst

Original signature of Authorized Person (copies or stamps not accepted)

2/17/26

Date

Board Use Only	Date Received: 3/5/26	Amount: $1000 ck 702

Proof of FDA

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
Bayer Medical Care Inc.
1 Bayer Drive
INDIANOLA, PA 15051
Registration Number: 2520313
FEI Number*: 2520313
Status: Active
Date Of Registration Status: 2026

Owner/Operator:
Bayer Medical Care Inc.[6]
1 Bayer Drive
Indianola, PA US 15051
Owner/Operator Number: 2520313[7]

Official Correspondent:
Troy A Jack
1 Bayer Drive
Indianola, PA 15051
Phone: 412-3528280

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2520313&OwnerOperatorName=&ProductCode=&Devicel

Verified M.H 3/6/26

Page Last Updated: 12/08/2025

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2520313&OwnerOperatorName=&ProductCode=&Devicel

Bayer Medical Care Inc.

Corporate Address: 1 Bayer Drive, Indianola, PA 15051 USA
FEIN: 25-1151038
radiology.bayer.com

Drug Labeler Code: N/A
Incorporation State: DE
Incorporation Date: 1/25/1996

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
IND	1 Bayer Drive Indianola, PA 15051 County: Allegheny	2520313	N/A - No CS		No	(412) 767-2400	

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Heather G Tourre	[redacted]	Designated Representative	No	[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Schering Berlin Inc.	100 Bayer Blvd. Whippany, NJ 07981	N/A	100%	N/A	[redacted]	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Sean Connelly Sullivan	[redacted]	President	No	[redacted]		
Kathleen Ann Dunst		Secretary				
Kristin Zimmerman		Assistant Secretary				
Jeff McFarland		Tax Officer				
Darcey Livingston Rhoades		Assistant Secretary	No	[redacted]		
Maria del Rocio Romero Alonzo		Treasurer				
David Schramm		Assistant Secretary				

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
Corporation Service Company			

Company Particulars

Incorp Good Standing

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BAYER MEDICAL CARE INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SECOND DAY OF FEBRUARY, A.D. 2026.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203161255

Date: 02-22-26

2585748 8300

SR# 20260713668

You may verify this certificate online at corp.delaware.gov/authver.shtml

Verification of Home State License (PA)

Pennsylvania Department of Health

Pennsylvania Department of Health

Drug, Device and Cosmetic Program

Version 4.0.0

Enter the 10-digit Certificate Number or Registrant's Name (or first few letters).

Lookup

Description of Certificate Categories

You may contact our office at (717) 787-4779 if the Certificate Number/Registrant you are researching is not found.

Bayer Medical Care Inc. 1 Bayer Drive; Indianola, PA 15051
Certificate(s): **3000006058** issued: 12/01/1990 expires: 12/31/2026; **8000000135** issued: 09/01/1994 expires: 12/31/2026

The entity noted above holds an active registration and/or license with the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program.

No formal probation, suspension, revocation, or formal disciplinary action has been issued directly by the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program against the aforementioned specific registration and/or license. Contact the DDC program with any further questions at (717) 787-4779 or email: ra-ddc@pa.gov

Back to DD&C Home

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Assembly Version 4.0.0.0

Database Version Could not retrieve database version. Check that the database is registered as a Data-tier Application.

Certificate of Licensure

Certificate No. 8000000135
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Drug & Device Registration

2525 N. 7th Street Suite 210D
Harrisburg, PA 17110
(717) 787-4779

Category:

Wholesaler/Distributor

BAYER MEDICAL CARE INC.
1 BAYER DRIVE
INDIANOLA, PA 15051

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Wholesale Prescription Drug License Act, Act #145, approved December 14, 1992.

Issuance Date: September 01, 1994
Expiration Date: The Last Day of December, 2026

Jeanne Parisi
Deputy Secretary for Quality Assurance

Pennsylvania
Department of Health

Debra L. Bogen, MD, FAAP
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

HS License

Liability Insurance

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 05/16/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA, LLC. 800 Market Street, Suite 1800 St. Louis, MO 63101-2500 CN102140943--GAW5-25-26	CONTACT NAME: Marsh | U.S. Operations & Technology PHONE (A/C, No, Ext): 866-966-4664 FAX (A/C, No): E-MAIL ADDRESS: StLouis.CertRequest@marsh.com
INSURED Bayer Medical Care, Inc. c/o Bayer Corporation 800 N. Lindbergh Blvd. St. Louis, MO 63167	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : HDI Global Insurance Co. — 41343 INSURER B : Old Republic Insurance Company — 24147 INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** CHI-010936504-00 **REVISION NUMBER:** 0

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			GLD1136616	04/01/2025	04/01/2026	EACH OCCURRENCE	$	5,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	100,000
							MED EXP (Any one person)	$	5,000
							PERSONAL & ADV INJURY	$	5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	5,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$	5,000,000
	OTHER:							$	
B	AUTOMOBILE LIABILITY			MWTB 319159 25	04/01/2025	04/01/2026	COMBINED SINGLE LIMIT (Ea accident)	$	2,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$	
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$	
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$	
	☐ DED ☐ RETENTION $							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			MWC 319158 25	04/01/2025	04/01/2026	X PER STATUTE ☐ OTH-ER		
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$	2,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	2,000,000
							E.L. DISEASE - POLICY LIMIT	$	2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Bayer Medical Care, Inc.
1 Bayer Drive
Indianola, PA 15051

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA LLC

Marsh USA LLC

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Bond

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 014262618

Application/License No. _____

Bayer Medical, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1 Bayer Drive, Indianola, PA 15051; 150 Victory Road, Saxonburg, PA 16056; 625 Alpha Drive, Pittsburg, PA 15238 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street, Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 13, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 13th day of August, 2025.

APPLICANT/PRINCIPAL

Jennifer Wattleson
Authorized Representative

SURETY COMPANY

Surety Company's Representative

Kathleen K. Freund, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Alexandra Johnson
Witness

Witness

SIGNED and SEALED in the presence of:

Merdi Bolkus
Witness

Terrence P. Freund
Witness

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

Liberty Mutual SURETY

POWER OF ATTORNEY

Certificate No: 8204866

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint,

Kathleen K. Freund

all of the city of Denver, state of CO each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of July, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 1st day of July, 2024, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 13th day of August, 2025.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com

Marsh MSurety POA LMIC OCIC WAIC Multi Co 012025

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Bayer Medical Care Inc. MDEG License # (if applicable): N/A

Physical Address: 1 Bayer Drive

City: Indianola State: PA Zip: 15051

Mailing Address (if different from physical address): c/o State License Servicing, Inc. 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: radiology.bayer.com

Licensing Company Email: BMC@slsny.com

Section 2: Personal Information

First: Heather Middle: G Last: Tourre

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Irwin State: PA Zip: [redacted]

Telephone: [redacted] Email: heather.tourre@bayer.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pennsylvania State University		08/1998 - 12/2002	
Address	**City**	**State**	**Zip**
201 Old Main	University Park	PA	16802
Diploma/Degree obtained, if any			
Bachelor of Science in Industrial Engineering			

School Name		From - To (MM/YY – MM/YY)	
Hempfield Area High School		05/1994 - 05/1998	
Address	**City**	**State**	**Zip**
4345 PA-136	Greensburg	PA	15601
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2023 - Present	[redacted]	Irwin	PA	[redacted]
From - To (MM/YY – MM/YY)		City	State	
11/2017 - 02/2023		Trafford	PA	
From - To (MM/YY – MM/YY)		City	State	
10/2010 - 11/2017		Turtle Creek	PA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Bayer Medical Care Inc.			2004 - Present	
Business Address		**City**	**State**	**Zip**
1 Bayer Drive		Indianola	PA	15051
Phone	**Title**		**Number of Employed Hours**	
(412) 420-7616	Designated Representative		~ 45,000 hours	

Description of Duties

Lead the Medical Device Quality cluster at the O'Hara and Indianola sites by setting the overall direction and managing quality activities for Electromechanical devices and Sterile Disposables. Collaborate with manufacturing, commercial, and regulatory organizations to align quality and compliance strategies with Bayer's objectives and strategic mission. Provide technical expertise on cross-functional corporate initiatives and develop effective Quality Management and Regulatory strategies to support manufacturing goals and achieve organizational objectives.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Heather G Tourre, **certify that as the MDEG Administrator for**

Bayer Medical Care Inc.,

that I (initial that you have read and meet the following requirements):

1. HGT Have a high school diploma or its equivalent;
2. HGT Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. HGT Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. HGT Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Heather G Tourre
Print Name (First, Last)

Heather G. Tourre
Original Signature (electronic, copies or stamps not accepted)

2/13/2026
Date

Board Use Only	Date Received: 3/5/26

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Bayer Medical Care Inc.

Pharmacy/Wholesaler License # (if applicable): Applying

Physical Address: 1 Bayer Drive

City: Indianola State: PA Zip: 15051

Mailing Address (if different from physical address): c/o State License Servicing, Inc. 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: radiology.bayer.com

Licensing Company Email: BMC@slsny.com

Section 2: Personal Information

First: Heather Middle: G Last: Tourre

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Irwin State: PA Zip: [redacted]

Telephone: [redacted] Email: heather.tourre@bayer.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pennsylvania State University		08/1998 - 12/2002	
Address	**City**	**State**	**Zip**
201 Old Main	University Park	PA	16802
Diploma/Degree obtained, if any			
Bachelor of Science in Industrial Engineering			

School Name		From - To (MM/YY – MM/YY)	
Hempfield Area High School		05/1994 - 05/1998	
Address	**City**	**State**	**Zip**
4345 PA-136	Greensburg	PA	15601
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2023 - Present	[redacted]	Irwin	PA	[redacted]
11/2017 - 02/2023		Trafford	PA	
10/2010 - 11/2017		Turtle Creek	PA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Bayer Medical Care Inc.			2004 - Present	
Business Address		City	State	Zip
1 Bayer Drive		Indianola	PA	15051
Phone	Title		Number of Employed Hours	
(412) 767-2400	Designated Representative		~ 45,000 hours	
Description of Duties				
Lead the Medical Device Quality cluster at the O'Hara and Indianola sites by setting the overall direction and managing quality activities for Electromechanical devices and Sterile Disposables. Collaborate with manufacturing, commercial, and regulatory organizations to align quality and compliance strategies with Bayer's objectives and strategic mission. Provide technical expertise on cross-functional corporate initiatives and develop effective Quality Management and Regulatory strategies to support manufacturing goals and achieve organizational objectives.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Heather G Tourre, **certify that as the designated representative for**

Bayer Medical Care Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. HGT I am at least 21 years of age;
3. HGT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. HGT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. HGT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. HGT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. HGT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Heather G Tourre

Print Name (First, Last)

Heather G. Tourre

Original Signature (electronic, copies or stamps not accepted)

2/13/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Heather G Tourre

Print Name (First, Last)

Heather G. Tourre — 2/13/2026

Original Signature (electronic, copies or stamps not accepted) — Date

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Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Allegheny

I, Heather G Tourre, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Heather G. Tourre — 2/13/2026

Original Signature Heather G Tourre — **Date**

Subscribed and Sworn to before me this 13th day of February.

Kimberly A Stefanik

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Kimberly A. Stefanik, Notary Public
Allegheny County
My commission expires November 10, 2028
Commission number 1210908
Member, Pennsylvania Association of Notaries

(Seal)

List of Employees

Name	Position Title	Personnel Area Desc
DINIZ, LUCIANA ANTONIAZZI	ASSOC DIR FIN BP ASKBIO	PA-INDIANOLA
ZIMMERMAN, MARIA JOY	MFG ASSOC I	PA-INDIANOLA
HERMUS, KENNY	SOFTWARE ENG I APPLICATION	PA-INDIANOLA
SILVEIRA, LUCAS	MACHINE OPR I	PA-INDIANOLA
CAMPAGNA, MARY	MATERIAL HANDLER	PA-INDIANOLA
BIXLER, BRIAN	MACHINE OPR I	PA-INDIANOLA
ROGERS, NORRIS	MFG ASSOC I	PA-INDIANOLA
NOVOTNY, MILENA	PORTFOLIO ASSOC DIR MKTG	PA-INDIANOLA
MARTINEZ QUEVEDO, LIZBETH	PRE STERILE II	PA-INDIANOLA
DUFF, JUNE	MFG ASSOC I	PA-INDIANOLA
MARKS, LUCAS	SR ENG PACKAGING	PA-INDIANOLA
BASINGER, LEVI	MACHINE OPR I	PA-INDIANOLA
HENRY JR, GEORGE	MFG ASSOC I	PA-INDIANOLA
CAMPBELL, TARYN	ASSOC ENG SW V&V	PA-INDIANOLA
GEHMAN, ALEC	SR ENG DESIGN	PA-INDIANOLA
GUEYE, MAMADOU	MACHINE OPR I	PA-INDIANOLA
BOTTLES, KAITLYN	QUAL INSPECTOR STA	PA-INDIANOLA
SATLER, IAN	SR ENG SW BIOTECH CL	PA-INDIANOLA
DOERR, MICHAEL	MFG ASSOC I	PA-INDIANOLA
MOORE, MORGAN	PRE STERILE I	PA-INDIANOLA
MILLER, JACOB	ENG II CYBERSECURITY	PA-INDIANOLA
MCDOUGAL, ELENA	SR ENG INDUSTRIAL	PA-INDIANOLA
SURESHCHANDER, AAYUSH	SR ENG SW	PA-INDIANOLA
MUKENDI, WILLY	MFG ASSOC I	PA-INDIANOLA
LOTZ, JUSTIN	MGR GLOBAL DEVICE LABELING STRATEGY	PA-INDIANOLA
KALINA, CONNOR	SR ENG SW	PA-INDIANOLA
CLIFFORD, MATTHEW	MFG ASSOC I	PA-INDIANOLA
SMITH, ZANE	SR MATERIAL HANDLER	PA-INDIANOLA
ARCUDI, IAN	SR ENG EMBEDDED TEST SW	PA-INDIANOLA
BERDIK, BRANDON	CALL TRIAGE SUPPORT AND DISPATCH ASSOC	PA-INDIANOLA
JOHNSON, ASHLEY	ANALYST CUST SUPP	PA-INDIANOLA
MAHENDRA BABU, BHAMINI NEELAKA	ENG II SW V&V	PA-INDIANOLA
APPIKATLA, HIMA BINDU	SR ENG SW	PA-INDIANOLA
LUNKAPPA, RANJITHA	SR ENG DEVOPS	PA-INDIANOLA
GATES, ASHLEY	CALL TRIAGE SUPPORT AND DISPATCH ASSOC	PA-INDIANOLA
POLURU, PRANAY	SR AUTOMATION ENGINEER	PA-INDIANOLA
NICHOLAS, MARISSA	ENG II SW BIOTECH	PA-INDIANOLA
REPPART, CASSIE	ENG PACKAGING	PA-INDIANOLA
SEGER, ZACHARY	SR ENG EM	PA-INDIANOLA
BEST, CHAD	MATERIAL HANDLER	PA-INDIANOLA
MULLER, ASHLEY	MFG ASSOC I	PA-INDIANOLA
KARADEEMA, EMILY	PRE STERILE II	PA-INDIANOLA
SKOWRONSKI, ASHLEY	SR MATERIAL HANDLER	PA-INDIANOLA
JOHNSON, ERICK	STAFF ENG SW BIOTECH CL	PA-INDIANOLA
ADAMS, AMINA	MACHINE OPR II	PA-INDIANOLA
SMELTZER, MATTHEW	SR ENG SYS	PA-INDIANOLA
KOTOK, MATTHEW	PRINCIPAL ENG MFG	PA-INDIANOLA
ELLIS, KELLEY	STAFF ENG SYSTEMS V&V	PA-INDIANOLA
DEVA, NISHANTH REDDY	ASSOC DIR REG STRATEGY DEVICES	PA-INDIANOLA
WADHANE, SAMEER	SR ENG SW V&V	PA-INDIANOLA
ROSHTO, AMBER	PRE STERILE II	PA-INDIANOLA
KLINE, CYNTHIA	MFG ASSOC I	PA-INDIANOLA
DAVIS, GAIL	MGR CUST SVC I	PA-INDIANOLA
BARDON, STEPHANIE	PRINCIPAL SW ENG	PA-INDIANOLA
GIANAMORE, EMILY	PORTFOLIO ASSOC DIR MRKTG	PA-INDIANOLA
HAMMACK, JERRY	SR ENG QUAL	PA-INDIANOLA
SLIVKA, MALENA	STAFF ENG QUAL	PA-INDIANOLA
CENDROWSKI, JAMIE	PRE STERILE I	PA-INDIANOLA
MCINTYRE, DEBORAH	SR MATERIAL HANDLER	PA-INDIANOLA
STREED, JONI	PRE STERILE I	PA-INDIANOLA
POTTS, WILLIAM	TECH MAINT	PA-INDIANOLA
WESTCOTT, JOSEPH	QUAL COORD	PA-INDIANOLA
ALLEN, NANETTE	BUSINESS SUPPORT EXPERT	PA-INDIANOLA
BARONE, WILLIAM	PRINCIPAL ENG RSRCH	PA-INDIANOLA
SRIVASTAVA, HEMANT	PRINCIPAL SOFTWARE ENGINEER	PA-INDIANOLA
DAVIS, TIMOTHY	PROC LEADER	PA-INDIANOLA
CARDINALE, JEAN	MACHINE OPR II	PA-INDIANOLA
HILL, HERBERT	SR ENG RISK MGMT	PA-INDIANOLA
DIAZ, ELIX	MFG ASSOC I	PA-INDIANOLA
SPACHT, GARY	MACHINE OPR II	PA-INDIANOLA
ACRIE, WALTER	PRE STERILE I	PA-INDIANOLA
SCHADEMAN, BYRON	MACHINE OPR II	PA-INDIANOLA
BANN, RICHARD	SR MATERIAL HANDLER	PA-INDIANOLA
FRANCIONI, CATHERINE	END TO END SUPPLY NETWORK EXPERT	PA-INDIANOLA
KNIGHT, CHRISTOPHER	MACHINE OPR II	PA-INDIANOLA
HENRY, RONALD	LINE LEADER	PA-INDIANOLA
RUDOLF, BRENDA	MFG ASSOC I	PA-INDIANOLA
MILLER, TONYA	PRE STERILE II	PA-INDIANOLA
RICHTER, PHILLIP	PRE STERILE I	PA-INDIANOLA
WALLECK, CHRISTIAN	PRINCIPAL ENG AUTOMATION	PA-INDIANOLA
BARKER, KAREN	PRE STERILE I	PA-INDIANOLA
DANGI, ANU	APPLICATION SR TESTING LEAD	PA-INDIANOLA
BEST, JESSICA	MACHINE OPR I	PA-INDIANOLA
FERCHAW, MIKAYLA	ASSOC DIRECTOR HFE	PA-INDIANOLA
MAHESH, NIVITHA	SR PRINCIPAL ENG DIG SOL	PA-INDIANOLA
MARCO, NICHOLAS	ASSOC DIR DATA MGMT GLBL REG OP EXCELLEN	PA-INDIANOLA
WEST, ABIGAIL	STAFF ENG RISK MGMT	PA-INDIANOLA
THAKUR, JANHAVI	STAFF ENG SW	PA-INDIANOLA

HUTCHINGS, SHARON	MFG ASSOC I	PA-INDIANOLA
SMITH, TAMMY	MFG ASSOC I	PA-INDIANOLA
GARCIA, MIGUEL	TECH MAINT	PA-INDIANOLA
HERRING, GLENN	SR SUPPLY CHAIN PROJ MGR	PA-INDIANOLA
EVAK, WILLIAM	SUPV PROD	PA-INDIANOLA
RILEY, JAMES	STAFF ENG QUAL	PA-INDIANOLA
SADAM, HARPRIT	STAFF ENG SW	PA-INDIANOLA
KUMAR, PAWAN	DIR DIGITAL STRAT PROD OPS	PA-INDIANOLA
PICKUR, LINDA	MFG ASSOC I	PA-INDIANOLA
HALLER, SHARON	COMPUTER SYSTEM VALIDATION LEAD	PA-INDIANOLA
JANKOWSKI, SHANNON	PROG DIR LCE	PA-INDIANOLA
POGEL, SAMANTHA	ASSOC DIR ENG QUAL SYSTEM PROC EXCELLENC	PA-INDIANOLA
HERRMANN, STUART	R&D QUALITY LEAD	PA-INDIANOLA
ARTERITANO, MICHAEL	PRE STERILE I	PA-INDIANOLA
KUC, LINDA	MFG ASSOC I	PA-INDIANOLA
MOTTURA, KEVIN	PROC LEADER	PA-INDIANOLA
BOOKER, STEVEN	PROC LEADER	PA-INDIANOLA
PROIETTI, GABRIEL	PRE STERILE II	PA-INDIANOLA
HORNFECK, KENNETH	CHIEF ENG INTEGO NEO	PA-INDIANOLA
METKLER, LINDSAY	GBL PROD QUAL VIGILANCE MGR	PA-INDIANOLA
FANALA, BRENDA	ASSOC DIR GLBL REG OP EXCELLENCE	PA-INDIANOLA
MIKUS, TRACEY	PRE STERILE I	PA-INDIANOLA
MCGUIRE, MATTHEW	SR ENG SYS	PA-INDIANOLA
GUPTA, SAURABH	STAFF ENG SW	PA-INDIANOLA
SWETOF, MARCY	PRE STERILE I	PA-INDIANOLA
SWETOF, EMILY	MACHINE OPR I	PA-INDIANOLA
KOZAR, KYLE	STAFF ENG QUAL	PA-INDIANOLA
HICKMAN, DOMONIQUE	PRE STERILE II	PA-INDIANOLA
WATKINS, ANDREA	LAB TECH	PA-INDIANOLA
PARRISH, JESSICA	LINE LEADED	PA-INDIANOLA
AGBALE, TAIYEWO	PRE STERILE I	PA-INDIANOLA
ZDOBINSKI, HUNTER	MACHINE OPR II	PA-INDIANOLA
RUSIEWICZ, BENJAMIN	MACHINE OPR I	PA-INDIANOLA
KOZAR, KORY	STAFF ENG RISK MGMT	PA-INDIANOLA
IBRAHIM, MUFUTAU	MFG ASSOC I	PA-INDIANOLA
GOOD, JENNIFER	SR MGR FIELD BUS	PA-INDIANOLA
ANDREWS, ROBERT	MFG ASSOC I	PA-INDIANOLA
MOSSO, JOHN	SR STAFF SOFTWARE ENGINEER LOT	PA-INDIANOLA
CLISE, JONATHAN	SR MGR BUS SYSTEMS AUTOMATION	PA-INDIANOLA
MENEGO, IAN	STAFF ENG SD	PA-INDIANOLA
YIGDALL, JONATHAN	PROJ MGR MFG	PA-INDIANOLA
DEMPSEY, PAUL	OE SPECIALIST 2	PA-INDIANOLA
MULCAHY, LEONA	GLOBAL PRODUCT TEAM LEAD NGCT	PA-INDIANOLA
YOO, JAMES HOON	DIR OF RAD SW ARCHITECTURE	PA-INDIANOLA
JUBIC, CHRISTOPHER	DIR MARKET INTELLIGENCE	PA-INDIANOLA
HERNAEZ, HENRY	LEAD SOFTWARE STRATEGIST	PA-INDIANOLA
TUNDER, STACEY	SR PLANNER	PA-INDIANOLA
SPATHOLT, MATTHEW	DIR CONTRACT STRATEGY	PA-INDIANOLA
STEIN, KANE	RA OPS EXCEL PROG MGR NPD	PA-INDIANOLA
BRENNER, LORI	SR PROJ MGR QUAL	PA-INDIANOLA
PULLEO, ANTHONY	DIRECTOR LABELING RAD DEVICES	PA-INDIANOLA
SCHUK, WILL	STAFF ENG ELECT	PA-INDIANOLA
DEPETRO, ABBY	QUAL SYS COORD SPEC	PA-INDIANOLA
HENNEMUTH, MALLORY	STAFF ENG PLANT MFG	PA-INDIANOLA
CZULADA, ABBY	MGR GBL DEVICE LABELING STRAT	PA-INDIANOLA
KALAFUT, JOSHUA	ASSOC DIR HSE	PA-INDIANOLA
KREIDER, SONJA	PRE STERILE II	PA-INDIANOLA
REMIS, SHARON	ASST WHSE SPVR	PA-INDIANOLA
HINKLE, JOHNATHAN	PROJ ENG	PA-INDIANOLA
JOHNSON, HOLLY	ASSOC DIR INFORMATICS PROJ MGR	PA-INDIANOLA
SIEFFERT, NATHAN	SCIENTIST	PA-INDIANOLA
ROBINSON, MARIA	ASSOC DIR INFORMATICS PROJ MGR	PA-INDIANOLA
SUTTON, REBECCA	STAFF ENG ADV SYS INTEGRATION	PA-INDIANOLA
REYNOLDS, DEANNA	DIR DEVICE PROJECTS	PA-INDIANOLA
BOCK, BRITTANY	PROJ ENG MFG	PA-INDIANOLA
OSAN, ANDREW	STAFF ENG MECH	PA-INDIANOLA
FRANCIONI, DOMINIC	SR MGR E2E SUPPLY NETWORK	PA-INDIANOLA
RAGIN, YANCY	ASSOC DIR V&V	PA-INDIANOLA
BIDWELL, LAURA	HFE STUDY TRAINER	PA-INDIANOLA
BARRETT, MARC	DIR EXTERNAL MFG	PA-INDIANOLA
FRANK, KELLY	DIR PORTFOLIO MARKETING	PA-INDIANOLA
ROTE, PATRICIA	MACHINE OPR II	PA-INDIANOLA
SKIRBLE, TYLER	SR ENG SW	PA-INDIANOLA
DIATTA, MOHAMADOU	SR ENG SW	PA-INDIANOLA
MEANS, KATHLEEN	STAFF ENG SD	PA-INDIANOLA
CLARKE, BRANDON	SR PRINCIPAL ENG SYS	PA-INDIANOLA
PAPICH, JENNIFER	CHIEF ENG MOLECULAR IMAGING	PA-INDIANOLA
WILHELM, AMY	SR INSIDE SALES REP	PA-INDIANOLA
O'ROURKE, PATRICK	DIRECTOR OF SW ARCHITECTURE CSP	PA-INDIANOLA
JAY, CHANDRASEKAR	MD COMPLIANCE ENG	PA-INDIANOLA
WEIDNER, JACOB	MAINT SPVR	PA-INDIANOLA
POTLURI, MANOHAR	PDL WFS	PA-INDIANOLA
CALIXTO ANTUNES, LEONARDO	DIRECTOR RAD RA MEDICAL DEVICE	PA-INDIANOLA
HAGGERTY, PATRICK	STAFF ENG	PA-INDIANOLA
DALTON, GREGORY	R&D QUALITY LEAD	PA-INDIANOLA
DLESK, JESSICA	EXEC ASST SUPP QUAL	PA-INDIANOLA
MATHEWS, BRUCE	DATA ANALYTICS MGR	PA-INDIANOLA
PRICE, ERIC	ASSOC DIR ENG QUAL SD	PA-INDIANOLA
MILLETT, NICHOLAS	STAFF ENG SW	PA-INDIANOLA

YOUKERS, JASON	PRINCIPAL ENG ELECT	PA-INDIANOLA
BROOKS, RYAN	SR PROJ MGR SUPPLY CHAIN	PA-INDIANOLA
NEDLEY, RYAN	LEAD CAPABILITY CLUSTER CONTROLLER	PA-INDIANOLA
TEJEDA, MABEL ALEXANDRA	PORTFOLIO ASSOC DIR MKTG	PA-INDIANOLA
EGAN, ASHLEY	STAFF ENG STERILITY ASSURANCE	PA-INDIANOLA
MAHOUSKI, MATTHEW	PROJ MGR EMO	PA-INDIANOLA
EPPS, MARCOS	GLOBAL FLUID DELIVERY LEAD	PA-INDIANOLA
ARMSTRONG, LASCHALLE	DIR SD PKG & PROD SUSTAINABILITY EGRG	PA-INDIANOLA
BRUST, MARITA	DIR QUAL SITE INDIANOLA	PA-INDIANOLA
FERCHAW, ALEXA	SR ENG RISK MGMT	PA-INDIANOLA
SARTORI, KARLA	HEAD OF US MKTG R&D DIGITAL SOLUTIONS BU	PA-INDIANOLA
WATERS, CHAD	PRINCIPAL TECH	PA-INDIANOLA
SUNDARESAN, BALAJI	DIR MACHINE LEARNING & AI	PA-INDIANOLA
SYSOL, JACKIE	PROJ ENG SUPP QUAL	PA-INDIANOLA
SKLENCAR, MICHAEL	SR PROJ MGR	PA-INDIANOLA
DAULTON, ALEXIS	ENG II SW	PA-INDIANOLA
HORWATT, KEVIN	SR PROD SUPV	PA-INDIANOLA
BLACK, SHINARA	SR MATERIAL HANDLER	PA-INDIANOLA
SANDIDGE, SYDNEY	SR ENG HUMAN FACTORS	PA-INDIANOLA
BRINKER, MICHELLE	SR DIR REG STRAT DEVICES	PA-INDIANOLA
EISENHART, EVAN	ENG AUTOMATION	PA-INDIANOLA
BARR, LUKE	ASSOC MFG LEAD	PA-INDIANOLA
RAFFERTY, AMY	PRINCIPAL ENG PLANT	PA-INDIANOLA
DERVIN, JACQUELINE	ANALYST CUST SUPP	PA-INDIANOLA
JAROSZ, HELENA	ENG SD	PA-INDIANOLA
REDOVAN, STEPHANIE	STAFF ENG PLANT	PA-INDIANOLA
WITT, COLLEEN	DIR REG STRATEGY DEVICES	PA-INDIANOLA
LULICH, THOMAS	EMO LEAD AMERICAS	PA-INDIANOLA
AYODHIMANI, PADMA	DIR GBL PRODUCT PLATFORM	PA-INDIANOLA
D'ANGELO, EMMELINE	PRINCIPAL ENG QUAL SYS	PA-INDIANOLA
SCHEIDLMEIER, JASON	EARLY PRODUCT TEAM LEAD NGMR	PA-INDIANOLA
BORLAND, JACOB	SR ENG ASSURANCE	PA-INDIANOLA
GIMBEL, DEBRA	ASSOC DIR REG STRATEGY DEVICES	PA-INDIANOLA
ADEM, SRIKANT	SR MGR DATA ANALYTICS	PA-INDIANOLA
COUSINS, CHASE	MFG ASSOC I	PA-INDIANOLA
MCGUINNESS, SUSANNE	SR BRAND MGR SVCS	PA-INDIANOLA
STAWINSKI, LORI	MATERIAL HANDLER	PA-INDIANOLA
WASILEWSKI, LISA	DIR OPERATIONAL PLANNING POOL LEAD	PA-INDIANOLA
PAMER, LINDSEY	CHIEF ENGINEER, NGMR	PA-INDIANOLA
FISHER, WILLIAM	MFG ASSOC I	PA-INDIANOLA
MICHEL, JOHN	SW ENG II	PA-INDIANOLA
ZAMBRANO, HOWALD	SR TECH FAC	PA-INDIANOLA
TEKELY, RHONDA	MACHINE OPR I	PA-INDIANOLA
STEWART, STACEY	CUSTOMER RESPONSE SQUAD LEAD	PA-INDIANOLA
DITTY, MACKENZIE	STAFF ENG SYSTEMS V&V	PA-INDIANOLA
PATTAN, MUNWAR ALI KHAN	SR DATA ANALYTICS MGR	PA-INDIANOLA
DOMINKUSH, DANIEL	MFG ASSOC I	PA-INDIANOLA
PAUSTENBACH, SUSAN	MFG ASSOC I	PA-INDIANOLA
BAUGHMAN, COLE	SW ENG II	PA-INDIANOLA
DZUKA, MAGGIE	ENG II SW	PA-INDIANOLA
HARTNETT, SAMANTHA	DEVICE DESIGN ENG SD	PA-INDIANOLA
GIDDENS, RHONDA	MFG ASSOC I	PA-INDIANOLA
MCCOY, HEATHER	SR MGR GBL DEVICE LABELING STRAT	PA-INDIANOLA
SWANSON, JACOB	TECH MAINT	PA-INDIANOLA
JOHNSON, JASON	CLIN COMPLIANCE LEAD	PA-INDIANOLA
KLEIN, SUZANNE	SR EXEC ASST	PA-INDIANOLA
FITZGERALD, BRIANNA	STAFF ENG QUAL	PA-INDIANOLA
FENSTERMACHER, BRIAN	SW UI/UX DESIGNER	PA-INDIANOLA
WISHNESKI, KYLIE	CO-OP SYSTEMS ENG	PA-INDIANOLA
HEINS, KRISTINA	COOP SYSTEMS ENG	PA-INDIANOLA
GUPTA, ANUSHKA	CO OP SOFTWARE DEVELOPMENT	PA-INDIANOLA
WU, YANG	REG ASSOC INTERN CO OP	PA-INDIANOLA
SCHRIVER, REAGAN	COOP ENG HUMAN FACTORS	PA-INDIANOLA
SIRWADKAR, SHIVANI	DATA ANALYTICS MGR	PA-INDIANOLA
RILEY, BRENNON	ASSOC TECH	PA-INDIANOLA
ELTON, JOHN	DIR MACHINE LEARNING AND AI	PA-INDIANOLA
HAEGG, MICHAEL	STAFF ENG SW	PA-INDIANOLA
MARSH, CHELSEA	HEAD ENGRG HARDWARE	PA-INDIANOLA
SHARMA, MOHIT	ASSOC DIR R&D DATA LAKE SYS APP	PA-INDIANOLA
BARTOS, TRACI	DIR R&D OPERATIONAL EXCELLENCE	PA-INDIANOLA
PATTERSON, TERRI	DIR SAP BUSINESS PROCESS EXCELLENCE	PA-INDIANOLA
ROLFE, JAMES	DIR DEVICE PROCESSES	PA-INDIANOLA
KRISHNAN, BABU	HEAD DEVICE SW DEVP	PA-INDIANOLA
SCHMIDT, SVEN	SENIOR CATALYST STRATEGY REFRESH	PA-INDIANOLA
HEUSEY, ADAM	PRE STERILE II	PA-INDIANOLA
ORANGE, ADRION	SR ENG SUPP QUAL	PA-INDIANOLA
GROGAN, AIMEE	MFG ASSOC I	PA-INDIANOLA
MARIN, JENNI ALEJANDRA	ENG STERILITY ASSURANCE	PA-INDIANOLA
ANDERSON, ALEXANDER	SOFTWARE ENG I	PA-INDIANOLA
MOYER, ALEXANDER	R&D DATA AND SYS MGR	PA-INDIANOLA
BRALVE, ALLISON	SW REQ ENG	PA-INDIANOLA
BELL, ALYSSA	STAFF ENG SYS	PA-INDIANOLA
ADLER, AMBER	MFG ASSOC I	PA-INDIANOLA
NAPLES, ANDREW	PRINCIPLE ENG MECH	PA-INDIANOLA
WASHABAUGH, ANITA	SENIOR LOCAL COORDINATOR	PA-INDIANOLA
SHARMA, ANKUR-AARON	CAPABILITY CLUSTER LEAD MA MD AND SAMD	PA-INDIANOLA
JORGE DE SARACHAGA, ANJAR	NA CH PH CORE PROGRAM MGR	PA-INDIANOLA
MARTIN, APPOLLOS	MFG ASSOC I	PA-INDIANOLA
PAMIDI, NAGARJUNA	STAFF ENG SW	PA-INDIANOLA

PADILLA, ARMANDO	PROJ MGR LCE	PA-INDIANOLA
KLINGE, AUSTIN	MFG ASSOC I	PA-INDIANOLA
KURTZ, BARBARA	MGR SUPPLIER QUAL PROJ SYSTEMS	PA-INDIANOLA
HAMZAH, NABILA HAKIM BINTI	BUYER PLANNER EM MD	PA-INDIANOLA
GOLDSCHMIDT, BENJAMIN	STAFF ENG ELDP	PA-INDIANOLA
KLEMMENSEN, BETH	MFG ASSOC I	PA-INDIANOLA
CASTILLO, WILLIAM	ASSOC PROG DIR	PA-INDIANOLA
BISCEGLIA, ROBERT	ANALYST CUST SUPP	PA-INDIANOLA
RAMER, ROBERT	VALUE STREAM LEAD	PA-INDIANOLA
VIBOONSOOK, WONGRAWEE	ASSOC DIR SW DEV	PA-INDIANOLA
CYPHER, BRADLEY	PRINCIPAL SW ENG	PA-INDIANOLA
PIJANOWSKI, BRANDON	SW ENG II	PA-INDIANOLA
ACRI, BRENDAN	STAFF ENG SYS	PA-INDIANOLA
BONGARTZ, BRENT	PROC LEADER	PA-INDIANOLA
SYLER, BRETT	MFG ASSOC I	PA-INDIANOLA
MOODY, BRIAN	SR ANALYST CONTRACT REBATE OPS COMM	PA-INDIANOLA
DZENIS, BRIAN	MATL LOG SPEC	PA-INDIANOLA
NELSON, CAMREN	SR ENG FAC	PA-INDIANOLA
BERRY, CARLOS	MFG ASSOC I	PA-INDIANOLA
DRISCHLER, CASEY	MFG ASSOC I	PA-INDIANOLA
HOSTETLER, CASEY	ANALYST CUST SUPP	PA-INDIANOLA
LAZOR, CASSIDY	SR SPEC SVC SPPT	PA-INDIANOLA
MCMAHAN, CHELSEY	CAPABILITY CLUSTER CONTROLLER	PA-INDIANOLA
BURTOFT, CHERYL	MFG ASSOC I	PA-INDIANOLA
CREAMER, CHRISTINE	PROGRAM DIR LCE LEAD	PA-INDIANOLA
WAGNER, CHARLES	ASSOC DIR INFORMATICS PROJ MGR	PA-INDIANOLA
DELO, COREY	MACHINE OPR I	PA-INDIANOLA
KEIBLER SUPPA, CRISTY	MFG ASSOC I	PA-INDIANOLA
BAIER, DAKOTA	MFG ASSOC I	PA-INDIANOLA
BROWN, DARIA	ASSOC DIR REG STRATEGY DEVICES	PA-INDIANOLA
DEDOLA, DAVID	GLBL SERVICE ENGINEERING ASSOC	PA-INDIANOLA
FARRELL, DAVID	SR BUYER	PA-INDIANOLA
JONES, DONALD	MFG ASSOC I	PA-INDIANOLA
PREISACH, DONNA	PRE STERILE II	PA-INDIANOLA
MCCONAHY, DOUGLAS	SR STAFF ENG SW	PA-INDIANOLA
HUNKELE, EDWARD	MFG ASSOC I	PA-INDIANOLA
RABIN, EDDEN	SR ENG V&V	PA-INDIANOLA
BARNABEI, ERIC	STAFF ENG	PA-INDIANOLA
HUMENAY, ERIC	STAFF ENG SW	PA-INDIANOLA
STEEVES, EVAN	STAFF ENG SW QUAL	PA-INDIANOLA
ANIM, FRANCIS	ASSOC ENG CYBER	PA-INDIANOLA
DENNIS, FRANK	MFG ASSOC I	PA-INDIANOLA
SKOWRONSKI, GARY	MACHINE OPR I	PA-INDIANOLA
GAUTAM, KUMAR	STAFF ENG SW	PA-INDIANOLA
ROBINSON, GRANT	ENG SW REQUIREMENTS	PA-INDIANOLA
MESZAROS, GREGORY	PROJ ENG QUAL SYS	PA-INDIANOLA
SMITH, HANNAH	PORTFOLIO ASSOC DIR MKTG	PA-INDIANOLA
SEFATPOUR, HASTI	SUPPLY PLANNING CHANGE MGMT POOL LEAD	PA-INDIANOLA
CLOSE, HEATH	STAFF ENG MFG	PA-INDIANOLA
ALLISON, HORTENSE	VP REGULATORY MEDICAL DEVICES	PA-INDIANOLA
CHUKWUEMEKA, IKENNA	MFG ASSOC I	PA-INDIANOLA
AKINBOYE, OLUWASEGUN	SCRUM MASTER	PA-INDIANOLA
SCHLEIDEN, JACQUELYNN	VALUE STREAM LD PRODUCT SERV SUPPORT	PA-INDIANOLA
FARMAKIS, JACKSON	CO-OP ENG AUTOMATION	PA-INDIANOLA
KLEYSTEUBER, JADE	PROC LEADER	PA-INDIANOLA
DEGROSKY, JEFFREY	ENG II SW	PA-INDIANOLA
CLEVENGER, JEFFREY	MFG ASSOC I	PA-INDIANOLA
GREENWALD, JEFFREY	TECH PACK LAB QUAL	PA-INDIANOLA
LEZARK, JEFFREY	PRE STERILE I	PA-INDIANOLA
SCHINKE, JENNIFER	ENG SW REQUIREMENTS	PA-INDIANOLA
TIEU, NGOC	CONNECTIVITY SUPPORT AND MAINT TECH	PA-INDIANOLA
COMER, JEWELL	MFG ASSOC I	PA-INDIANOLA
SCHEN, JAMES	SR STAFF ENG	PA-INDIANOLA
SHARICK, JOSEPH	ENG II SW BIOTECH	PA-INDIANOLA
FYOCK, JOHN	MACHINE OPR I	PA-INDIANOLA
ITALIANO, JOHN	MFG ASSOC I	PA-INDIANOLA
SHEARER, JOHN	STAFF ENG ELEC	PA-INDIANOLA
RIZZI, JONATHAN	PRINCIPAL PROCESS ENG	PA-INDIANOLA
SMITH, JOSHUA	ASSOC PRIN ENG DEVICE DESIGN	PA-INDIANOLA
KOCH, JOSHUA	SR ENG QUAL	PA-INDIANOLA
STANISHA, JOSH	SR ENG EM MD	PA-INDIANOLA
EVANS, JOHN	ASSOC DIR INFORMATICS PROJ MGR	PA-INDIANOLA
SCHIETROMA, KAREN	PRE STERILE I	PA-INDIANOLA
NAVANEETHAN, KASINATHAN	SR PRINCIPAL ENG QUAL	PA-INDIANOLA
HENDERSON, KAITLYN	MFG ASSOC I	PA-INDIANOLA
MAINS, KATELYNN	DIR REG STRATEGY DEVICES	PA-INDIANOLA
RAHMANI, KAWA	PRINCIPLE ENG SW	PA-INDIANOLA
CARNAHAN, KELLI	MFG ASSOC I	PA-INDIANOLA
SCOVERN, KENNETH	MGR FAC MAINT	PA-INDIANOLA
WITMER, KORY	R&D QUALITY LEAD	PA-INDIANOLA
SKOLNY, KRYSTYNA	MFG ASSOC I	PA-INDIANOLA
TANCZOS, KYLE	STAFF ENG SW	PA-INDIANOLA
SCOTT, LENA	SR ENG SYSTEMS	PA-INDIANOLA
BURKE, LOGAN	SR TECH	PA-INDIANOLA
BOVAN, LOUIS	ENG V&V	PA-INDIANOLA
AIRHART, LUCAS	SVC SUPP SPEC	PA-INDIANOLA
FLAHERTY, LYNN	PROJ MGR EMO	PA-INDIANOLA
BREED, MASON	SR STAFF ENG SW	PA-INDIANOLA
SNYDER, MATTHEW	MACHINE OPR I	PA-INDIANOLA

MOSES, MATTHEW	STAFF ENG SW BIOTECH CL	PA-INDIANOLA
MCHUGH, MATTHEW	GLBL SERVICE ENGINEERING ASSOC	PA-INDIANOLA
NOVAK, MELANIE	END TO END SUPPLY NETWORK EXPERT	PA-INDIANOLA
HARTSFIELD, MELISSA	MFG ASSOC I	PA-INDIANOLA
MIKHAIL, MERVAT	PRE STERILE I	PA-INDIANOLA
MCDEVITT, MICHAEL	SR ENG SW SYSTEMS	PA-INDIANOLA
KALBAUGH, MICHELLE	PRE STERILE II	PA-INDIANOLA
CREASON, MICHELLE	PRE STERILE II	PA-INDIANOLA
SALUNKHE, MIHIR	SR ENG CYBER	PA-INDIANOLA
GREENE, MICHAEL	MFG ASSOC I	PA-INDIANOLA
DEVLIN, MICHAEL	MACHINE OPR II	PA-INDIANOLA
SCHALL, MOSES	SR FAC MAINT TECH	PA-INDIANOLA
REESMAN, NATHAN	MATERIAL HANDLER	PA-INDIANOLA
ENGLISH, DONALD	MFG ASSOC I	PA-INDIANOLA
GRIFFEY, NICHOLAS	PRE STERILE II	PA-INDIANOLA
WILEY, NICHOLAS	GCIS COMMERCIAL LEAD	PA-INDIANOLA
PRESCOTT, NICOLAS	PRINCIPAL ENG TESTING RELEASE	PA-INDIANOLA
ZINN, NOLAN	SR ENG SW	PA-INDIANOLA
NGUYEN, PATRICK	MATERIAL HANDLER	PA-INDIANOLA
SLOMKA, PATTY	SR SVC SUPP SPEC	PA-INDIANOLA
BANACHOSKI, PATRICIA	MFG ASSOC I	PA-INDIANOLA
SCHLABACH, PAUL	ASSOC ENG CYBER	PA-INDIANOLA
RODRIGUEZ, PETER	ASSOC DIR SUPPLY BASE PROJ	PA-INDIANOLA
MARASCALCO, PHILIP	DIR MED CLIN AFFRS DEVICES	PA-INDIANOLA
GEORGE, PHILLIP	SR MATERIAL HANDLER	PA-INDIANOLA
MCMEEKIN, RACHAEL	MACHINE OPR I	PA-INDIANOLA
MILLER, RACHAEL	MACHINE OPR II	PA-INDIANOLA
CROKER, RANDALL	MFG ASSOC I	PA-INDIANOLA
LEE, RANDY	PRINCIPAL ENG SYSTEMS V&V	PA-INDIANOLA
CREASON, RANDALL	MACHINE OPR I	PA-INDIANOLA
BROWN, RANIYA	SOFTWARE DEVP INTERN	PA-INDIANOLA
CARREIRO, RATNA	PRE STERILE I	PA-INDIANOLA
KANNABIRAN, RAVICHANDRAN	DIR OF SW ARCHITECTURE WFS LCE	PA-INDIANOLA
RIDGELEY, RAYMOND	MFG ASSOC I	PA-INDIANOLA
THEURET, ROBERT	SR PORTFOLIO MGR RAD R&D PSO	PA-INDIANOLA
BAIKO, ROBERT	STAFF ENG SD	PA-INDIANOLA
VANTINE, ROBERT	MATERIAL HANDLER	PA-INDIANOLA
MILLER, ROBERT	MACHINE OPR II	PA-INDIANOLA
GREIL, ROBERT	ASSOC PROGRAM DIR LCE	PA-INDIANOLA
KONG, FANRONG	SR PRINCIPAL ENG SW	PA-INDIANOLA
PEEBLES, SAMANTHA	ENG SD	PA-INDIANOLA
ROBERSON, SAMUEL	PRE STERILE I	PA-INDIANOLA
HUDSON, SHANNON	PRE STERILE I	PA-INDIANOLA
CLISE, SHANNON	SR ANALYST CONTRACT REBATE OPS COMM	PA-INDIANOLA
MAYASANDRA, SHARATH KUMAR	DIR RAD SW QA AND OPERATIONS	PA-INDIANOLA
PISANO, SHARON	MFG ASSOC I	PA-INDIANOLA
CARR, SHARON	PRE STERILE I	PA-INDIANOLA
BONETTI, SHAWN	STAFF ENG SW	PA-INDIANOLA
SMITH, SHAWNNON	MATERIAL HANDLER	PA-INDIANOLA
CHAUK, SHRINIWAS	BEST BAYER	PA-INDIANOLA
GHOSH, SOUMITRA	SR DIR BUS LICENSING RADIOLOGY	PA-INDIANOLA
ZILKA, STEPHEN	TECH ASSIST CENTER SUPT COORD	PA-INDIANOLA
LASICA, STEVEN	PRINCIPAL ENG MFG	PA-INDIANOLA
FRANCISCUS, SUSAN	STAFF ENG QUAL	PA-INDIANOLA
EBKEN, SUZANNE	MFG ASSOC I	PA-INDIANOLA
POL, TERRY	SOL ARCH DIGITAL PROD TRNR	PA-INDIANOLA
KINST, THOMAS	CTFD PRODUCT SQUAD LEAD	PA-INDIANOLA
ROBINSON, THOMAS	PRIN TECH LABS	PA-INDIANOLA
GINOCCHI, THOMAS	DIGITAL LEAD AMERICAS RADIOLOGY COMMERC	PA-INDIANOLA
NUCCETELLI, TONYA	SR SPEC SVC SUPP APPS	PA-INDIANOLA
BERTELLE, TRACY	MFG ASSOC I	PA-INDIANOLA
KOPPADA, TRIPURA DEVI	STAFF ENG SW	PA-INDIANOLA
GLENN, TYLER	MFG ASSOC I	PA-INDIANOLA
ALTMYER, ZACHARY	STAFF ENG SD	PA-INDIANOLA
JONES, ZACHERY	SITE LOG POOL LEAD INDIANOLA	PA-INDIANOLA
SCHUFFERT, LORI	SR EXEC ASST	PA-INDIANOLA
SMITH, SCOTT	SR PRINCIPAL ENG	PA-INDIANOLA
DOLINAR, JOHN	PROG LEAD NPD MARKETED PORTFOLIO STA	PA-INDIANOLA
MATTER, KATHLEEN	SENIOR LOCAL COORDINATOR	PA-INDIANOLA
JACKSON, TROY	QUAL SYSTEM SPEC	PA-INDIANOLA
MILLER, BRENDA	SR COMPLIANCE SPECIALIST	PA-INDIANOLA
KREDGEN, JOSEPH	QA COMPLIANCE & MD SOFTWARE QUALITY LEAD	PA-INDIANOLA
SOPEL, VALERIE	SR COORD QUAL	PA-INDIANOLA
LOBERT, JODY	SR PRINCIPAL LABELING SPEC	PA-INDIANOLA
BURGET, JOHNETTA	SR DOCUMENTATION SPEC	PA-INDIANOLA
MAIESE, TIMOTHY	SR PRINCIPAL DESIGNER ELEC	PA-INDIANOLA
PRANIEWICZ, ROBERT	SR PRINCIPAL DFX ENG	PA-INDIANOLA
CAIN, BRIAN	SR PRINCIPAL ENG	PA-INDIANOLA
WOLFE, SCOTT	SR PRINCIPAL TECH	PA-INDIANOLA
FISHER, MARCELLA	CONTRACT SVCS SPEC	PA-INDIANOLA
DESENSI, FRANK	GLBL SERVICE STRATEGY MGR	PA-INDIANOLA
KING, JONI	SR SVC SUPP APPLICATIONS SPEC	PA-INDIANOLA
MAROLD, JOSEPH	ASSOC DIR BUS ANALYTICS	PA-INDIANOLA
ADAMS, BRADLEY	SQ EMBEDDED LEADER	PA-INDIANOLA
SPOHN, MICHAEL	DIR TECH	PA-INDIANOLA
HAURY, JOHN	DIR TECH	PA-INDIANOLA
BUTLER, SHONDA	CLIN STRAT ACCT MGR	PA-INDIANOLA
IDOON, BARRY	PRODUCT DEVELOPMENT LEAD ACTARGO	PA-INDIANOLA
STEFANIK, KIMBERLY	EXEC ASST	PA-INDIANOLA

DEDIG, JAMES	SR PRINCIPAL DESIGNER MECH	PA-INDIANOLA
SCHRIVER, RALPH	CHIEF ENG CV2	PA-INDIANOLA
JACK, TROY	SR DIRECTOR GBL REG OPS	PA-INDIANOLA
LEROCH, MATTHEW	HEAD EXTERNAL PARTNERSHIPS	PA-INDIANOLA
MYERS, ANDRE	ENG MECH	PA-INDIANOLA
BLUE, CHRISTOPHER	SR PRINCIPAL TECH MECH	PA-INDIANOLA
RHOADES, VALERIE	RAD SALES OPS ASSOC	PA-INDIANOLA
LEWIS, WILLIAM	SR PRINCIPAL TECH MFG	PA-INDIANOLA
DEWIT, RICHARD	SVP HEAD OF DIGITAL BUSINESS	PA-INDIANOLA
CRINER, FRANK	PROJ ENG	PA-INDIANOLA
KIMMEL, SHAWN	GLOBAL PRODUCT TEAM LEAD CV2	PA-INDIANOLA
TAGGART, BENJAMIN	ASSOC DIR TECH	PA-INDIANOLA
FAULK, JERRY	SR PRINCIPAL TECH	PA-INDIANOLA
MCWILLIAMS, JARRELL	HEAD ENGRG SYS AND V&V	PA-INDIANOLA
DICKERSON, BRIAN	SR PRINCIPAL ENG MFG	PA-INDIANOLA
DICKERSON, KARLA	CRITICAL ISSUE MGR	PA-INDIANOLA
JACKSON, RICHARD	SR PRINCIPAL TECH	PA-INDIANOLA
QUEER, FRED	ENG SYSTEMS V&V	PA-INDIANOLA
LI, YANG	HEAD LIFECYCLE ENGRG RAD CHINA	PA-INDIANOLA
JONES, DARREN	STAFF ENG SD	PA-INDIANOLA
SELLINGER, CLINTON	MGR GBL DEVICE LABELING STRAT	PA-INDIANOLA
FERCHAW, ERIC	DIR PLANT ENG	PA-INDIANOLA
RUOZZI, AMY	MACHINE OPR II	PA-INDIANOLA
KELLY, OLIVIA	MFG ASSOC I	PA-INDIANOLA
OMECINSKI, ROBERT	MACHINE OPR II	PA-INDIANOLA
GAISER, BRENT	SR TECH MAINT	PA-INDIANOLA
MAINHART, ROGER	SR PRINCIPAL TECH MAINT	PA-INDIANOLA
GASTECKI, JOHN	MACHINE OPR II	PA-INDIANOLA
MAINHART, LORI	RAD SUPP SPEC	PA-INDIANOLA
YOUNG, FRANK	ASSOC TECH	PA-INDIANOLA
SAKALA, DALLAS	PROC LEADER	PA-INDIANOLA
KURTZ, LINDA	MFG ASSOC I	PA-INDIANOLA
FYALA, CHRISTINE	MFG ASSOC I	PA-INDIANOLA
HUGHES, GARY	PRINCIPAL TECH MAINT	PA-INDIANOLA
WEIST, VALERIE	PRE STERILE II	PA-INDIANOLA
BEER, KIMBERLY	WHSE SPVR	PA-INDIANOLA
MULLER, KATHLEEN	MFG ASSOC I	PA-INDIANOLA
SMITH, BRANDY	QUAL COORD	PA-INDIANOLA
SWEENEY, LEIGH	MACHINE OPR II	PA-INDIANOLA
PENN, TIM	PRE STERILE I	PA-INDIANOLA
FANTUZZO, STEVEN	END TO END ANALYST	PA-INDIANOLA
HAZLETT, DEBBIE	PRE STERILE I	PA-INDIANOLA
SNYDER, MARSHA	PROC LEADER	PA-INDIANOLA
ROZZANO, MONICA	SUPV PROD	PA-INDIANOLA
ZAWALNICKI, KELLY	RAD SALES OPS SPEC	PA-INDIANOLA
ADKINS, JACILEE	QUAL LEAD DIG SOL	PA-INDIANOLA
BAILEY, BRYAN	DIR TECH	PA-INDIANOLA
PANAGIS, PANAYIS	DIR DIGITAL SOLUTIONS QUAL	PA-INDIANOLA
GOSDEN, EMMA	COMMERCIAL LEAD CELL GENE THERAPY NBD	PA-INDIANOLA
THOMPSON, VERONICA	PROC LEADER	PA-INDIANOLA
HERSMAN, NICHOLAS	DIR SVC ANALYTICS	PA-INDIANOLA
ADAMS, FRANCIS	SR MATERIAL HANDLER	PA-INDIANOLA
MITCHELL, JULIA	COMMERCIAL QUALITY MD LEAD	PA-INDIANOLA
KUBIAK, CAROL	SR TRNG COORD	PA-INDIANOLA
PANZA, BETH	MGR STRATEGIC INITIATIVES	PA-INDIANOLA
STANEK, GINA	ASSOC DIR SALES OPS	PA-INDIANOLA
NEFF, JARED	EXTERNAL MFG STRATEGY PROG LEAD	PA-INDIANOLA
KONDRICK, LISA	PROC CHG CTRL	PA-INDIANOLA
MCCLAIN, SUZETTE	SUPPLY CHAIN SPEC	PA-INDIANOLA
REMPER, JENNIFER	MFG ASSOC I	PA-INDIANOLA
GAYDOSH, LISA	PORTFOLIO DIR	PA-INDIANOLA
JASEK, JESSICA	DIR END TO END SUPPLY NETWORK	PA-INDIANOLA
HOBI, BERNARD	PRODUCT DEVELOPMENT LEAD CENTARGO	PA-INDIANOLA
DETOMA, JACOB	DIR SITE ENG INDIANOLA	PA-INDIANOLA
SMITH, JAMIE	PRE STERILE II	PA-INDIANOLA
SIDOOWAY, LYNN	SR DIR RADIOLOGY MST	PA-INDIANOLA
HODINKO, DOUGLAS	DIR END TO END SUPPLY NETWORK	PA-INDIANOLA
LAZZARA, CHRISTOPHER	COMMERCIAL LEAD PLCVFD	PA-INDIANOLA
LYONS, REDA	MACHINE OPR II	PA-INDIANOLA
KJANICA, MYRA	MFG ASSOC I	PA-INDIANOLA
BISHOP, KEVIN	MACHINE OPR II	PA-INDIANOLA
BOURQUIN, SUSAN	COMPLIANCE SPEC	PA-INDIANOLA
CAPONE, CHRISTOPHER	DIR TECH	PA-INDIANOLA
ORSAN, GERALD	GLOBAL PRODUCT TEAM LEAD CENTARGO	PA-INDIANOLA
GAISER, DALE	SR TECH MAINT	PA-INDIANOLA
PAKULSKI, DANICA	COMPLIANCE SPEC	PA-INDIANOLA
KUKIC, MISTY	STAFF SCIENTIST	PA-INDIANOLA
ROCKNEY, ALEXANDRA	DIR PORTFOLIO MARKETING	PA-INDIANOLA
BECKER, JOHN	PRINCIPAL TECH	PA-INDIANOLA
NEGLEY, NATHAN	PRINCIPAL TECH	PA-INDIANOLA
BROWN, RONALD	PRINCIPAL ENG ELECT	PA-INDIANOLA
CULLUM, LYNDA	PRE STERILE I	PA-INDIANOLA
MOCREA, LISA	SR TECH LAB	PA-INDIANOLA
LAWTHER, ROBERT	TECH APPLICATIONS SPEC	PA-INDIANOLA
MORTON, RICHARD	ASSOC DIR TECH	PA-INDIANOLA
MCDANEL, JOSHUA	SR PRINCIPAL TECH	PA-INDIANOLA
HUTELMYER, ANDREW	PRODUCT DEVELOPMENT LEAD CEVEGO	PA-INDIANOLA
ZOWACKI, MICHELLE	PS PROGRAM LEAD	PA-INDIANOLA
ARMSTRONG, MELISSA	ENGAGEMENT MGMT SQUAD LEAD	PA-INDIANOLA

OSBORNE, DANIEL	SR DIR INDIANOLA SC	PA-INDIANOLA
SHRIRAM, SRI	PL MRXP SSEP INTEGO	PA-INDIANOLA
TOTZKE, HENRY	R&D QUALITY LEAD	PA-INDIANOLA
MERRITT, JAMES	PRINCIPAL ENG ELEC	PA-INDIANOLA
DEROSA, DARRYL	SR CTRLR AMERICAS	PA-INDIANOLA
CACKOVIC, EDWARD	SR PROJ MGR MFG	PA-INDIANOLA
SEMAN, RICHARD	TECHNICAL DIR SD	PA-INDIANOLA
BOYLE, MATTHEW	SR DIR SUPPLIER QUAL RAD	PA-INDIANOLA
MCKASKLE, JENNIFER	DIR STRATEGIC ALLIANCE	PA-INDIANOLA
CIMADOR, JANICE	PRE STERILE I	PA-INDIANOLA
BAN, JOSEPH	MFG ASSOC I	PA-INDIANOLA
MCGRANAHAN, GAYLE	SR MATERIAL HANDLER	PA-INDIANOLA
DESENSI, FRANCESCO	HEAD DIGITAL SOLUTIONS TECH SW DEVP	PA-INDIANOLA
JULIUS, KIERA	PRINCIPAL ENG	PA-INDIANOLA
LIZIK, HEATHER	SOLUTIONS SQUAD LEAD BREAST	PA-INDIANOLA
TRAN, TUAN	PROGRAM DIR LCE	PA-INDIANOLA
CAVANAUGH, CHRISTOPHER	PRINCIPAL ENG DEVICE PROC MFG	PA-INDIANOLA
SWANTNER, MICHAEL	ASSOC DIR	PA-INDIANOLA
MERCHANT, ROBERT	SR MATERIAL HANDLER	PA-INDIANOLA
HAZLET, JODEE	SVC CONTRACT DATA MGMT SPEC	PA-INDIANOLA
VOLKAR, JOHN	SR DIR DEVICE EARLY DEVP	PA-INDIANOLA
TWOMBLY, SAMANTHA	PROC LEADER	PA-INDIANOLA
ALLWORTH, DARREN	SR MATERIAL HANDLER	PA-INDIANOLA
MACLEOD, DAVID	SR MATERIAL HANDLER	PA-INDIANOLA
ZEVOLA, NICOLE	RAD SALES OPS SPEC	PA-INDIANOLA
STEFFEN, CINDY	GLOBAL PORTFOLIO LEAD	PA-INDIANOLA
EISEMAN, MARSHALL	MGR NA DIGITAL SUPP	PA-INDIANOLA
CAMPBELL, PATRICK	PRINCIPAL ENG MECH	PA-INDIANOLA
SALUNKHE, BIPIN	HEAD DEVICE RSRCH DEVP	PA-INDIANOLA
SIMS, SHELLEY	SUPPLY CHAIN SPEC II	PA-INDIANOLA
KNOX, JENNIFER	RAD SALES OPS ASSOC	PA-INDIANOLA
SRIVASTAVA, ABHINAV	DIR ENG QUAL	PA-INDIANOLA
ZAPATKA, EVELINA	LEAD ESM DEVICE	PA-INDIANOLA
DEROSE, MATTHEW	HEAD CUST ENGAGEMENT MGMT	PA-INDIANOLA
OWENS, CHRISTOPHER	STRATEGY MANAGER	PA-INDIANOLA
ZIER, JASON	PRINCIPAL ENG SYSTEMS V&V	PA-INDIANOLA
GROVE, MICHAEL	ASSOC DIR EXTERNAL MFG	PA-INDIANOLA
MOHRBACH, ROBERT	SR PRINCIPAL TECH	PA-INDIANOLA
EVANS, BRITNEY	MGR SUPPLY CHAIN	PA-INDIANOLA
KAMEL, MAGED	R&D QUALITY LEAD	PA-INDIANOLA
HEINRITZ, CHRISTOPHER	PRINCIPAL ENG QUAL	PA-INDIANOLA
PICHORA, KRISTIN	PORTFOLIO ASSOC DIR MKTG	PA-INDIANOLA
OLAYER, MATTHEW	OE SITE CLUSTER III LEAD	PA-INDIANOLA
ECKMAN, TODD	SR PLANNER	PA-INDIANOLA
DAVIS, MEGAN	PORTFOLIO ASSOC DIR MKTG	PA-INDIANOLA
GRUMSKI, JOSHUA	FIELD FORCE EFFECTIVENESS CUST EXCEL	PA-INDIANOLA
SHAULIS, STEPHANIE	DIR ENG CAPA QUAL	PA-INDIANOLA
NUSSKERN, DAVID	PROD TEAM FIN BUS PARTNER PH PS	PA-INDIANOLA
SPENCE, PATRICK	ASSOC DIR EXTERNAL MFG	PA-INDIANOLA
RUFFIN, JOHNNIE	SR STAFF ENG	PA-INDIANOLA
PRICE, CORY	STAFF ENG MFG	PA-INDIANOLA
PAKULSKI, JEFFREY	STAFF ENG QUAL	PA-INDIANOLA
KETZEL, PHILIP	ASSOC DIR EXTERNAL MFG	PA-INDIANOLA
WILLIAMS, CHAD	HEAD RADIOLOGY CYBER SECURITY	PA-INDIANOLA
JOSEPH, TIMOTHY	PROG DIR	PA-INDIANOLA
WRIGHT, CHRISTOPHER	VENTURE MGR	PA-INDIANOLA
HUGHES, JOHN	TECH MAINT	PA-INDIANOLA
MOHRBACH, AMANDA	SR MGR SAP PROCESS	PA-INDIANOLA
TAPPE, ILZE	ASSOC TECH	PA-INDIANOLA
CHRISTIE, RYAN	DATA SCIENCE & CUSTOMER INSIGHTS	PA-INDIANOLA
DOTSON, RICHARD	STAFF ENG SW	PA-INDIANOLA
PATTERSON, JON	ASSOC DIR SALES OPS ANALYTICS	PA-INDIANOLA
LOCKWARD, SHANON	RAD SALES OPS SPEC	PA-INDIANOLA
HUA, PING	MFG ASSOC I	PA-INDIANOLA
DEVIDO, LAUREN	SR DIGITAL TECH SPEC	PA-INDIANOLA
SMATHERS, JASON	SR STAFF ENG	PA-INDIANOLA
COOPER, DAVID	SR TECH QUAL LAB	PA-INDIANOLA
JULIANO, MARK	MGR PROJ ENG QUAL	PA-INDIANOLA
STEHLE, WILLIAM	STAFF ENG MFG	PA-INDIANOLA
PFAFF, JOHN	SR STAFF ENG SW	PA-INDIANOLA
RAULUK, ALEXANDRA	PROFESSIONAL SVCS SQUAD LEAD	PA-INDIANOLA
LIGHTNER, DONNA	PRE STERILE II	PA-INDIANOLA
ROEPCKE, KAIANNA	QC MICROBIOLOGY MD LEAD	PA-INDIANOLA
KAPP, DANA	RAD SALES OPS SPEC	PA-INDIANOLA
HEID, CHARLES	DIR EXTERNAL MFG ASIA PACIFIC	PA-INDIANOLA
SMITH, STEPHEN	DIR MA OPS AND SYS MGMT	PA-INDIANOLA
BELILES, KEVIN	SR ENG SYS	PA-INDIANOLA
FADDISH, LAUREN	PS PROGRAM LEAD	PA-INDIANOLA
HOSTETLER, SHANE	RAD CUSTOMER PROCESS MGR	PA-INDIANOLA
BOSER, EMILY	ASSOC DIR INFORMATICS PROJ MGR	PA-INDIANOLA
MOOREHEAD, JOSEPH	PROCESS LEADER	PA-INDIANOLA
ECKERT, DIANE	CLIN COMPLIANCE LEAD	PA-INDIANOLA
GOVERT, EARL	TECH TRNG EXPERT	PA-INDIANOLA
TOLA, AMY	PRINCIPAL ENG RISK MGMT	PA-INDIANOLA
PETRILLI, JANEL	NA CORE PH CH IMPLEMENTATION LEAD	PA-INDIANOLA

4X

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH N/A	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Bayer Medical Care Inc.

Physical Address: 625 Alpha Dr

City: Pittsburgh State: PA Zip: 15238

Mailing Address (if different from physical address): c/o State License Servicing, Inc., 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: radiology.bayer.com

Name of Designated Representative (DR): Sean Connelly Sullivan

Licensing Company Email: BMC@slsny.com DR Email: sean.sullivan@bayer.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Clinics, Institutions, US Government		☒ Others: Manufacturer - Own Label

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A No Discipline to report

Kathleen Ann Durst

Original Signature (electronic, copies or stamps not accepted)

02/17/20

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A
Address: _____ City: _____ State: _____ Zip: _____
Name: N/A
Address: _____ City: _____ State: _____ Zip: _____
Name: N/A
Address: _____ City: _____ State: _____ Zip: _____
Name: N/A
Address: _____ City: _____ State: _____ Zip: _____

N/A **Section 4: Publicly Traded Corporation**

State of Incorporation: _____
Parent Company (if any): _____
Corporation Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): Schering Berlin Inc.
Corporation/Organization Name: Bayer Medical Care Inc.
Mailing Address: c/o State License Servicing, Inc. 225 Dolson Avenue, 4th Floor
City: Middletown State: NY Zip: 10940
Telephone: (845) 544-2482 Email: BMC@slsny.com
Contact Person Name: Christine Cannon

N/A **Section 6: Partnership**

Partnership Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

N/A **Section 7: Sole Owner**

Owner's Name: _____
Business Name: _____
Business Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: FDA #: 3004056159	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Bayer Medical Care Inc.

Facility Name

Kathleen Ann Dunst

Print Name of Authorized Person Submitting Application

Kathleen Ann Dunst — Original signature of Authorized Person (copies or stamps not accepted)

2/17/26 — Date

Board Use Only	Date Received: 2/5/26	Amount: $1000 Ck 703

Proof of FDA

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
Bayer Medical Care Inc.
625 Alpha Dr
Pittsburgh, PA 15238
Registration Number: 3004056159
FEI Number*: 3004056159
Status: Active
Date Of Registration Status: 2026

Owner/Operator:
Bayer Medical Care Inc.[6]
1 Bayer Drive
Indianola, PA US 15051
Owner/Operator Number: 2520313[7]

Official Correspondent:
Troy A Jack
1 Bayer Drive
Indianola, PA 15051
Phone: 412-3528260

* Firm Establishment Identifier (FEI) should be used for identification of entities within the Imports message set

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Verified 3/6/26 M.H

Page Last Updated: 12/08/2025

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2520313&OwnerOperatorName=&ProductCode=&Devicel

Bayer Medical Care Inc.

Corporate Address: 1 Bayer Drive, Indianola, PA 15051 USA
FEIN: 25-1151038
radiology.bayer.com

Drug Labeler Code: N/A
Incorporation State: DE
Incorporation Date: 1/25/1996

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
ADP	625 Alpha Dr Pittsburgh, PA 15238 County: O'Hara Twp - Allegheny Cty	3004056159	N/A - No CS	809561884	No	(412) 767-2400	N/A

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Sean Connelly Sullivan	[redacted]	President	No	[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Schering Berlin Inc.	100 Bayer Blvd. Whippany, NJ 07981	N/A	100%	N/A	14-1585871	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Sean Connelly Sullivan	[redacted]	President	No	[redacted]		
Kathleen Ann Dunst		Secretary				
Kristin Zimmerman		Assistant Secretary				
Jeff McFarland		Tax Officer				
Darcey Livingston Rhoades		Assistant Secretary	No	[redacted]		
Maria del Rocio Romero Alonzo		Treasurer				
David Schramm		Assistant Secretary				

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
Corporation Service Company			

Company Particulars

Incorp Good Standing

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BAYER MEDICAL CARE INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SECOND DAY OF FEBRUARY, A.D. 2026.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203161255

Date: 02-22-26

2585748 8300

SR# 20260713668

You may verify this certificate online at corp.delaware.gov/authver.shtml

Verification of Home State License (PA)

Pennsylvania Department of Health

Pennsylvania Department of Health

Drug, Device and Cosmetic Program

Version 4.0.0

Enter the 10-digit Certificate Number or Registrant's Name (or first few letters).

Lookup

Description of Certificate Categories

You may contact our office at (717) 787-4779 if the Certificate Number/Registrant you are researching is not found.

Bayer Medical Care Inc. 625 Alpha Drive; Pittsburgh, PA 15238
Certificate(s): **6000006348** issued: 11/19/2003 expires: 12/31/2026

The entity noted above holds an active registration and/or license with the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program.

No formal probation, suspension, revocation, or formal disciplinary action has been issued directly by the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program against the aforementioned specific registration and/or license. Contact the DDC program with any further questions at (717) 787-4779 or email: ra-ddc@pa.gov

Back to DD&C Home

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Bureau of Community Program Licensure and Certification : Drug, Device and Cosmetic Program : Quality Assurance

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Assembly Version 4.0.0.0

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Certificate of Registration

Certificate No. 6000006348
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Category:

Devices

Drug & Device Registration

2525 N. 7th Street Suite 210D
Harrisburg, PA 17110
(717) 787-4779

BAYER MEDICAL CARE INC.
625 ALPHA DRIVE
PITTSBURGH, PA 15238

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64, approved September 9, 1972.

Issuance Date: November 19, 2003
Expiration Date: The Last Day of December, 2026

Jeanne Parisi
Deputy Secretary for Quality Assurance

Pennsylvania
Department of Health

Debra L. Bogen, MD, FAAP
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

HS License

Cert. of Liability Ins.

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 05/16/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA, LLC. 800 Market Street, Suite 1800 St. Louis, MO 63101-2500 CN102140943--GAW5-25-26	CONTACT NAME: Marsh | U.S. Operations & Technology PHONE (A/C, No, Ext): 866-966-4664 FAX (A/C, No): E-MAIL ADDRESS: StLouis.CertRequest@marsh.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : HDI Global Insurance Co.	41343
INSURED Bayer Medical Care, Inc. c/o Bayer Corporation 800 N. Lindbergh Blvd. St. Louis, MO 63167	INSURER B : Old Republic Insurance Company	24147
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** CHI-010936504-00 **REVISION NUMBER:** 0

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			GLD1136616	04/01/2025	04/01/2026	EACH OCCURRENCE	$ 5,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 5,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 5,000,000
	OTHER:							$
B	AUTOMOBILE LIABILITY			MWTB 319159 25	04/01/2025	04/01/2026	COMBINED SINGLE LIMIT (Ea accident)	$ 2,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N			MWC 319158 25	04/01/2025	04/01/2026	X PER STATUTE ☐ OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N/A					E.L. EACH ACCIDENT	$ 2,000,000
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 2,000,000
							E.L. DISEASE - POLICY LIMIT	$ 2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Bayer Medical Care, Inc.
1 Bayer Drive
Indianola, PA 15051

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA LLC

Marsh USA LLC

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Bond

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 014262618

Application/License No. _____

Bayer Medical, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1 Bayer Drive, Indianola, PA 15051; 150 Victory Road, Saxonburg, PA 16056; 625 Alpha Drive, Pittlsburg, PA 15238 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street, Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 13, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 13th day of August, 2025.

APPLICANT/PRINCIPAL

Jennifer Watterson
Authorized Representative

SURETY COMPANY

Surety Company's Representative

Kathleen K. Freund, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Alexandra Johnson
Witness

Witness

SIGNED and SEALED in the presence of:

Merdi Bolles
Witness

Terrence P. Freund
Witness

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

Liberty Mutual SURETY

POWER OF ATTORNEY

Certificate No 8204866

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint,

Kathleen K. Freund

all of the city of Denver, state of CO each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of July, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 1st day of July, 2024, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 13th day of August 2025.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Bayer Medical Care Inc. MDEG License # (if applicable): _____

Physical Address: 625 Alpha Dr

City: Pittsburgh State: PA Zip: 15238

Mailing Address (if different from physical address): c/o State License Servicing, Inc. 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: radiology.bayer.com

Licensing Company Email: BMC@slsny.com

Section 2: Personal Information

First: Sean Middle: Connelly Last: Sullivan

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Pittsburgh State: PA Zip: [redacted]

Telephone: [redacted] Email: sean.sullivan@bayer.com

Are you a citizen of the United States? × Yes | No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The University of Pittsburgh – Katz Graduate School of Business		1/08 - 6/09	
Address	**City**	**State**	**Zip**
3950 Roberto Clemente Dr	Pittsburgh	PA	15260
Diploma/Degree obtained, if any			
Executive Masters in Business Administration (EMBA)			

School Name		From - To (MM/YY – MM/YY)	
The Pennsylvania State University		08/98 - 12/02	
Address	**City**	**State**	**Zip**
201 Old Main	University Park	PA	16802
Diploma/Degree obtained, if any			
B.S. Industrial Engineering			

School Name		From - To (MM/YY – MM/YY)	
Upper St. Clair High School		8/94 - 6/98	
Address	**City**	**State**	**Zip**
1825 McLaughlin Run Rd.	Pittsburgh	PA	15241
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2009 - Present	[redacted]	Pittsburgh	PA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Bayer Medical Care Inc.			02/2005 - Present	
Business Address		City	State	Zip
625 Alpha Drive		Pittsburgh	PA	15238
Phone	Title		Number of Employed Hours	
(412) 580-1334	President		~ 43,330 hours	
Description of Duties				
Responsible for two production sites on two different continents (North America and Australia) which consistently deliver on financial and production budgets/targets, Drove organizational acceptance and subsequent implementation of a reverse logistics, Accountable for 200 FTE's, over $30MM in yearly departmental and plant expenses and $2MM in yearly plant capital expenditures.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Sean Connelly Sullivan, **certify that as the MDEG Administrator for**

Bayer Medical Care Inc.,

that I (initial that you have read and meet the following requirements):

1. SCS Have a high school diploma or its equivalent;
2. SCS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SCS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SCS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sean, Sullivan
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/5/2026
Date

Board Use Only	Date Received: 3/5/26

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Bayer Medical Care Inc.

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 625 Alpha Dr

City: Pittsburgh State: PA Zip: 15238

Mailing Address (if different from physical address): c/o State License Servicing, Inc. 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: radiology.bayer.com

Licensing Company Email: BMC@slsny.com

Section 2: Personal Information

First: Sean Middle: Connelly Last: Sullivan

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Pittsburgh State: PA Zip: [redacted]

Telephone: [redacted] Email: sean.sullivan@bayer.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The University of Pittsburgh – Katz Graduate School of Business		01/08 06/09	
Address	**City**	**State**	**Zip**
3950 Roberto Clemente Dr	Pittsburgh	PA	15260
Diploma/Degree obtained, if any			
Executive Masters in Business Administration (EMBA)			

School Name		From - To (MM/YY – MM/YY)	
The Pennsylvania State University		08/98 - 12/02	
Address	**City**	**State**	**Zip**
201 Old Main	University Park	PA	16802
Diploma/Degree obtained, if any			
B.S. Industrial Engineering			

School Name		From - To (MM/YY – MM/YY)	
Upper St. Clair High School		8/94 - 6/98	
Address	**City**	**State**	**Zip**
1825 McLaughlin Run Rd.	Pittsburgh	PA	15241
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2009 - Present	[redacted]	Pittsburgh	PA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Bayer Medical Care Inc.			02/2005 - Present	
Business Address		City	State	Zip
625 Alpha Dr		Pittsburgh	PA	15238
Phone	Title		Number of Employed Hours	
(412) 767-2400	President		~ 43,330 hours	
Description of Duties				
Responsible for two production sites on two different continents (North America and Australia) which consistently deliver on financial and production budgets/targets, Drove organizational acceptance and subsequent implementation of a reverse logistics, Accountable for 200 FTE's, over $30MM in yearly departmental and plant expenses and $2MM in yearly plant capital expenditures.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Sean Connelly Sullivan, **certify that as the designated representative for**

Bayer Medical Care Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sean Connelly Sullivan
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/5/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sean Connelly Sullivan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/5/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Allegheny

I, Sean Connelly Sullivan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature Sean Connelly Sullivan

2/5/2026

Date

Subscribed and Sworn to before me this 5th day of February.

Kimberly A Stefanik

Notary Public Signature

(Seal)

Commonwealth of Pennsylvania - Notary Seal
Kimberly A. Stefanik, Notary Public
Allegheny County
My commission expires November 10, 2028
Commission number 1210908

Member, Pennsylvania Association of Notaries

List of Employees

Name	Position Title	Personnel Area Desc
BECKOM-BARRON, SEANDEL	MFG ASSOC II	PA-PITTSBURGH OHARA
ARNOLD, KESHAUN	MFG ASSOC II	PA-PITTSBURGH OHARA
NUZUM, LUCAS	SR BUYER	PA-PITTSBURGH OHARA
SOSA, SONIA	MFG SPEC III	PA-PITTSBURGH OHARA
ROJAS PEREZ, IRIS	MFG ASSOC III	PA-PITTSBURGH OHARA
BRIGHT, JAICE	DOCUMENTATION SPEC	PA-PITTSBURGH OHARA
HOPPER, DAVID	MFG ASSOC III	PA-PITTSBURGH OHARA
SANTANA, HIRAM	MFG ASSOC III	PA-PITTSBURGH OHARA
ABRAHAM, ALLISON	SR BUYER	PA-PITTSBURGH OHARA
WALKER, DAWN	MFG ASSOC III	PA-PITTSBURGH OHARA
SHAKER, FARHAD	SR MATERIAL HANDLER	PA-PITTSBURGH OHARA
WOODWARD, MATTHEW	MFG ASSOC III	PA-PITTSBURGH OHARA
WHITMAN, MARIAH	MFG ASSOC III	PA-PITTSBURGH OHARA
NORTON, RYAN	BUYER II	PA-PITTSBURGH OHARA
BELLISSIMO, CHRISTOPHER	ASSOC TECH SVC	PA-PITTSBURGH OHARA
MORENO, DEYMARIS	MFG SPEC	PA-PITTSBURGH OHARA
KORCZYNSKI, CHAD	MATL LOG SPEC	PA-PITTSBURGH OHARA
CROSSEY, RYAN	SR PROC LEADER	PA-PITTSBURGH OHARA
GEORGE, ANGIE	SR MATERIAL HANDLER	PA-PITTSBURGH OHARA
GUZOWSKI, ROBERT	SR MATERIAL HANDLER	PA-PITTSBURGH OHARA
FLICKINGER, TREVOR	QUALITY COORDINATOR	PA-PITTSBURGH OHARA
NICHOLSON, JAN	PRINCIPAL TECH SVC	PA-PITTSBURGH OHARA
RZOTKIEWICZ, JUSTIN	PROJ ENG	PA-PITTSBURGH OHARA
LUBIC, NICHOLAS	SR PROJ MGR	PA-PITTSBURGH OHARA
GRAHAM, WILLIAM	PRINCIPAL TECH ELEC	PA-PITTSBURGH OHARA
CARTER, CHERICE	MFG ASSOC III	PA-PITTSBURGH OHARA
SCHRAG, LORRIE	TECH QUAL	PA-PITTSBURGH OHARA
STONER, DARLA	MFG ASSOC III	PA-PITTSBURGH OHARA
TOVAR, ADRIANA	COS COMM OPS AMERICAS	PA-PITTSBURGH OHARA
WOOD, LAYNE	LOG EXECUTION ANALYST	PA-PITTSBURGH OHARA
KRAUS, KURT	SR MATERIAL HANDLER	PA-PITTSBURGH OHARA
GREIL, COURTNEY	OE SPECIALIST 1	PA-PITTSBURGH OHARA
GARVEY, JUSTIN	SUPPLY CHAIN MGR I	PA-PITTSBURGH OHARA
DAFNER, STEPHEN	LOGISTICS MGR RAD	PA-PITTSBURGH OHARA
SCOTT, MATTHEW	PROC LEADER	PA-PITTSBURGH OHARA
SUCHEVICH, AMANDA	PROJ ENG QA & CM	PA-PITTSBURGH OHARA
BYLER, ERIC	SR PRINCIPAL TECH ENGRG	PA-PITTSBURGH OHARA
LAIN, EMILY	PROJ ENG	PA-PITTSBURGH OHARA
QU, YUAN	STAFF ENG ELEC	PA-PITTSBURGH OHARA
CATALANE, DANIEL	SR PLANNER	PA-PITTSBURGH OHARA
KASPRZYK, DYLAN	STAFF ENG TEST VALID ACCEPT	PA-PITTSBURGH OHARA
MACASAET, DANILO	PROJ MGR MFG	PA-PITTSBURGH OHARA
JACK, EMILY	MFG ASSOC III	PA-PITTSBURGH OHARA
WILLIAMS, JUSTIN	TRNG COORD	PA-PITTSBURGH OHARA
SMITH, TYLER	SR ENG TECH MFG	PA-PITTSBURGH OHARA
GOELLER, JESSICA	PROJ MGR	PA-PITTSBURGH OHARA
GROHOLSKI, VICTORIA	REGIONAL COORDINATOR USA	PA-PITTSBURGH OHARA
BARNES, BENJAMIN	MFG SPEC	PA-PITTSBURGH OHARA
COULTER, BILLIE	MFG ASSOC II	PA-PITTSBURGH OHARA
DIEHL, CAROLE	MATL LOG SPEC	PA-PITTSBURGH OHARA
DRESSEL, CHAD	SR TECH FAC	PA-PITTSBURGH OHARA
LONG, CHARLES	SR ENG TECH MFG	PA-PITTSBURGH OHARA
RUTKOWSKI, CHRISTOPHER	TECH FAC	PA-PITTSBURGH OHARA
CORSI, CHRISTINA	EXEC ASST SITE COORD	PA-PITTSBURGH OHARA
OCONNOR, CODY	MFG ASSOC III	PA-PITTSBURGH OHARA
MARROW, COURTLAND	MFG ASSOC III	PA-PITTSBURGH OHARA
FELTON, DAVID	STAFF ENG	PA-PITTSBURGH OHARA
WAGONER, MARSHALL	ASSEMBLER II	PA-PITTSBURGH OHARA
GUNTRUM, DONNA	SUPR SERVICE DEPOT	PA-PITTSBURGH OHARA
COMINSKY, DOUGLAS	SR TECH SVC	PA-PITTSBURGH OHARA
BRINK, ERIKA	MFG ASSOC III	PA-PITTSBURGH OHARA
LUZIK, JACOB	SR MATERIAL HANDLER	PA-PITTSBURGH OHARA
WEISBERG, JEFFREY	MFG ASSOC III	PA-PITTSBURGH OHARA
HOLTHAUS, JORDAN	PROJ ENG	PA-PITTSBURGH OHARA
PECK, KATELYN	ASSOC TECH SVC	PA-PITTSBURGH OHARA
SERAFIN, KAYLEIGH	SR BUYER	PA-PITTSBURGH OHARA
ZAJAC, KIMBERLY	PROJ SPEC	PA-PITTSBURGH OHARA
BLACK, MARINA	MFG SPEC	PA-PITTSBURGH OHARA
YUHAS, MARTIN	ASSOC DIR ENGRG	PA-PITTSBURGH OHARA
GEORGE, MICHAEL	MGR FAC	PA-PITTSBURGH OHARA

PELIKAN, MICHAEL	SUPR PROD	PA-PITTSBURGH OHARA
BOWMAN, NICKOLAS	MATL LOG SPEC	PA-PITTSBURGH OHARA
RIZZUTO, OLIVIA	SR BUYER	PA-PITTSBURGH OHARA
LEONE, PATRICIA	MFG ASSOC III	PA-PITTSBURGH OHARA
GARLAND, PRAISE	MFG ASSOC II	PA-PITTSBURGH OHARA
OZMELEK, BENJAMIN	DIR ENG QUAL EM	PA-PITTSBURGH OHARA
JACK, RUSSELL	ASSOC TECH SVC	PA-PITTSBURGH OHARA
PENN, RYAN	MFG ASSOC II	PA-PITTSBURGH OHARA
BAUM, SAMUEL	ASSOC ENG	PA-PITTSBURGH OHARA
HARVANEK, SARAH	BUYER II	PA-PITTSBURGH OHARA
WOJTKIEWICZ, ANTHONY	SR MATERIAL HANDLER	PA-PITTSBURGH OHARA
AIRHART, PATRICIA	EXPORT MGMT SPEC II	PA-PITTSBURGH OHARA
SCHWENNING, TYLER	SR TECH	PA-PITTSBURGH OHARA
SCHETLIN, TYLER	TECH MACHINE SHOP	PA-PITTSBURGH OHARA
VASUDEVAN, CHANDRASEKARAN	ASSOC DIR ENG TEST	PA-PITTSBURGH OHARA
EDGAR, VINCENT	SR ENG SUPP QUAL	PA-PITTSBURGH OHARA
BOLDEN, ODA	SITE LOG POOL LEAD OHARA	PA-PITTSBURGH OHARA
YOCKEL, MICHAEL	PRINCIPAL ENG QUAL	PA-PITTSBURGH OHARA
EMELOFF, MICHAEL	PRINCIPAL ENG TECH MFG	PA-PITTSBURGH OHARA
NEFF, KIMBERLY	SR PLANNER	PA-PITTSBURGH OHARA
VOECKEL, KIRK	SVC SPEC	PA-PITTSBURGH OHARA
MITCHELL, JENNIFER	EXPORT MGMT SPEC II	PA-PITTSBURGH OHARA
PAPCUN, GEORGE	PROG DIR RAD CONFIG MGT	PA-PITTSBURGH OHARA
SMELTZER, DONALD	PRINCIPAL ENG TECH MFG	PA-PITTSBURGH OHARA
PARIS, KATHY	SR SVC SUPP SPEC	PA-PITTSBURGH OHARA
CELLUCCI, RICHARD	PRINCIPAL TECH SVC	PA-PITTSBURGH OHARA
SKOFF, ARTHUR	PRINCIPAL TECH SVC	PA-PITTSBURGH OHARA
CARVELL, BARBARA	QUALITY COORDINATOR	PA-PITTSBURGH OHARA
MCSWEENY, ROBIN	QUALITY COORDINATOR	PA-PITTSBURGH OHARA
YOUNG, JUNE	ASSOC TECH MACHINE SHOP	PA-PITTSBURGH OHARA
MOONEY, DONNA	MFG ASSOC III	PA-PITTSBURGH OHARA
PHILLIPPI, KIMBERLY	ASSOC LOG OPS COORD	PA-PITTSBURGH OHARA
ZAK, PAMELA	SR MATERIAL HANDLER	PA-PITTSBURGH OHARA
JERICH, CATHERINE	MFG ASSOC III	PA-PITTSBURGH OHARA
MCCUTCHEON, KAREN	SR PRINCIPAL DOC SPEC	PA-PITTSBURGH OHARA
YAKSETICH, DAVID	SR MATERIAL HANDLER	PA-PITTSBURGH OHARA
NICHOLSON, JAMES	SR TECH SVC	PA-PITTSBURGH OHARA
IMM, DONALD	MFG ASSOC III	PA-PITTSBURGH OHARA
TALIANI, MARIO	SR TECH MFG	PA-PITTSBURGH OHARA
BANN, MICHAEL	MFG ASSOC III	PA-PITTSBURGH OHARA
DUBOIS, SUSAN	SR SUPPLY CHAIN SPEC	PA-PITTSBURGH OHARA
ADAMS, CHRISTOPHER	PRINCIPAL TECH MFG	PA-PITTSBURGH OHARA
PINGLEY, TODD	QUALITY PROCESS SPECIALIST	PA-PITTSBURGH OHARA
SIMMONS, KEITH	PROJ SPEC	PA-PITTSBURGH OHARA
BLOUGH, STEVEN	PRINCIPAL ENG SOFTWARE	PA-PITTSBURGH OHARA
TOWNSEND, TOBI	MFG ASSOC III	PA-PITTSBURGH OHARA
TOURRE, HEATHER	DIR QUAL SITE OHARA	PA-PITTSBURGH OHARA
WOLFE, LYNN	PRINCIPAL TECH QUAL	PA-PITTSBURGH OHARA
STURM, CHRISTOPHER	SR MATERIAL HANDLER	PA-PITTSBURGH OHARA
ARENSBERG, RICHARD	SR TECH ELEC	PA-PITTSBURGH OHARA
HARMON, CLYDE	SR MATERIAL HANDLER	PA-PITTSBURGH OHARA
HARE, JAMES	SR MATERIAL HANDLER	PA-PITTSBURGH OHARA
SULLIVAN, SEAN	VP SITE OHARA	PA-PITTSBURGH OHARA
BERDIK, STEFICA	SR PROC LEADER	PA-PITTSBURGH OHARA
URIK, KRISTI	LOG EXECUTION ANALYST	PA-PITTSBURGH OHARA
MISNER, JASON	QUALITY COORDINATOR	PA-PITTSBURGH OHARA
BARRACLOUGH, FREDRICK	QUALITY COORDINATOR	PA-PITTSBURGH OHARA
FLOCCARI, MARY	LOG EXECUTION ANALYST	PA-PITTSBURGH OHARA
IMM, BLAINE	PRINCIPAL TECH MFG	PA-PITTSBURGH OHARA
PAULL, BRANDIS	ASSOC DIR OF QUALITY	PA-PITTSBURGH OHARA
ZANOTTI, JASON	LOG OPS COORD	PA-PITTSBURGH OHARA
COLLINS, ERICA	QUALITY COORDINATOR	PA-PITTSBURGH OHARA
BRADMON, BRYAN	SR PROJ MGR	PA-PITTSBURGH OHARA
COOPER, JAMES	QUALITY COORDINATOR	PA-PITTSBURGH OHARA
BUMBERA, JESSICA	SITE HSE MGR	PA-PITTSBURGH OHARA
HENDRICKSON, JENNIFER	PRINCIPAL DOCUMENTATION SPEC	PA-PITTSBURGH OHARA
WARREN, SEAN	SR TECH	PA-PITTSBURGH OHARA
SHINE, RUSSELL	SR TECH SVC	PA-PITTSBURGH OHARA
SMITH, TRACI	PRINCIPAL ENG	PA-PITTSBURGH OHARA
DALOISE, KIMBERLY	PROJ ENG	PA-PITTSBURGH OHARA

4Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: CARL ZEISS MEDITEC USA, INC.

Physical Address: 5300 CENTRAL PARKWAY

City: DUBLIN State: CA Zip: 94568

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-341-6968 Website: www.zeiss.com/med

Name of Designated Representative (DR): JOANNA CHOW

Licensing Company Email: state.licenses.med.us@zeiss.co DR Email: joanna.chow@zeiss.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
8/14/23		NV	RENO	WASHOE

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
23-039-O	Nevada Board of Pharmacy

Reason/Charge
Unlicensed furnishing of prescription medical devices

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Carl Zeiss Meditec USA, Inc.	N/A

Name of Business/Industry/Entity
Carl Zeiss Meditec USA, Inc.

Provide explanation below:

On August 14, 2023, Carl Zeiss Meditec USA, Inc. (CZMU) was cited for the unlicensed furnishing of medical devices to persons in Nevada and was issued an order by the Nevada State Board of Pharmacy (NV BOP) to cease and desist furnishing prescription devices to persons in Nevada. The Board assessed an administrative fine against CZMU in the amount of $5000.00. CZMU paid the fine assessed, and on August 16, 2023 we ceased all shipment of devices into Nevada.

In consultation with the NV BOP, we were able to rectify the matter and obtain an appropriate wholesale license to resume business in the State by September 12, 2023.

Original Signature (electronic, copies or stamps not accepted)

01/14/26
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: CARL ZEISS MEDITEC, INC.

Address: 5300 CENTRAL PKWY City: DUBLIN State: CA Zip: 94568

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NEW YORK

Parent Company (if any): CARL ZEISS MEDITEC, INC.

Corporation/Organization Name: CARL ZEISS MEDITEC USA, INC.

Mailing Address: 5300 CENTRAL PARKWAY

City: DUBLIN State: CA Zip: 94568

Telephone: 925-557-4100 Email: irene.ruether@zeiss.com

Contact Person Name: IRENE RUETHER

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓ N/A	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓ N/A	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓ N/A	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓ N/A	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓ N/A	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

CARL ZEISS MEDITEC USA, INC.

Facility Name

FEDERICO VILLEGAS

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

01/14/26

Date

Board Use Only	Date Received: 1/20/26	Amount: $1000.00

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
CARL ZEISS MEDITEC USA, INC.
5300 Central Pkwy
Dublin, CA 94568
Registration Number: 3041396758
FEI Number*: 3041396758
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2026

Owner/Operator:
Carl Zeiss Meditec, Inc.[6]
5300 Central Parkway
Dublin, CA US 94568
Owner/Operator Number: 9053564[7]

Official Correspondent:
Paul Swift
5300 Central Parkway
Dublin, CA 94568
Phone: 01-817-9258507

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9053564&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9053564&OwnerOperator

Page Last Updated: 02/09/2026

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsc | 日本語 | فارسی | English

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of **Health & Human Services**

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9053564&OwnerOperator

Applicant: Carl Zeiss Meditec USA, Inc.

Re: Name and title of each corporate officer and director

Directors:	Justus Wehmer	
	Magnus Reibenspeiss	
Officers:	Federico Villegas	President
	Irene Ruether	Treasurer
	Aaron Kim	Secretary

Carl Zeiss Meditec USA, Inc. is a wholly owned subsidiary of **Carl Zeiss Meditec, Inc.** Accordingly, there are no individual shareholders, stockholders, partners or owners of Carl Zeiss Meditec USA, Inc.

Carl Zeiss Meditec, Inc. and **Carl Zeiss Meditec USA, Inc.** are both located at 5300 Central Parkway Dublin, CA 94568

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	CARL ZEISS MEDITEC USA, INC.
Entity No.:	4747310
Registration Date:	05/21/2021
Entity Type:	Stock Corporation - Out of State - Stock
Formed In:	NEW YORK
Status:	Active

The above referenced entity is active on the Secretary of State's records and is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of November 18, 2025.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 389614738

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	CARL ZEISS MEDITEC USA, INC.
DOS ID Number:	5793959
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	07/22/2020
Statement Status:	Current
Statement Due Date:	07/31/2026

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on November 21, 2025 at 11:04 A.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100009182252 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

CALIFORNIA STATE BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal License

Wholesale Drug Permit

License No. WLS 8525
Receipt No. 53460225

Valid Until: 1/1/2027

CARL ZEISS MEDITEC USA INC
5300 CENTRAL PARKWAY
DUBLIN, CA 94568

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

---- NON-TRANSFERABLE ----- POST IN PUBLIC VIEW -----

FORM WPHWLS (09/30/19) WLS

CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Wholesale Drug Permit

LICENSE NO. WLS 8525

ISSUE DATE 1/17/2025

CARL ZEISS MEDITEC USA INC
5300 CENTRAL PARKWAY
DUBLIN, CA 94568

The above is licensed with the State Board of Pharmacy as a Corporation

CHOW JOANNA CHUI YEE — EXEMPTEE IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL 1/1/2026

RECEIPT NUMBER 00772210

This original license must be kept for the life of the license and posted in public view.

In accordance with section 4060 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is NONTRANSFERABLE and must be renewed annually on or before the indicated date. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, shareholder (more than 10 percent share change), designated representative-in-charge, manager or vice president of operations. If you are planning to change location or designated representative-in-charge, the approval must be in advance of the change.

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

----- POST IN PUBLIC VIEW -----

OPHWS1 09/30/19 WLS

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY): 09/30/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Aon Risk Services Central, Inc.
Philadelphia PA Office
100 North 18th Street
16th Floor
Philadelphia PA 19103 USA

CONTACT NAME:
PHONE (A/C, No, Ext): (866) 283-7122 FAX (A/C, No.): (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Travelers Property Cas Co of America	25674
INSURER B:	Allianz Global Risks US Insurance Co.	35300
INSURER C:	Travelers Casualty & Surety Company	19038
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Carl Zeiss Meditec USA, Inc.
5300 Central Parkway
Dublin, CA 94568, USA

COVERAGES **CERTIFICATE NUMBER:** 570115075098-1 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [ ] X [ ] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			USL00103125	09/30/2025	09/30/2026	EACH OCCURRENCE	$1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
							MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$1,000,000
							GENERAL AGGREGATE	$2,000,000
							PRODUCTS - COMP/OP AGG	$1,000,000
A	AUTOMOBILE LIABILITY X ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY			T1NJ-CAP-1R573604	09/30/2025	09/30/2026	COMBINED SINGLE LIMIT (Ea accident)	$2,000,000
							BODILY INJURY (Per person)	
							BODILY INJURY (Per accident)	
							PROPERTY DAMAGE (Per accident)	
B	X UMBRELLA LIAB [ ] X OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED X RETENTION $100,000			USL00103325	09/30/2025	09/30/2026	EACH OCCURRENCE	$5,000,000
							AGGREGATE	$5,000,000
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N (Mandatory in NH) N/A If yes, describe under DESCRIPTION OF OPERATIONS below			UB-B9432178-25-51-K All Other States	09/30/2025	09/30/2026	X PER STATUTE [ ] OTH-ER	
C				UB-B9430204-25-51-R WC,AZ,MA,WI	09/30/2025	09/30/2026	E.L. EACH ACCIDENT	$1,000,000
							E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of Insurance

CERTIFICATE HOLDER

Carl Zeiss Meditec USA, Inc.
5300 Central Parkway
Dublin, CA 94568, USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc

Holder Identifier :

Certificate No : 570115075098-1

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. GSA14000002

Application/License No. _____

CARL ZEISS MEDITEC USA, INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5300 Central Pkwy Dublin, CA 94568 (Address of Applicant/Principal), as PRINCIPAL, and THE GRAY CASUALTY & SURETY COMPANY (Surety Company), a corporation organized under the laws of the state of LA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is P.O. Box 6202 Metairie, LA 70009-6202 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on December 16, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 16th day of December, 2025.

APPLICANT/PRINCIPAL
CARL ZEISS MEDITEC USA, INC.

COMPANY

Authorized Representative

SURETY
THE GRAY CASUALTY & SURETY COMPANY

Surety Company's Representative

Lisa A. Ward, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Cheryl Moretti

Witness

SIGNED and SEALED in the presence of:

Witness Vanessa Dominguez

Witness Terri L. Morrison

Countersigned by

N/A
Nevada Resident Agent

SEAL

Posted February 20, 2020

Aon Risk Services Southwest, Inc.
12/16/2025 15:16 2722704012707

THE GRAY INSURANCE COMPANY
THE GRAY CASUALTY & SURETY COMPANY

GENERAL POWER OF ATTORNEY

Bond Number: GSA14000002 **Principal:** CARL ZEISS MEDITEC USA, INC.

Project: Pharmaceutical Wholesaler Bond

KNOW ALL BY THESE PRESENTS, THAT The Gray Insurance Company and The Gray Casualty & Surety Company, corporations duly organized and existing under the laws of Louisiana, and having their principal offices in Metairie, Louisiana, do hereby make, constitute, and appoint: **Lisa A. Ward, Michael J. Herrod, and Terri L. Morrison of Houston, Texas jointly and severally** on behalf of each of the Companies named above its true and lawful Attorney(s)-in-Fact, to make, execute, seal and deliver, for and on its behalf and as its deed, bonds, or other writings obligatory in the nature of a bond, as surety, contracts of suretyship as are or may be required or permitted by law, regulation, contract or otherwise, provided that no bond or undertaking or contract of suretyship executed under this authority shall exceed the amount of $25,000,000.00.

This Power of Attorney is granted and is signed by facsimile under and by the authority of the following Resolutions adopted by the Boards of Directors of both The Gray Insurance Company and The Gray Casualty & Surety Company at meetings duly called and held on the 26th day of June, 2003.

"RESOLVED, that the President, Executive Vice President, any Vice President, or the Secretary be and each or any of them hereby is authorized to execute a power of Attorney qualifying the attorney named in the given Power of Attorney to execute on behalf of the Company bonds, undertakings, and all contracts of surety, and that each or any of them is hereby authorized to attest to the execution of such Power of Attorney, and to attach the seal of the Company; and it is

FURTHER RESOLVED, that the signature of such officers and the seal of the Company may be affixed to any such Power of Attorney or to any certificate relating thereto by facsimile, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be binding upon the Company now and in the future when so affixed with regard to any bond, undertaking or contract of surety to which it is attached.

IN WITNESS WHEREOF, The Gray Insurance Company and The Gray Casualty & Surety Company have caused their official seals to be hereinto affixed, and these presents to be signed by their authorized officers this 4th day of November, 2022.

THE GRAY INSURANCE COMPANY SEAL

By: Michael T. Gray
President
The Gray Insurance Company

Cullen S. Piske
President
The Gray Casualty & Surety Company

THE GRAY CASUALTY & SURETY COMPANY SEAL

State of Louisiana
ss:
Parish of Jefferson

On this 4th day of November, 2022, before me, a Notary Public, personally appeared Michael T. Gray, President of The Gray Insurance Company, and Cullen S. Piske, President of The Gray Casualty & Surety Company, personally known to me, being duly sworn, acknowledged that they signed the above Power of Attorney and affixed the seals of the companies as officers of, and acknowledged said instrument to be the voluntary act and deed, of their companies.

Leigh Anne Henican
Notary Public
Notary ID No. 92653
Orleans Parish, Louisiana

Leigh Anne Henican
Notary Public, Parish of Orleans State of Louisiana
My Commission is for Life

I, Mark S. Manguno, Secretary of The Gray Insurance Company, do hereby certify that the above and forgoing is a true and correct copy of a Power of Attorney given by the companies, which is still in full force and effect. IN WITNESS WHEREOF, I have set my hand and affixed the seals of the Company this 16th day of December , 2025 .

I, Leigh Anne Henican, Secretary of The Gray Casualty & Surety Company , do hereby certify that the above and forgoing is a true and correct copy of a Power of Attorney given by the companies, which is still in full force and effect. IN WITNESS WHEREOF, I have set my hand and affixed the seals of the Company this 16th day of December , 2025 .

THE GRAY INSURANCE COMPANY SEAL

THE GRAY CASUALTY & SURETY COMPANY SEAL

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG CARL ZEISS MEDITEC USA, INC. MDEG License # (if applicable) _____

Physical Address 5300 CENTRAL PARKWAY

City DUBLIN State CA Zip 94568

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-341-6968 Website www.zeiss.com/med

Licensing Company Email state.licenses.med.us@zeiss.com

Section 2: Personal Information

First JOANNA Middle _____ Last CHOW

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITI [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City HAYWARD State CA Zip [redacted]

Telephone [redacted] Email joanna.chow@zeiss.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
TOURO UNIVERSITY		08/09 - 05/14	
Address	**City**	**State**	**Zip**
1310 CLUB DR	VALLEJO	CA	94592
Diploma/Degree obtained, if any			
DOCTOR OF PHARMACY AND MASTER OF PUBLIC HEALTH			

School Name		From - To (MM/YY – MM/YY)	
CHABOT COLLEGE		08/07 - 05/08	
Address	**City**	**State**	**Zip**
25555 HESPERIAN BLVD	HAYWARD	CA	94545
Diploma/Degree obtained, if any			
ASSOCIATE OF ARTS IN COMMUNICATION			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF CALIFORNIA, DAVIS		08/02 - 08/05	
Address	**City**	**State**	**Zip**
1 SHIELDS AVE	DAVIS	CA	95616
Diploma/Degree obtained, if any			
BACHELOR OF SCIENCE IN BIOCHEMISTRY AND MOLECULAR BIOLOGY			

School Name		From - To (MM/YY – MM/YY)	
JAMES LOGAN HIGH SCHOOL		08/98 - 05/02	
Address	**City**	**State**	**Zip**
1800 H STREET	UNION CITY	CA	94587
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/15 - NOW	[redacted]	HAYWARD	CA	[redacted]
10/96 - 06/15		UNION CITY	CA	
08/10 - 05/14		VALLEJO	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
CARL ZEISS MEDITEC USA, INC.			05/24 - PRESENT	
Business Address		City	State	Zip
5300 CENTRAL PKWY		DUBLIN	CA	94568
Phone	Title		Number of Employed Hours	
800-341-6968	COMPLIANCE PROGRAM MANAGER		3,200+	
Description of Duties				
Maintains an accurate database to track the status of wholesaler licensing applications, renewals, and forms, oversee documentation for IOL inventory reconciliations and expired product pulls to support regulatory compliance				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/18/2026
Date

I, JOANNA CHOW, **certify that as the MDEG Administrator for**

CARL ZEISS MEDITEC USA, INC.,

that I (initial that you have read and meet the following requirements):

1. JC Have a high school diploma or its equivalent;
2. JC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joanna Chow

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/18/2026

Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler CARL ZEISS MEDITEC USA, INC.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 5300 CENTRAL PARKWAY

City DUBLIN State CA Zip 94568

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-341-6968 Website www.zeiss.com/med

Licensing Company Email state.licenses.med.us@zeiss.com

Section 2: Personal Information

First JOANNA Middle CHUI YEE Last CHOW

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITI [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City HAYWARD State CA Zip [redacted]

Telephon [redacted] Email joanna.chow@zeiss.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
TOURO UNIVERSITY			08/09 - 05/14	
Address		City	State	Zip
1310 CLUB DR		VALLEJO	CA	94592
Diploma/Degree obtained, if any				
DOCTOR OF PHARMACY AND MASTER OF PUBLIC HEALTH				
School Name			From - To (MM/YY – MM/YY)	
CHABOT COLLEGE			08/07 - 05/08	
Address		City	State	Zip
25555 HESPERIAN BLVD		HAYWARD	CA	94545
Diploma/Degree obtained, if any				
ASSOCIATE OF ARTS IN COMMUNICATION				
School Name			From - To (MM/YY – MM/YY)	
UNIVERSITY OF CALIFORNIA, DAVIS			08/02 - 08/05	
Address		City	State	Zip
1 SHIELDS AVE		DAVIS	CA	95616
Diploma/Degree obtained, if any				
BACHELOR OF SCIENCE IN BIOCHEMISTRY AND MOLECULAR BIOLOGY				
School Name			From - To (MM/YY – MM/YY)	
JAMES LOGAN HIGH SCHOOL			08/98 - 05/02	
Address		City	State	Zip
1800 H STREET		UNION CITY	CA	94587
Diploma/Degree obtained, if any				
HIGH SCHOOL DIPLOMA				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/15 - NOW	[redacted]	HAYWARD	CA	[redacted]
10/96 - 06/15		UNION CITY	CA	
08/10 - 05/14		VALLEJO	CA	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
CARL ZEISS MEDITEC USA, INC.			05/24 - PRESENT	
Business Address		**City**	**State**	**Zip**
5300 CENTRAL PKWY		DUBLIN	CA	94568
Phone	**Title**		**Number of Employed Hours**	
800-341-6968	COMPLIANCE PROGRAM MANAGER		3,200+	
Description of Duties				
Maintains an accurate database to track the status of wholesaler licensing applications, renewals, and forms, oversee documentation for IOL inventory reconciliations and expired product pulls to support regulatory compliance				

Business Name			From - To (MM/YY – MM/YY)	
SAFEWAY PHARMACY			03/18 - 05/24	
Business Address		**City**	**State**	**Zip**
22280 FOOTHILL BLVD		HAYWARD	CA	94541
Phone	**Title**		**Number of Employed Hours**	
510-582-5706	PHARMACY MANAGER		12,000+	
Description of Duties				
Coordinated with approved wholesalers for orders, ensured compliance with state and federal requirements, reviewed incoming drug shipments, maintain accurate inventory records, coordinated returns of expired or damaged drugs				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, JOANNA CHOW, **certify that as the designated representative for**

CARL ZEISS MEDITEC USA, INC.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. jc I am at least 21 years of age;
3. jc I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. jc I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. jc I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. jc I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. jc I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

JOANNA CHOW

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/8/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JOANNA CHOW

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/8/2026

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

See attached

(Seal)

CALIFORNIA ACKNOWLEDGMENT CIVIL CODE § 1189

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Alameda }

On January 8, 2026 (Date) before me, Cheryl Moretti, Notary Public (Here Insert Name and Title of the Officer)

personally appeared Joanna Chow (Name(s) of Signer(s))

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

CHERYL MORETTI
Notary Public - California
Alameda County
Commission # 2423311
My Comm. Expires Oct 24, 2026

Place Notary Seal and/or Stamp Above

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature Cheryl Moretti
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Nevada State Board of Pharmacy Designated Representative Application

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

Capacity(ies) Claimed by Signer(s)

Signer's Name: _____	Signer's Name: _____
☐ Corporate Officer – Title(s): _____	☐ Corporate Officer – Title(s): _____
☐ Partner – ☐ Limited ☐ General	☐ Partner – ☐ Limited ☐ General
☐ Individual ☐ Attorney in Fact	☐ Individual ☐ Attorney in Fact
☐ Trustee ☐ Guardian or Conservator	☐ Trustee ☐ Guardian or Conservator
☐ Other: _____	☐ Other: _____
Signer is Representing: _____	Signer is Representing: _____

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Name in General Display	Business Title	Location	Worker's Manager(s)
Joseph B Affel	Field Support Engineer IV	Remote - USA PA	Richard Toth
Sonia Afrin	QA Specialist, Sr Staff	Dublin, CA (ZICC)	Abdullah Qazi
John Matthew Alberini	Sales Executive	Remote - USA OH	Cruz Buchanan
Adam Craig Altschuler	Head of Finance	Dublin, CA (ZICC)	Federico Villegas
Michelle A Ambrecht	Regulatory Affairs Specialist, Principal	Remote - USA WA	Paul Swift
Amy L Anderson	Project Management Coordinator	Dublin, CA (ZICC)	Marty Rohman
Richard C Ashley	Digital Technical Support Engineer I	Dublin, CA (ZICC)	Ken Garrido
Cherice Bacosa	Service Operations Administrator	Dublin, CA (ZICC)	Davina Calvillo
Bruce D Bailey	Clinical Applications Specialist I	Remote - USA CA	Connie LeAnn McKeehen
Patricia Anne Baker	Commissions Analyst	Dublin, CA (ZICC)	Craig Altschuler
Mark T Berry	Clinical Applications Specialist III	Remote - USA VA	Natalie Elliott Hamilton
Thomas W Breitschwerd	Field Support Engineer III	Remote - USA NY	Sidi Marouane Sbai
Skyler C Briggs	Supervisor, Field Service	Remote - USA UT	Paul Cullenen
Marina Broytman	Sales Success Specialist	Dublin, CA (ZICC)	Esperanza Villalta
Aaron H Buch	Sales Executive	Remote - USA WA	Cambyse Keshavarz
Davina Calvillo	Manager, Service Operations	Dublin, CA (ZICC)	Victoria Isabell Norris
Colin M Campbell	Sales Executive	Remote - USA OK	Caleb A Ruckdeschel
Marc Lopez	National Field Service Manager	Remote - USA CA	Deanne Giles
James R Carter	VP Ophthalmic Surgical Sales	Remote - USA MA	Lisa Gail Romo
Daniel R Chavers	Strategic Accounts Director	Remote - USA AL	Cindy Metrose
Brian L Close	Head of Ophthalmic Diagnostic Sales – US	Remote - USA CA	Chad A Miles
Erick John E Cuenco	Technical Support Engineer II	Dublin, CA (ZICC)	Hinsley D Critchlow
Paul Cullenen	National Field Service Manager	Remote - USA NY	Deanne Giles
Brent R Dalton	Supervisor, Field Service	Remote - USA IA	Paul Cullenen
Christopher R Danko	Sr Regional Director, Sales	Remote - USA IL	James Carter
Massimo DeCarli	Field Support Engineer IV	Remote - USA CT	Sidi Marouane Sbai
Melito C Deguzman	Technical Support Engineer I	Dublin, CA (ZICC)	Randy Manna
Connie LeAnn McKeehen	Supervisor, Clinical Applications	Remote - USA WA	Brian L Close
Karla Dement	Manager, Sales Excellence	Dublin, CA (ZICC)	Mike Cullinane
Miguel Diaz	Field Support Engineer III	Remote - USA FL	Kevin Pigford
Michael C Dixon	Supervisor, Field Service	Remote - USA FL	Marc Lopez
Athas G Dounelis	Sales Executive	Remote - USA NJ	Samuel J Iezzi

Melissa M Dowell	Head of Tradeshows & Events	Dublin, CA (ZICC)	Ann M McCafferty
Melvin E Edwards	Field Support Engineer II - Refractive	Remote - USA TX	Terry Lankford
Robert Elias	Field Support Engineer IV	Remote - USA PA	Richard Toth
Angela Renee Elliott	Head of Clinical Education and Learning MED US	Remote - USA KY	Chad A Miles
Suzette N Erian	Business Process Analyst	Dublin, CA (ZICC)	Indira P Vemala
Jonathan Eric Fann	Sales Effectiveness Trainer- CRM/Operations	Dublin, CA (ZICC)	Renee Elliott
Aurelio A Gecale	Digital Technical Support Engineer II	Dublin, CA (ZICC)	Ken Garrido
Gina M Giuliano	Customer Care Project Manager	Remote - USA CA	Victoria Isabell Norris
Steven R Goluskin	Sales Success Specialist	Dublin, CA (ZICC)	Victoria Isabell Norris
Rachel R Groh	Clinical Applications Specialist III	Remote - USA NY	Natalie Elliott Hamilton
Thomas Halloran	Field Support Engineer III	Remote - USA OH	Jeff Stokes
Natalie Elliott Hamilton	Supervisor, Clinical Applications	Remote - USA KY	Brian L Close
Ronnie Terrill Harris	Field Support Engineer III	Remote - USA GA	Mike Dixon
Guido Marcel Hattendorf	Sr US KOL Management and Clinical Development	Remote - USA AZ	Ann M McCafferty
Jennifer Lee Ide	Business Process Analyst	Dublin, CA (ZICC)	Indira P Vemala
Samuel J Iezzi	Sr Regional Director, Sales	Remote - USA PA	Brian L Close
Pavel Apostolov Iliev	Field Support Engineer II	Remote - USA GA	Kevin Pigford
Gregory L Jones	Field Support Engineer III	Remote - USA OK	Jeff Maynard
Tina Renee Schinella	Sales Contracts Administrator	Dublin, CA (ZICC)	Craig Altschuler
Nasim S Kamran	Commissions Analyst	Dublin, CA (ZICC)	Craig Altschuler
Andrew P Keenan	Sales Executive	Remote - USA PA	Samuel J Iezzi
Maureen M Kelleher	Sales Inventory Lead	Dublin, CA (ZICC)	Ranie Acebedo
Jason G Kennedy	Technical Support Engineer, Sr	Dublin, CA (ZICC)	Ken Garrido
Cambyse Keshavarz	Sr Regional Director, Sales	Remote - USA CO	Brian L Close
Daniel J Ketner	Clinical Applications Specialist II	Remote - USA MD	Natalie Elliott Hamilton
Mattie T Thompson	Service Operations Administrator	Dublin, CA (ZICC)	Davina Calvillo
Carlos E Klos	Field Support Engineer II	Remote - USA WI	Brent R Dalton
Robert W Knight	Field Support Engineer IV	Remote - USA AZ	Jeff Maynard
Amber G Lamendola	Sales Success Specialist	Dublin, CA (ZICC)	Esperanza Villalta
David Wayne Lebel	Sr Regional Director, Sales	Remote - USA GA	James Carter
Marifi A Lim	Sr. SAP Business Hub Expert	Dublin, CA (ZICC)	Mark Cowan
William R Machesney	Clinical Sales Director	Remote - USA CA	Renee Elliott
Noha I Mahmoud	Field Support Engineer II - Refractive	Remote - USA CA	Terry Lankford

Leonard Marquez	Technical Support Engineer I	Dublin, CA (ZICC)	Marty Rohman
Jeffrey M Maynard	Supervisor, Field Service	Remote - USA TX	Paul Cullenen
Cynthia J Metrose	Head of Strategic Accounts and Digital	Remote - USA CT	Chad A Miles
Chad A Miles	Head of US Sales - Ophthalmic Device	Remote - USA WA	Federico Villegas
Khadijah Rasheen Miller	Service Operations Administrator	Dublin, CA (ZICC)	Davina Calvillo
Donald Mills	Field Support Engineer II	Remote - USA SC	Kevin Pigford
Robert T Moore	Sales Executive	Remote - USA NC	Zach Stone
Sandra Lynn Morris	Sales Inventory Specialist	Dublin, CA (ZICC)	Esperanza Villalta
David B Moss	OS/MS Field Service Specialist	Remote - USA FL	Paul Cullenen
Lisa Gail Romo	Head Of Microsurgery US, Head Of Sales Neuro/El	Dublin, CA (ZICC)	Federico Villegas
Donald Michael Nasso	Field Support Engineer III	Remote - USA VA	Mike Dixon
Terry Wayne Nastasi	Field Support Engineer IV	Remote - USA LA	Aubrey Bowman
Victoria Isabell Norris	Head of Service Operations	Dublin, CA (ZICC)	Mark Cowan
Christopher Paul Nuciforo	Strategic Accounts Director	Remote - USA IL	Cindy Metrose
Peter J O'Connor	Field Implementation Specialist III	Remote - USA OH	Mark Cowan
Tyler D Olsby	Clinical Applications Specialist III	Remote - USA MN	Connie LeAnn McKeehen
Todd Otani	Clinical Scientist, Sr	Dublin, CA (ZICC)	Eric Schorsch
Preetika J Perez	Enterprise Account Manager	Remote - USA CA	Mark Cowan
Dennis M Ramirez	Senior Enterprise Account Manager	Remote - USA CA	Mark Cowan
Donald R Renfrow	New Product Introduction Engineer	Dublin, CA (ZICC)	Deanne Giles
Marty L Rohman	Mgr, Customer Support	Dublin, CA (ZICC)	Deanne Giles
Michael A Romano	Sales Executive	Remote - USA FL	Zach Stone
Jeffery David Rospert	Radiotherapy Sales Director, Americas	Remote - USA OH	Lisa Gail Romo
Thomas A Roush	Sales Executive	Remote - USA CA	Cambyse Keshavarz
Brian M Rowell	Digital Market Development Manager	Remote - USA FL	Cindy Metrose
Caleb A Ruckdeschel	Sr Regional Director, Sales	Remote - USA TX	Brian L Close
Sidi Marouane Sbai	Supervisor, Field Service	Remote - USA NY	Marc Lopez
Linda Faye Shirley	OS/MS Field Service Specialist	Remote - USA TX	Marc Lopez
Nathan Sichter	OS/MS Specialist	Remote - USA KS	Marc Lopez
Andrew Edwin Simpson	Field Service Project Manager	Remote - USA TN	Victoria Isabell Norris
Rupinder Singh	Technical Support Engineer I	Dublin, CA (ZICC)	Randy Manna
Weylin Anthony Snider	Field Support Engineer III	Remote - USA CO	Brent R Dalton
Kevin W Steadman	Technical Support Engineer II	Dublin, CA (ZICC)	Marty Rohman

Anthony Bonifacio Sumab	Sales Success Specialist	Dublin, CA (ZICC)	Esperanza Villalta
Le Du Trinh	Sales Analyst	Dublin, CA (ZICC)	Craig Altschuler
Scott D Tucker	Sales Executive	Remote - USA CA	Cambyse Keshavarz
James E Urban	Sales Executive	Remote - USA MD	Samuel J Iezzi
Christine L Vazquez	Data Analyst, Sr.	Dublin, CA (ZICC)	Indira P Vemala
Indira P Vemala	Director, Tools & Analytics	Dublin, CA (ZICC)	Mark Cowan
Gerhard Arthur Voegele	Field Support Engineer III	Remote - USA MD	Jeff Stokes
Corinne A Debenedetti	Lead Service Operations Administrator	Dublin, CA (ZICC)	Davina Calvillo
Atef K Zaroura	Field Support Engineer III-CA	Remote - USA CA	Robert Arguello
James I Arnold	Field Service Specialist	Remote - USA FL	Marc Lopez
Jimmy V Leyva	Inside Sales Specialist	Dublin, CA (ZICC)	Mark Nicola
Simona Martin	Refractive Account Manager III	Remote - USA CA	Kenneth Fraley
Daniel J Thomas	Clinical Sales Specialist	Remote - USA MO	Scott Alan Smith
Michael A Wiebelt	Sr. Sales Effectiveness Trainer	Remote - USA LA	Renee Elliott
Ranie Acebedo	Manager, Sales Success	Dublin, CA (ZICC)	Mike Cullinane
Yvonne Lamb	Refractive Account Manager III	Remote - USA FL	Dawn Pelfrey
Kay DeMonge	Academic & Stategic Accounts Sales Sr Manager,	Remote - USA IL	Dave Dommel
Michael Yamzon	Digital Project Manager II	Remote - USA CA	Mark Cowan
Yvonne Noble	Lead Service Operations Administrator	Dublin, CA (ZICC)	Davina Calvillo
Jerry Lee Estraca	Field Support Engineer III	Remote - USA TX	Aubrey Bowman
Jenifer Nicole Jackson	Service Operations Administrator	Dublin, CA (ZICC)	Davina Calvillo
Tracy Carrie Morales	Clinical Applications Specialist III	Remote - USA MA	Natalie Elliott Hamilton
Christopher Eugene Barne	Sales Executive	Remote - USA GA	Zach Stone
Bradley Andrew Martin	Sales Executive	Remote - USA KS	Cruz Buchanan
Katherine Elizabeth Martir	Service Operations Administrator	Dublin, CA (ZICC)	Davina Calvillo
Fernando Mendez	Technical Support Engineer I	Dublin, CA (ZICC)	Marty Rohman
Monica Aguilar	Service Operations Administrator	Dublin, CA (ZICC)	Davina Calvillo
Anthony Gregory Sena	Sales Success Specialist	Dublin, CA (ZICC)	Esperanza Villalta
Joshua Duane Dale	Field Support Engineer III	Remote - USA MI	Jeff Stokes
Anthony Allan Montello	Field Support Engineer II	Remote - USA WI	Marc Lopez
Vanezza Silos	Sales Success Specialist	Dublin, CA (ZICC)	Esperanza Villalta
Nakeya Pewitt	Clinical Applications Specialist III	Remote - USA MI	Natalie Elliott Hamilton
Ramin Anthony Sadigh	Sr. Regional Sales Manager	Remote - USA CA	Cambyse Keshavarz

Barbra Lassalle	Service Operations Administrator	Dublin, CA (ZICC)	Davina Calvillo
James Nicholas Rudick	Field Support Engineer III	Remote - USA AL	Kevin Pigford
Michael Guffin	Sr Enterprise Account Manager	Remote - USA FL	Mark Cowan
Christopher Mintsioulis	Digital Technical Support Engineer II	Dublin, CA (ZICC)	Ken Garrido
Randy Fong	Senior Inside Sales Specialist	Dublin, CA (ZICC)	Mark Nicola
Tran Vu Nguyen	Market Readiness Program Manager	Dublin, CA (ZICC)	Deanne Giles
Erich Schwinn	Sales Executive	Remote - USA NH	Samuel J Iezzi
Edmund Balugo	Technical Support Engineer I	Dublin, CA (ZICC)	Hinsley D Critchlow
Kevin Joseph Pigford	Supervisor, Field Service	Remote - USA TN	Paul Cullenen
Anibal Mauricio Matasol	Technical Support Engineer III	Dublin, CA (ZICC)	Randy Manna
Jennifer Ann Ambra	Marketing Communications Program Manager	Dublin, CA (ZICC)	Paul Rousseau
David Ross Skalky	Refractive Account Manager, Lead	Remote - USA NY	Dawn Pelfrey
Shawn Harris	Field Support Engineer III	Remote - USA TX	Jeff Maynard
Steven Holt	Inside Sales Specialist	Dublin, CA (ZICC)	Mark Nicola
David Dommel	Dir, US Dental Sales	Remote - USA TX	Lisa Gail Romo
Sandra L Padilla	Field Services Project Manager	Dublin, CA (ZICC)	Victoria Isabell Norris
Eric Alvarez	OS/MS Field Service Specialist	Remote - USA CA	Paul Cullenen
Ramona Lewis	Sales Success Specialist	Dublin, CA (ZICC)	Ranie Acebedo
Ann Carter	Clinical Applications Coordinator	Dublin, CA (ZICC)	Renee Elliott
Kyle Blank	Field Support Engineer III	Remote - USA CO	Brent R Dalton
David Ruckdeschel	Sr Regional Director, Sales	Remote - USA LA	Jason Stiles
Bridget Cunningham	Head of Customer Engagement	Dublin, CA (ZICC)	Federico Villegas
Bruce Johnson	Technical Support Engineer, Sr	Dublin, CA (ZICC)	Marty Rohman
Javed Ahmed	Technical Support Engineer II	Dublin, CA (ZICC)	Hinsley D Critchlow
Jeremy Holland	Refractive Account Manager III	Remote - USA TX	Kenneth Fraley
George Krzeczkowski	Field Support Engineer II	Remote - USA IL	Brent R Dalton
Kerry Boykins	Field Support Engineer II	Remote - USA NY	Sidi Marouane Sbai
Norman Miranda	Field Support Engineer III	Remote - USA AK	Skyler C Briggs
Robert Arguello	Supervisor, Field Service	Remote - USA NM	Marc Lopez
Terry Lee Hillman	Field Support Engineer II	Remote - USA IN	Marc Lopez
Brad Golden	Sales Executive	Remote - USA MN	Cruz Buchanan
Terry Lankford	National Field Service Manager, Refractive	Remote - USA IA	Deanne Giles
Gabriela Denise Leal Fuer	Field Support Engineer IV	Remote - USA MA	Sidi Marouane Sbai

Richard Overby	Inside Sales Specialist	Dublin, CA (ZICC)	Mark Nicola
Jatinder Pal Singh	Technical Support Engineer I	Dublin, CA (ZICC)	Randy Manna
Fermin Sierra	Field Support Engineer III	Remote - USA CA	Skyler C Briggs
Crystal Ceaser	Service Operations Administrator	Dublin, CA (ZICC)	Davina Calvillo
Sharmiane Swygert	Customer Care Advocate	Dublin, CA (ZICC)	Deanne Giles
Krysten Corey	Service Operations Administrator	Dublin, CA (ZICC)	Davina Calvillo
Tyler Davis	Regional Surgical Specialist	Remote - USA MO	Max McGowan
Keith Papulski	Technical Support Engineer I	Dublin, CA (ZICC)	Hinsley D Critchlow
Natasha French	Strategic Account Administrator	Dublin, CA (ZICC)	Deanne Giles
Clayton Kennedy	Technical Support Engineer II	Dublin, CA (ZICC)	Marty Rohman
Angelique Nasution	Digital Technical Support Engineer I	Dublin, CA (ZICC)	Ken Garrido
Cheryl Padden	Refractive Account Manager III	Remote - USA VA	Dawn Pelfrey
Samantha J Flynn	Digital Market Development Manager	Remote - USA MA	Cindy Metrose
Kimberly Ong	Clinical Applications Specialist II	Remote - USA AL	Natalie Elliott Hamilton
Christine Ricamara	Technical Support Engineer I	Dublin, CA (ZICC)	Randy Manna
Yolanda Holland	Sales Success Specialist	Dublin, CA (ZICC)	Mike Cullinane
Christopher Palmer	Dental Sales Rep	Remote - USA CA	Dave Dommel
Benjamin Kohler	Field Support Engineer II - Refractive	Remote - USA TN	Terry Lankford
Frank Kruki	Sr. Surgical Application Specialist	Remote - USA MI	Max McGowan
Todd Allen	Technical Support Engineer I	Dublin, CA (ZICC)	Marty Rohman
Perry Himsl	Field Support Engineer II - Refractive	Remote - USA SC	Terry Lankford
Matthew Miller	Sales Executive	Remote - USA PA	Samuel J Iezzi
Keith Lebish	Field Support Engineer III - Refractive	Remote - USA MO	Terry Lankford
Khai Bui	Field Support Engineer III	Remote - USA NY	Sidi Marouane Sbai
Timothy Ritchey	Senior National Sales Manager, Dental Independer	Remote - USA TX	Dave Dommel
John Mark Cowan	VP Customer Care	Dublin, CA (ZICC)	Federico Villegas
Daniel Clarke	Sales Executive	Remote - USA VA	Zach Stone
Sandra Favaro	Refractive Account Manager III	Remote - USA CA	Kenneth Fraley
Gregory Baker	Field Support Engineer III	Remote - USA CA	Robert Arguello
James O'Hara	Academic and Strategic Accounts Sales Manager,	Remote - USA WA	Dave Dommel
Kimberly Dawn Pelfrey	National Manager, Refractive Account Managers	Remote - USA OH	Renee Elliott
Carol-Anne Poursaied	Senior Practice Development Manager, Refractive	Remote - USA DE	Paul Rousseau
Julie Day	Refractive Account Manager II	Remote - USA IL	Dawn Pelfrey

Harold Perez-Miranda	Sr. Surgical Application Specialist	Remote - USA TX	David Ruckdeschel
John R Moynahan	Field Support Engineer II	Remote - USA MA	Richard Toth
Aubrey Bowman	Supervisor Field Service	Remote - USA OK	Marc Lopez
Ryan Seabourn	Field Support Engineer III	Remote - USA TX	Jeff Maynard
Elesh Modi	National Surgical Consultant	Remote - USA FL	Jason Stiles
Nimish Tolat	Head of Neuro Marketing	Dublin, CA (ZICC)	Ann M McCafferty
Troy Bamann	Sales Executive	Remote - USA NY	Samuel J Iezzi
Shelby DeFelice	Sales Executive	Remote - USA AZ	Caleb A Ruckdeschel
Paul Rousseau	Head of Refractive Sales & Marketing	Remote - USA SC	Chad A Miles
Sanjay Laroia	Technical Support Engineer I	Dublin, CA (ZICC)	Hinsley D Critchlow
Stephen Morris	Regional Sales Director, Surgical	Remote - USA NY	Jason Stiles
Cindy Chiu	Sales Effectiveness Trainer	Remote - USA IL	Renee Elliott
John Stone	Senior Regional Director, Sales	Remote - USA SC	Brian L Close
Richard Backus	Sr Account Manager	Remote - USA GA	Patrick J. Patterson
Deanne Giles	Head of Technical Services	Dublin, CA (ZICC)	Mark Cowan
Sarah Smith	Master Database Administrator, Strategic Accounts	Dublin, CA (ZICC)	Mike Cullinane
Ryan Bortz	Senior Surgical Application Specialist	Remote - USA AZ	Alex Grillo
Janine McDonald	Marketing Manager, Sr	Dublin, CA (ZICC)	Ann M McCafferty
Abdullah Qazi	Manager, Complaint Handling	Dublin, CA (ZICC)	Manjaya Hegde
Cruz Buchanan	Regional Director Sales	Remote - USA MO	Brian L Close
Keith Rich	Sales Executive	Remote - USA TX	Caleb A Ruckdeschel
Randy Manna	Manager, Technical Support	Dublin, CA (ZICC)	Deanne Giles
Christopher Scofield	Sales Executive	Remote - USA TX	Caleb A Ruckdeschel
John Thayer	Field Support Engineer III	Remote - USA TN	Kevin Pigford
James Saviola	Sr. Advisor, Regulatory & Clinical Affairs	Remote - USA MD	Paul Swift
Erick Carrasquillo	Field Support Engineer III	Remote - USA FL	Kevin Pigford
Shane Ring	Strategic Accounts Director - US Federal Governm	Remote - USA CA	Cindy Metrose
Christian LoBuglio	Sales Executive	Remote - USA NC	Zach Stone
Calee Hartman	Clinical Applications Specialist II	Remote - USA MO	Connie LeAnn McKeehen
Donaire Andara	Field Support Engineer II	Dublin, CA (ZICC)	Skyler C Briggs
Ron Santoni	Field Support Engineer III	Remote - USA PA	Jeff Stokes
Kenneth Patrick Garrido	Software Applications Operations Manager	Dublin, CA (ZICC)	Deanne Giles
Nichols Nhut Minh Hua	Technical Support Engineer, Sr	Dublin, CA (ZICC)	Randy Manna

Jami Dodge	Clinical Care Specialist, Sr	Remote - USA MI	Jeff Rospert
Ann M McCafferty	Head of Marketing	Dublin, CA (ZICC)	Lisa Gail Romo
Craig Wesley Peterson	Sales Executive	Remote - USA TX	Caleb A Ruckdeschel
Monique Chambers	Service Sales Administrator	Dublin, CA (ZICC)	Victoria Isabell Norris
Natalie Campos	Service Sales Administrator	Dublin, CA (ZICC)	Victoria Isabell Norris
Michael Contreras	Inside Sales Specialist	Dublin, CA (ZICC)	Mark Nicola
Carl Bernard Mallard Jr.	Field Support Engineer III	Remote - USA NC	Mike Dixon
Jasmine Sethi	Manager, Incoming Inventory & Resales	Dublin, CA (ZICC)	Lisa Gail Romo
Joanne Chen	QA Specialist, Sr	Dublin, CA (ZICC)	Abdullah Qazi
David Peterson	Field Implementation Specialist I	Remote - USA NC	Mark Cowan
Jesus Rivera-Santos	Field Support Engineer III	Remote - USA MA	Richard Toth
David Tran	Field Support Engineer II	Remote - USA TX	Jeff Maynard
Vanessa Beliso	Service Operations Administrator	Dublin, CA (ZICC)	Davina Calvillo
Michael Posada	Sales Inventory Specialist	Dublin, CA (ZICC)	Victoria Isabell Norris
Christopher Schaefer	Dental Sales Representative, Sr	Remote - USA TX	Dave Dommel
Gary Bakker	Technical Support Engineer II	Dublin, CA (ZICC)	Hinsley D Critchlow
Brett Pennock	Sr Regional Sales Manager	Remote - USA FL	Zach Stone
Rizaldy De Los Santos	Technical Support Engineer I	Dublin, CA (ZICC)	Randy Manna
William Andrews	Sales Executive	Remote - USA AL	Zach Stone
Xavier White	Senior Account Manager	Remote - USA TX	David Ruckdeschel
Terence Macias	Technical Support Engineer II	Dublin, CA (ZICC)	Randy Manna
Michael Cullinane	Head of Commercial Operations	Dublin, CA (ZICC)	Mark Cowan
Roger Baehr	Field Support Engineer II	Remote - USA NY	Richard Toth
Erick Kwan	Sr Regional Sales Manager	Remote - USA ID	Cambyse Keshavarz
Kevin Patterson	Senior Sales Manager, Refractive Laser	Remote - USA MA	Paul Rousseau
Justin Gearhart	Field Support Engineer III	Remote - USA OH	Marc Lopez
George Field	Field Support Engineer II	Remote - USA WA	Robert Arguello
Evan Bertucci	Sr Regional Sales Manager	Remote - USA MS	Caleb A Ruckdeschel
Stefan Jabkiewicz	Senior Account Manager	Remote - USA IL	Karis Youngblood
Theodore Kluge	Field Support Engineer II	Remote - USA PA	Sidi Marouane Sbai
Wade Damon	Digital Technical Support Engineer II	Dublin, CA (ZICC)	Ken Garrido
Jeffrey Stokes II	Supervisor, Field Service	Remote - USA OH	Paul Cullenen
Hugo Fernandes	Project Manager - Information Systems	Dublin, CA (ZICC)	Marty Rohman

Cassandra Parsons	Sales Manager, Digital Sales	Remote - USA TX	Brett Morris
Fabian Gross	Sr. Financial Analyst-Project Manager	Dublin, CA (ZICC)	Craig Altschuler
Frank Watley	Field Support Engineer II	Remote - USA TX	Aubrey Bowman
Ranjit Singh Dosanjh	Technical Support Engineer I	Dublin, CA (ZICC)	Hinsley D Critchlow
Richard Solis	Technical Support Engineer I	Dublin, CA (ZICC)	Randy Manna
Jonathan Garcia	Inventory Control Analyst, Sr	Dublin, CA (ZICC)	Jasmine Sethi
Jami S Horner	Clinical Applications Specialist III	Temple, TX	Charity A Holman
Charity A Holman	Head of Digital Customer Success	Temple, TX	Mark Cowan
Brian K Exum	IT Support Administrator	Temple, TX	Charity A Holman
Kevin Borie	Senior Strategic Account Manager - US Federal Gc	Remote - USA TX	Cindy Metrose
Jacob Samuel Gluck	Field Support Engineer II	Remote - USA FL	Mike Dixon
Jeffery Scott May	Field Support Engineer I	Remote - USA MO	Brent R Dalton
Mark Nicola	Manager, Service Contract Sales	Dublin, CA (ZICC)	Victoria Isabell Norris
Esperanza Villalta	Manager, Sales Success	Dublin, CA (ZICC)	Mike Cullinane
Jonathan Thomas	Trade Show & Events Manager	Dublin, CA (ZICC)	Melissa M Dowell
Andrew Potter	Field Support Engineer III	Remote - USA WA	Robert Arguello
Mark Kaderli	Senior Sales Manager, Refractive Laser	Remote - USA TX	Paul Rousseau
Doris Parker Faught	Data Management Sales Engineer	Remote - USA TX	Brett Morris
Matthew Paul	Senior Inside Sales Specialist	Dublin, CA (ZICC)	Mark Nicola
Ngoc Tran	Master Data Management Analyst	Dublin, CA (ZICC)	Indira P Vemala
Phat Luong	Field Support Engineer II - Refractive	Remote - USA CA	Terry Lankford
Andrew Audsley	Digital Sales Manager	Remote - USA NC	Brett Morris
Daniel Diep	Field Support Engineer II	Remote - USA NY	Richard Toth
Derek Baldwin	Sr Digital Technical Support Engineer	Remote - USA TX	Charity A Holman
Joseph Claytor	Field Support Engineer II	Remote - USA VA	Kevin Pigford
Brendon Neese	Field Support Engineer II	Remote - USA NH	Richard Toth
Nelson Dominguez	Field Support Engineer III	Remote - USA AR	Jeff Maynard
Jason Stiles	Head of US Surgical Sales	Remote - USA WA	Chad A Miles
Zachary Foreman	Field Support Engineer II	Remote - USA OH	Jeff Stokes
Benjamin Schumacher	Senior Account Manager	Remote - USA WA	Rodney Berry
Richard Pusateri	Senior Account Manager	Remote - USA PA	Max McGowan
Kelly McDonough	Sr Account Manager	Remote - USA MO	Scott Arthur Moser
Justin Kelley	Senior Account Manager	Remote - USA MN	Karis Youngblood

Scott Tucker	Senior Account Manager	Remote - USA MD	Max McGowan
Stuart Watts	Senior Account Manager, Surgical	Remote - USA CA	Rodney Berry
Ryan Nagi	Senior Account Manager	Remote - USA MI	Karis Youngblood
Donovan Plummer	Senior Account Manager	Remote - USA TX	David Ruckdeschel
Jeffrey O'Hara	Senior Account Manager	Remote - USA NC	Patrick J. Patterson
Philip Loprinzi	Senior Account Manager, Surgical	Remote - USA VA	Jason Stiles
Douglas Jacobus Nuijten	Clinical Applications Specialist II	Remote - USA TX	Connie LeAnn McKeehen
Maria Eugenia Garcia	Sales Success Specialist	Dublin, CA (ZICC)	Ranie Acebedo
Graydon Hodges	Regional Sales Manager	Remote - USA TN	Caleb A Ruckdeschel
Scott Thorson	Field Support Engineer II	Remote - USA IL	Brent R Dalton
Shawn Vaughn-Reed	Clinical Applications Specialist II	Remote - USA CO	Connie LeAnn McKeehen
Brett Morris	Director, US Digital Solutions and Services	Remote - USA CO	Cindy Metrose
Jarrod Ashmore	Field Support Engineer I	Remote - USA NE	Brent R Dalton
Anne Santilli	Global Business Manager, CDM	Remote - USA MA	Federico Villegas
Asim Ali	Financial Analyst, Sr	Dublin, CA (ZICC)	Craig Altschuler
Rachel Echols	Sales Success Specialist	Dublin, CA (ZICC)	Esperanza Villalta
Parker Bellinger	Sr. Regional Sales Manager	Remote - USA CA	Cambyse Keshavarz
Paul Swift	Head of Regulatory & Clinical Affairs	Remote - USA TX	Federico Villegas
Tanesha Bland	Regulatory Affairs Specialist, Sr	Remote - USA CA	Paul Swift
Lorena Cerrillo	Sales Success Specialist	Dublin, CA (ZICC)	Esperanza Villalta
Kimberly Pesola	Marketing Manager, Sr	Dublin, CA (ZICC)	Chad A Miles
Jessica Leia Whittle	Clinical Project Manager	Remote - USA CA	Eric Schorsch
Kyle Freeman	Field Support Engineer II	Remote - USA MI	Jeff Stokes
Harveyzon Delapena	Senior Account Manager	Remote - USA CA	Alex Grillo
Manjaya Hegde	Head of Quality Management	Dublin, CA (ZICC)	Federico Villegas
Vanessa Ly	Digital Technical Support Engineer II	Dublin, CA (ZICC)	Ken Garrido
Michael Morton	Field Implementation Specialist II	Remote - USA AZ	Mark Cowan
Enrique Moreno	QA Specialist, Sr	Dublin, CA (ZICC)	Abdullah Qazi
Calvin Carter	Technical Support Engineer I	Dublin, CA (ZICC)	Hinsley D Critchlow
Julio asdruval Mier	Field Support Engineer I	Remote - USA IL	Marc Lopez
Steven D Ponder	Technical Support Engineer II	Dublin, CA (ZICC)	Hinsley D Critchlow
Joshua LeBlanc	Technical Support Engineer I	Dublin, CA (ZICC)	Hinsley D Critchlow
Kenneth Fraley	Manager, Refractive Accounts - West	Remote - USA CA	Renee Elliott

Thomas Kelly	Senior Sales Effectiveness Trainer	Remote - USA SC	Renee Elliott
Jeremy Morris	Technical Support Engineer II	Dublin, CA (ZICC)	Randy Manna
Robyn Barry	Trade Show Specialist	Dublin, CA (ZICC)	Melissa M Dowell
Nicholas Van Derpool	Technical Support Engineer II	Dublin, CA (ZICC)	Marty Rohman
Jule Sims	Technical Support Engineer I	Dublin, CA (ZICC)	Hinsley D Critchlow
Mark Bautista	Clinical Applications Specialist I	Remote - USA IL	Connie LeAnn McKeehen
Michelle Mazzie	Service Sales Administrator	Dublin, CA (ZICC)	Victoria Isabell Norris
Louis McCray	Field Support Engineer II	Remote - USA NY	Richard Toth
Josue Gamez	Field Support Engineer II	Remote - USA TX	Jeff Maynard
Ayad Zaroura	Field Support Engineer II	Remote - USA CA	Robert Arguello
Mark C Taylor	Clinical Applications Specialist III	Remote - USA NC	Charity A Holman
Katharina Barbara Custer	Marketing Communications Program Manager	Dublin, CA (ZICC)	Chad A Miles
Christinne Haw	Document Compliance Specialist, Sr	Dublin, CA (ZICC)	Manjaya Hegde
Kasey Wruck	Refractive Account Manager	Remote - USA TN	Dawn Pelfrey
Mary Catherine Meadows	Refractive Account Manager	Remote - USA TN	Kenneth Fraley
Willie Brinkley	Field Implementation Specialist I	Remote - USA VA	Mark Cowan
Devon Kennedy	Sr. Manager, Refractive OD Co-Management	Remote - USA CA	Paul Rousseau
Juliana Barrios	Executive Assistant	Dublin, CA (ZICC)	Lisa Gail Romo
Chaitali Gawde	Senior Regulatory Affairs Specialist	Dublin, CA (ZICC)	Marysa Lyew
Laura Schweizer	Refractive Account Manager	Remote - USA WA	Kenneth Fraley
Dawn M Langefels	Executive Assistant	Dublin, CA (ZICC)	Federico Villegas
Chrishelle Van Cleave	Clinical Applications Specialist III	Remote - USA TX	Charity A Holman
Tofan kumar Mohapatra	Business Process Analyst	Dublin, CA (ZICC)	Indira P Vemala
Michael Dominici	Marketing Manager, Sr	Dublin, CA (ZICC)	Nimish Tolat
Jennifer Hope DeGrave	Clinical Applications Specialist III	Temple, TX	Charity A Holman
Erica Bigham	Senior Strategic Accounts Manager	Remote - USA TX	Cindy Metrose
Daric Wade	Sr Digital Technical Support Engineer	Temple, TX	Charity A Holman
William Fassett	Field Implementation Specialist I	Remote - USA WA	Mark Cowan
Tristan Weibel	Regional Sales Manager	Remote - USA WI	Caleb A Ruckdeschel
Irina Reynov	Business Intelligence Analyst	Dublin, CA (ZICC)	Mike Cullinane
Angela Cook	Clinical Applications Specialist II	Remote - USA TX	Charity A Holman
Aditya Ramesh Rao	Regulatory Affairs Specialist	Dublin, CA (ZICC)	Marysa Lyew
Alex Grillo	Regional Sales Director, Surgical	Remote - USA CA	Jason Stiles

James Mays	Field Support Engineer I	Remote - USA MO	Brent R Dalton
Carlos Davila	Field Support Engineer III	Remote - USA FL	Kevin Pigford
Rachel Harper	Sales Success Specialist	Dublin, CA (ZICC)	Ranie Acebedo
John Howard	Senior Account Manager	Remote - USA CO	Rodney Berry
Kristen Hansen Kulovany	Digital Market Development Manager	Remote - USA IL	Cindy Metrose
James Rice	Surgical Application Specialist	Remote - USA GA	Patrick J. Patterson
Yohannes Dagne	Surgical Applications Specialist	Remote - USA WA	Rodney Berry
Regina Jones	Surgical Applications Specialist	Remote - USA MS	Scott Arthur Moser
Jorge Ozuna Adams	Field Support Engineer I	Remote - USA NC	Kevin Pigford
Wayne Helfrich	Regional Sales Manager	Remote - USA MI	Cruz Buchanan
LIANG HU	Field Support Engineer I	Remote - USA IL	Brent R Dalton
Christopher Gallegos	Field Support Engineer II	Remote - USA TX	Aubrey Bowman
Dhara Buch	Regulatory Affairs Specialist, Staff	Remote - USA MA	Paul Swift
Matthew Cavanaugh	Regional Sales Manager	Remote - USA MO	Zach Stone
Zane Frazier	Regional Sales Manager	Remote - USA NY	Samuel J Iezzi
Matthew Jonathan Wess	Digital Market Development Manager	Remote - USA ID	Cindy Metrose
Linda Clarke	Sr. Credit Management Specialist	Dublin, CA (ZICC)	Craig Altschuler
Gerald Corgill	Account Manager	Remote - USA AL	Scott Arthur Moser
Mudzhib Dadgar	Sr. Marketing Manager - Digital Platforms	Dublin, CA (ZICC)	Ann M McCafferty
David Thomas	Inside Sales Specialist	Dublin, CA (ZICC)	Mark Nicola
Marysa Elizabeth Lyew	Manager, Regulatory Affairs	Remote - USA CA	Paul Swift
Omar Eldasher	Field Support Engineer II - Refractive	Remote - USA PA	Terry Lankford
Maria Maschmeier	Marketing Manager, Sr	Dublin, CA (ZICC)	Ann M McCafferty
Scott Arthur Moser	Regional Director, Surgical	Chesterfield, MO	Jason Stiles
Veronica Esguerra Hardca	Senior Posterior Consumables Specialist	Remote - USA CA	Alex Grillo
Tyler Austin Moser	Senior Equipment Specialist	Remote - USA MO	Karis Youngblood
Michele Meert	Regional Sales Manager	Remote - USA MO	Chris Danko
Shawn Youtsey	Senior Posterior Consumable Specialist	Remote - USA AZ	Alex Grillo
Jessica Millan	Service Operations Administrator	Dublin, CA (ZICC)	Davina Calvillo
Richard Toth	Supervisor Field Service	Remote - USA NJ	Paul Cullenen
Diana Jasive Cabello Herr	Field Support Engineer II	Remote - USA TX	Jeff Maynard
Victoria Mendez	Sales Success Specialist	Dublin, CA (ZICC)	Ranie Acebedo
Emmanuel Kazanis	Senior Account Manager	Remote - USA NJ	Stephen Morris

Guandi Lamar George	Field Support Engineer II	Remote - USA AZ	Aubrey Bowman
Theresa Luna	Billing Specialist	Dublin, CA (ZICC)	Victoria Isabell Norris
Stephanie Coventry	Digital Clinical Applications Specialist III	Remote - USA NY	Brett Morris
Kristen Cavazos	Anterior Consumables Specialist	Remote - USA MI	Scott Alan Smith
Jonathan Lim	Technical Support Engineer I	Dublin, CA (ZICC)	Marty Rohman
Christine Lindsay	Surgical Application Specialist, Sr	Remote - USA IL	Karis Youngblood
Jason Lamendola	Billing Specialist	Dublin, CA (ZICC)	Victoria Isabell Norris
Maksim Afanasov	Field Support Engineer III	Remote - USA FL	Mike Dixon
Francisco Javier Palma M	Field Support Engineer II	Remote - USA NJ	Sidi Marouane Sbai
Patrick Rivers	Regional Sales Manager, Microsurgical Instrument	Remote - USA AL	David Wayne Lebel
Travis Brooks	Field Support Engineer II	Remote - USA WA	Skyler C Briggs
Lilia Ramos	Sales Success Specialist I	Dublin, CA (ZICC)	Esperanza Villalta
Ivan Slavov	Field Support Engineer II	Remote - USA CA	Skyler C Briggs
Dilipkumar Patel	Field Support Engineer II	Remote - USA FL	Skyler C Briggs
Noah Westberry	Technical Support Engineer I	Dublin, CA (ZICC)	Hinsley D Critchlow
Brian Weals	Senior Account Manager	Remote - USA OH	Max McGowan
Nancy Pham	Sr Marketing Manager	Dublin, CA (ZICC)	Ann M McCafferty
Olga Restrepo	Senior Account Manager	Remote - USA FL	Patrick J. Patterson
Jim Pariso	Business Process Analyst	Dublin, CA (ZICC)	Indira P Vemala
Jonathan Patton	Senior Account Manager	Remote - USA KS	Karis Youngblood
Alexander Barrington Step	Digital Technical Support Engineer I	Dublin, CA (ZICC)	Ken Garrido
Bradley Bernier	Field Support Engineer I	Remote - USA MN	Brent R Dalton
Eric Schorsch	Head of Clinical Affairs	Remote - USA TN	Paul Swift
Maxwell Dawson	Field Support Engineer II	Remote - USA AL	Mike Dixon
Tu Dinh	Marketing Communications Specialist	Dublin, CA (ZICC)	Chad A Miles
Michael Heieck	Field Support Engineer II	Remote - USA FL	Mike Dixon
Alan Robbins	Digital Technical Support Engineer I	Dublin, CA (ZICC)	Ken Garrido
Lingxiao Schandel	Staff Regulatory Affairs Specialist	Remote - USA UT	Marysa Lyew
Eddie Haythorn	Field Support Engineer II	Remote - USA IL	Marc Lopez
Robin Julene Eckett	Sales Effectiveness Training Coordinator	Dublin, CA (ZICC)	Renee Elliott
Allen Kim	Technical Support Engineer I	Dublin, CA (ZICC)	Randy Manna
Hinsley D Critchlow	Manager, Technical Support	Dublin, CA (ZICC)	Deanne Giles
Anthony Hall	Field Support Engineer II	Remote - USA LA	Jeff Maynard

Andrew Kevin Uy	Technical Support Engineer I	Dublin, CA (ZICC)	Randy Manna
Donna Nobida	Trade Show and Events Manager	Dublin, CA (ZICC)	Melissa M Dowell
Sarah Foster	Field Support Engineer II	Remote - USA TN	Mike Dixon
Michael Jacoub	Digital Technical Support Engineer I	Dublin, CA (ZICC)	Ken Garrido
Tuan Anh Do	Field Support Engineer II	Remote - USA VA	Mike Dixon
Ethan Alvarado	Field Support Engineer II	Remote - USA WA	Skyler C Briggs
Delvin Williams	Field Support Engineer I	Remote - USA NC	Kevin Pigford
Ronald Carey Mallow	Field Support Engineer I	Remote - USA MD	Jeff Stokes
Scot Waugaman	Field Support Engineer II	Remote - USA PA	Sidi Marouane Sbai
David Rodriguez	Field Support Engineer II	Remote - USA SC	Mike Dixon
Scott Alan Smith	Head of US Anterior Business/Sales	Remote - USA NC	Chad A Miles
Jeff A Judkins	Clinical Sales Specialist	Remote - USA AZ	Scott Alan Smith
Spencer James Bais	U.S. Training Manager - MICOR 700 and miLOOP	Remote - USA NY	Scott Alan Smith
Lisa M Peters	Sales Administrative Manager - Cataract Technolo	Remote - USA MA	Scott Alan Smith
Kiran Joseph C. Korah	Field Support Engineer II	Remote - USA NJ	Richard Toth
Hugo de Araujo Mesquita	Field Support Engineer II	Remote - USA FL	Mike Dixon
LaVerne McLean	Service Operations Administrator	Dublin, CA (ZICC)	Davina Calvillo
Austin Christopher Pelfrey	Field Support Engineer I - Refractive	Remote - USA OH	Terry Lankford
Joanna Chow	Compliance Program Manager	Dublin, CA (ZICC)	Mike Cullinane
Divon D Pleasant	Technical Support Engineer I	Dublin, CA (ZICC)	Randy Manna
Jonathan Talavera	Technical Support Engineer I	Dublin, CA (ZICC)	Hinsley D Critchlow
Larson Hall	Field Support Engineer I	Remote - USA CA	Skyler C Briggs
Paul Andrew Hamilton	Technical Support Engineer I	Dublin, CA (ZICC)	Randy Manna
Jefferson Lord Lara	Field Support Engineer II	Remote - USA CA	Skyler C Briggs
Melissa Renfrow	Technical Support Engineer I	Remote - USA TX	Charity A Holman
Dina Rodriguez	Sales Success Specialist	Dublin, CA (ZICC)	Victoria Isabell Norris
Erik Arias	Field Support Engineer II	Remote - USA AR	Aubrey Bowman
Kelvin Jason Lebish	Field Support Engineer I - Refractive	Remote - USA MO	Terry Lankford
Luke Ladd	Field Support Engineer I - Refractive	Remote - USA NJ	Terry Lankford
Ray C. Liu	Technical Support Engineer	Dublin, CA (ZICC)	Randy Manna
Jason Cheng	Field Support Engineer II	Remote - USA NY	Richard Toth
Swoosh Romero	Field Support Engineer II	Remote - USA CA	Robert Arguello
Levi Robert Phippen-Olso	Field Support Engineer I	Remote - USA WA	Skyler C Briggs

Jean-Paul Morici	Field Support Engineer I - Refractive	Remote - USA FL	Terry Lankford
Hunter Cole	Field Support Engineer I	Remote - USA VA	Kevin Pigford
Gloria Patricia Bello	Marketing Communication Specialist, Sr	Dublin, CA (ZICC)	Ann M McCafferty
Tiffany Krentz	Anterior Consumables Specialist	Remote - USA TN	Scott Alan Smith
Joseph Christy	Senior Account Manager - SUR	Remote - USA CA	Alex Grillo
Leah Schwartz	Senior Posterior Consumables Specialist	Remote - USA MO	Scott Arthur Moser
Chris Bachus	Senior Account Manager, Surgical	Remote - USA OH	Scott Arthur Moser
Charles Belliotti	Field Support Engineer II	Remote - USA AZ	Jeff Maynard
Karis Youngblood	Region Director, SUR	Remote - USA IL	Jason Stiles
Sheanna Rogers	Senior Marketing Communications Specialist	Dublin, CA (ZICC)	Nimish Tolat
Ivan Finkelstein	Senior Account Manager	Remote - USA AZ	Alex Grillo
Daniel Blake Piasecki	Senior Posterior Consumables Specialist	Remote - USA PA	Max McGowan
Francisco H Garcia	Senior Posterior Consumables Specialist	Remote - USA CA	Rodney Berry
Charles Joseph Gesner	Anterior Consumables Specialist	Remote - USA NY	Scott Alan Smith
Stephen Edward Cole	Field Support Engineer II	Remote - USA VA	Jeff Stokes
Adrian Guardado	Clinical Applications Specialist I	Remote - USA CA	Connie LeAnn McKeehen
Regina Karla C Rubio	Anterior Consumables Specialist	Remote - USA CA	Scott Alan Smith
Peter Haduong	Anterior Consumables Specialist	Remote - USA CA	Scott Alan Smith
Mike Stiles	Senior Equipment Specialist	Remote - USA GA	Scott Arthur Moser
John J. Bird	Senior Equipment Specialist	Remote - USA IL	Karis Youngblood
Mauricio Contreras	Anterior Consumables Specialist	Remote - USA TX	Scott Alan Smith
Ashly Alyas	Marketing Manager	Dublin, CA (ZICC)	Chad A Miles
Javier Americo Pagan	Anterior Consumables Specialist	Remote - USA GA	Scott Alan Smith
Theodore E. Knott	Field Support Engineer II	Remote - USA CT	Richard Toth
Neema Nabidavoodi	Field Support Engineer II	Remote - USA CA	Robert Arguello
Jonathan Stepakoff	Field Support Engineer II	Remote - USA WA	Robert Arguello
Lindsay McGovern	Senior Posterior Consumables Specialist	Remote - USA TX	David Ruckdeschel
Faith Tran	Sales Success Specialist	Dublin, CA (ZICC)	Ranie Acebedo
Kevin Liu	Sales Success Specialist	Dublin, CA (ZICC)	Esperanza Villalta
Shawn Hodina	Sr. Posterior Consumables Specialist	Remote - USA IL	Karis Youngblood
Mitchell R. West	Field Support Engineer II	Remote - USA MO	Aubrey Bowman
DeAndre J. Motley	Field Support Engineer II	Remote - USA MO	Aubrey Bowman
Constance Duvert	Marketing Manager	Dublin, CA (ZICC)	Ann M McCafferty

Khatanzorig Enkhbold	Technical Support Engineer I	Dublin, CA (ZICC)	Hinsley D Critchlow
Zackary Guardiancic	Technical Support Engineer I	Dublin, CA (ZICC)	Randy Manna
Johnnie Chiang	Technical Support Engineer I	Dublin, CA (ZICC)	Randy Manna
Stephen Hart	Field Support Engineer II	Remote - USA MI	Marc Lopez
Darin Larkin	Field Support Engineer II	Remote - USA WI	Marc Lopez
Francis Basbas	Inventory Demand and Control Manager	Dublin, CA (ZICC)	Jasmine Sethi
Erik McEwen	Field Support Engineer II	Remote - USA UT	Robert Arguello
Adesupo Odedina	Field Support Engineer II	Remote - USA GA	Mike Dixon
Aaron Ducre	Regional Sales Manager	Remote - USA IN	Cruz Buchanan
Gabriel Tobon	Senior Equipment Specialist	Remote - USA FL	Patrick J. Patterson
Adibah T. Kinder	Field Support Engineer II	Remote - USA PA	Sidi Marouane Sbai
Hassan Idris	Field Support Engineer II	Remote - USA OH	Marc Lopez
Daniel Cox	Sr. Posterior Consumables Specialist	Remote - USA NY	Stephen Morris
Madelyn Murawski	Sales Success Specialist	Dublin, CA (ZICC)	Ranie Acebedo
Iva Chinchen	Clinical Applications Specialist I	Remote - USA WA	Connie LeAnn McKeehen
Allison D'Addato	Sr. Posterior Consumables Specialist	Remote - USA NJ	Stephen Morris
Roderick Washington Sr	Field Support Engineer II	Remote - USA TX	Aubrey Bowman
John Christopher Hamel	Field Support Engineer II	Remote - USA UT	Robert Arguello
Trenese Manning	Service Operations Administrator	Dublin, CA (ZICC)	Davina Calvillo
Noel Molon	Technical Support Engineer	Dublin, CA (ZICC)	Hinsley D Critchlow
Hafiz M. Saqib	Field Support Engineer II	Remote - USA NY	Sidi Marouane Sbai
Patrick J. Patterson	Regional Sales Director, Surgical	Remote - USA FL	Jason Stiles
Michael O Jide	Field Support Engineer II	Remote - USA NY	Richard Toth
David Lee Ostrander	Senior Account Manager, Surgical	Remote - USA NY	Stephen Morris
Crystal Olvera	Service Sales Administrator	Dublin, CA (ZICC)	Victoria Isabell Norris
Aaron Patrick Forrest	Senior Equipment Specialist	Remote - USA LA	Scott Arthur Moser
Teddessa Mathurin	Surgical Applications Specialist	Remote - USA NY	Stephen Morris
Maria Lara	Senior Quality Assurance Specialist	Dublin, CA (ZICC)	Abdullah Qazi
Andrew Keener	Senior Equipment Specialist	Remote - USA WA	Rodney Berry
Andrew Wdowiak	Customer Service Specialist	Exeter	Jessica Lee Hardy
Karen A Montecalvo	Customer Service Specialist	Exeter	Jessica Lee Hardy
Wendy Lynn Burke	Field Service Technician	Remote - USA CA	Giovanni Francesco Pagano
Andrew Klinger	National Surgical Consultant	Exeter	Jason Stiles

Patrick Marcus	Field Service Technician	Remote - USA FL	Giovanni Francesco Pagano
Campbell Spivey	Posterior Consumable Specialist	Remote - USA AL	Scott Arthur Moser
Rebekah Anderson	Senior Posterior Consumable Specialist	Remote - USA CO	Rodney Berry
Peter Ervin	Senior Posterior Consumable Specialist	Remote - USA MD	Max McGowan
Coy Cockrell	Senior Field Service Technician	Remote - USA LA	Giovanni Francesco Pagano
Lyman Clark	Senior Posterior Consumable Specialist	Remote - USA IA	Karis Youngblood
Mark Forte	Field Service Technician	Remote - USA IA	Giovanni Francesco Pagano
Nicholas Carroll	Customer Service Specialist	Exeter	Jessica Lee Hardy
Jessica Lee Hardy	Customer Service Supervisor	Exeter	Max McGowan
Anil Kadgadkai	Field Service Technician	Remote - USA NJ	Giovanni Francesco Pagano
Gregory Price	Regional Surgical Specialist	Remote - USA NJ	Max McGowan
Rodney Berry	Regional Sales Director, Surgical	Remote - USA CO	Jason Stiles
Whitney Brigham	Sales Support Specialist	Exeter	Jessica Lee Hardy
Callie Gonsalves	Customer Service Specialist	Exeter	Jessica Lee Hardy
Brian Carter Owens	Field Service Technician	Remote - USA MD	Giovanni Francesco Pagano
Giovanni Francesco Paga	Director of Service and Training	Remote - USA FL	Max McGowan
Michael McGowan	Head of US Retina Business Sales	Remote - USA NJ	Chad A Miles
Brenda Mijares	Sales Success Specialist	Dublin, CA (ZICC)	Esperanza Villalta
Zachary Williams	Senior Equipment Specialist	Remote - USA TX	David Ruckdeschel
Caterina M. Massimino	Clinical Applications Specialist I	Remote - USA PA	Natalie Elliott Hamilton
Erik L. Kvarna	Field Support Engineer II	Remote - USA CA	Skyler C Briggs
Scott L Armstrong	Senior Equipment Specialist	Remote - USA CA	Alex Grillo
Mohammad Ayyad	Field Support Engineer I - Refractive	Remote - USA CA	Terry Lankford
Russell Sutton Lynch	Field Support Engineer II	Remote - USA OH	Jeff Stokes
Joshua David Hardman	Regional Surgical Specialist	Remote - USA OH	Max McGowan
Patrick B. Liebert	Sr. Posterior Consumable Specialist	Remote - USA NC	Patrick J. Patterson
Yves Robert Sainteus	Field Support Engineer II - Ranger/Traveler	Remote - USA MD	Paul Cullenen
Jonathan E. Nelson	Field Support Engineer II - Ranger/Traveler	Remote - USA IL	Paul Cullenen
Anthony Piscitello	Senior Account Manager, Surgical	Remote - USA TX	David Ruckdeschel
Roshan Ram Prakash Ma	Field Support Engineer II	Pleasanton, CA	Robert Arguello
Gerrad Allard-Cendejas	Field Support Engineer II - Ranger/Traveler	Remote - USA AZ	Paul Cullenen
Denise Morrabal	Clinical Applications Specialist I	Remote - USA FL	Natalie Elliott Hamilton
Amir Hooshang Hamidzac	Field Support Engineer II - Ranger/Traveler	Remote - USA TX	Paul Cullenen

4Z

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☑ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 02560	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Genzyme Corporation

Physical Address: 450 Water Street

City: Cambridge State: MA Zip: 02141

Mailing Address (if different from physical address): 100 Morris Street; Attn: Kara McMahon, Manager of State Licensing Operations

City: Morristown State: NJ Zip: 07960

Telephone: 617-252-7500 Website: www.sanofi.com

Name of Designated Representative (DR): Lane E. Wilson

Licensing Company Email: Kara.McMahon@sanofi.com DR Email: Lane.wilson@sanofi.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☑ Pharmacies	☑ Dangerous Drugs	☑ Manufacturer (Virtual)
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Distributors		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

1/24/26

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: MA

Parent Company (if any): See Attachment B

Corporation/Organization Name: Genzyme Corporation

Mailing Address: 100 Morris Street

City: Morristown State: NJ Zip: 07960

Telephone: 617-252-7500 Email: Kara.McMahon@sanofi.com

Contact Person Name: Kara.McMahon@sanofi.com

Section 6: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration See Attachment C 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment D		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment E	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment B		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment F	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment G		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - Wholly owned by parent company.		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment H	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment I	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
N/A **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)**				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Genzyme Corporation

Facility Name

Lane E. Wilson

Print Name of Authorized Person Submitting Application

Original Signature (electronic, copies or stamps not accepted)

03/26/26

Date

Board Use Only	Date Received: 1/30/26	Amount: CC $1000

/ NDC (index.cfm)

National Drug Code Directory

Current through January 15, 2026

You have searched Finished drug products

Search Results: *'Genzyme'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
ALDURAZYME	58468-0070-1	2.9 mg/5mL	INJECTION, SOLUTION, CONCENTRATE	INTRAVENOUS	BLA125058	Genzyme Corporation	58468-0070	laronidase	LARONIDASE	HUMAN PRESCRIPTION DRUG	04/30/2003	N/A	BLA	5 mL in 1 VIAL, GLASS (58468-0070-1)
Aubagio	58468-0210-1	14 mg/1	TABLET, FILM COATED	ORAL	NDA202992	Genzyme Corporation	58468-0210	teriflunomide	TERIFLUNOMIDE	HUMAN PRESCRIPTION DRUG	05/01/2013	N/A	NDA	1 BLISTER PACK in 1 CARTON (58468-0210-1) / 5 TABLET, FILM COATED in 1 BLISTER PACK
Aubagio	58468-0210-3	14 mg/1	TABLET, FILM COATED	ORAL	NDA202992	Genzyme Corporation	58468-0210	teriflunomide	TERIFLUNOMIDE	HUMAN PRESCRIPTION DRUG	05/01/2013	N/A	NDA	1 BLISTER PACK in 1 CARTON (58468-0210-3) / 5 TABLET, FILM COATED in 1 BLISTER PACK
Aubagio	58468-0210-4	14 mg/1	TABLET, FILM COATED	ORAL	NDA202992	Genzyme Corporation	58468-0210	teriflunomide	TERIFLUNOMIDE	HUMAN PRESCRIPTION DRUG	03/28/2019	N/A	NDA	1 BOTTLE in 1 CARTON (58468-0210-4) / 30 TABLET, FILM COATED in 1 BOTTLE
Aubagio	58468-0211-2	7 mg/1	TABLET, FILM COATED	ORAL	NDA202992	Genzyme Corporation	58468-0211	teriflunomide	TERIFLUNOMIDE	HUMAN PRESCRIPTION DRUG	05/01/2013	N/A	NDA	1 BLISTER PACK in 1 CARTON (58468-0211-2) / 5 TABLET, FILM COATED in 1 BLISTER PACK
Aubagio	58468-0211-3	7 mg/1	TABLET, FILM COATED	ORAL	NDA202992	Genzyme Corporation	58468-0211	teriflunomide	TERIFLUNOMIDE	HUMAN PRESCRIPTION DRUG	05/01/2013	N/A	NDA	1 BLISTER PACK in 1 CARTON (58468-0211-3) / 5 TABLET, FILM COATED in 1 BLISTER PACK
Aubagio	58468-0211-4	7 mg/1	TABLET, FILM COATED	ORAL	NDA202992	Genzyme Corporation	58468-0211	teriflunomide	TERIFLUNOMIDE	HUMAN PRESCRIPTION DRUG	03/28/2019	N/A	NDA	1 BOTTLE in 1 CARTON (58468-0211-4) / 30 TABLET, FILM COATED in 1 BOTTLE

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
Cablivi	58468-0225-1		KIT		BLA761112	Genzyme Corporation	58468-0225	caplacizumab		HUMAN PRESCRIPTION DRUG	02/06/2019	N/A	BLA	1 KIT in 1 CARTON (58468-0225-1) * 1 mL in 1 VIAL, GLASS (58468-0227-1) * 1 mL in 1 SYRINGE, GLASS (58468-0229-1)
Campath	58468-0357-1	30 mg/mL	INJECTION	INTRAVENOUS	BLA103948	Genzyme Corporation	58468-0357	ALEMTUZUMAB	ALEMTUZUMAB	HUMAN PRESCRIPTION DRUG	11/30/2009	N/A	BLA	1 VIAL, SINGLE-USE in 1 CARTON (58468-0357-1) / 1 mL in 1 VIAL, SINGLE-USE
Campath	58468-0357-3	30 mg/mL	INJECTION	INTRAVENOUS	BLA103948	Genzyme Corporation	58468-0357	ALEMTUZUMAB	ALEMTUZUMAB	HUMAN PRESCRIPTION DRUG	11/30/2009	N/A	BLA	3 VIAL, SINGLE-USE in 1 CARTON (58468-0357-3) / 1 mL in 1 VIAL, SINGLE-USE
CAPRELSA	58468-7820-3	100 mg/1	TABLET, FILM COATED	ORAL	NDA022405	Genzyme Corporation	58468-7820	Vandetanib	VANDETANIB	HUMAN PRESCRIPTION DRUG	07/25/2011	N/A	NDA	1 BOTTLE, PLASTIC in 1 CARTON (58468-7820-3) / 30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC
CAPRELSA	58468-7840-3	300 mg/1	TABLET, FILM COATED	ORAL	NDA022405	Genzyme Corporation	58468-7840	Vandetanib	VANDETANIB	HUMAN PRESCRIPTION DRUG	07/25/2011	N/A	NDA	1 BOTTLE, PLASTIC in 1 CARTON (58468-7840-3) / 30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC
Cerdelga	58468-0220-1	84 mg/1	CAPSULE	ORAL	NDA205494	Genzyme Corporation	58468-0220	eliglustat	ELIGLUSTAT	HUMAN PRESCRIPTION DRUG	09/03/2014	N/A	NDA	4 BLISTER PACK in 1 CARTON (58468-0220-1) / 14 CAPSULE in 1 BLISTER PACK
Cerdelga	58468-0220-2	84 mg/1	CAPSULE	ORAL	NDA205494	Genzyme Corporation	58468-0220	eliglustat	ELIGLUSTAT	HUMAN PRESCRIPTION DRUG	09/03/2014	N/A	NDA	1 BLISTER PACK in 1 CARTON (58468-0220-2) / 14 CAPSULE in 1 BLISTER PACK
Cerezyme	58468-4663-1	40 U/mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	BLA020367	Genzyme Corporation	58468-4663	IMIGLUCERASE	IMIGLUCERASE	HUMAN PRESCRIPTION DRUG	05/23/1994	N/A	BLA	1 VIAL, GLASS in 1 CARTON (58468-4663-1) / 10 mL in 1 VIAL, GLASS
Fabrazyme	58468-0040-1	5 mg/mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	BLA103979	Genzyme Corporation	58468-0040	AGALSIDASE BETA	AGALSIDASE BETA	HUMAN PRESCRIPTION DRUG	12/17/2008	N/A	BLA	1 VIAL, GLASS in 1 CARTON (58468-0040-1) / 7 mL in 1 VIAL, GLASS
Fabrazyme	58468-0041-1	5 mg/mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	BLA103979	Genzyme Corporation	58468-0041	AGALSIDASE BETA	AGALSIDASE BETA	HUMAN PRESCRIPTION DRUG	12/17/2008	N/A	BLA	1 VIAL, GLASS in 1 CARTON (58468-0041-1) / 1 mL in 1 VIAL, GLASS
LEMTRADA	58468-0200-1	12 mg/1.2mL	INJECTION, SOLUTION, CONCENTRATE	INTRAVENOUS	BLA103948	Genzyme Corporation	58468-0200	ALEMTUZUMAB	ALEMTUZUMAB	HUMAN PRESCRIPTION DRUG	11/18/2014	N/A	BLA	1 VIAL, SINGLE-USE in 1 CARTON (58468-0200-1) / 1.2 mL in 1 VIAL, SINGLE-USE

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
Lumizyme	58468-0160-1	5 mg/mL	INJECTION, POWDER, FOR SOLUTION	INTRAVENOUS	BLA125291	Genzyme Corporation	58468-0160	ALGLUCOSIDASE ALFA	ALGLUCOSIDASE ALFA	HUMAN PRESCRIPTION DRUG	05/24/2010	N/A	BLA	1 VIAL, SINGLE-USE in 1 CARTON (58468-0160-1) / 10.5 mL in 1 VIAL, SINGLE-USE
Nexviazyme	58468-0426-1	100 mg/10mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	BLA761194	Genzyme Corporation	58468-0426	avalglucosidase alfa-ngpt	AVALGLUCOSIDASE ALFA	HUMAN PRESCRIPTION DRUG	08/06/2021	N/A	BLA	1 VIAL, SINGLE-DOSE in 1 CARTON (58468-0426-1) / 10 mL in 1 VIAL, SINGLE-DOSE
Qfitlia	58468-0347-1	20 mg/.2mL	INJECTION, SOLUTION	SUBCUTANEOUS	NDA219019	Genzyme Corporation	58468-0347	fitusiran	FITUSIRAN	HUMAN PRESCRIPTION DRUG	03/28/2025	N/A	NDA	1 VIAL in 1 CARTON (58468-0347-1) / .2 mL in 1 VIAL
Qfitlia	58468-0348-1	50 mg/.5mL	INJECTION, SOLUTION	SUBCUTANEOUS	NDA219019	Genzyme Corporation	58468-0348	fitusiran	FITUSIRAN	HUMAN PRESCRIPTION DRUG	03/28/2025	N/A	NDA	1 SYRINGE in 1 CARTON (58468-0348-1) / .5 mL in 1 SYRINGE
Renvela	58468-0133-1	800 mg/1	TABLET, FILM COATED	ORAL	NDA022127	Genzyme Corporation	58468-0133	SEVELAMER CARBONATE	SEVELAMER CARBONATE	HUMAN PRESCRIPTION DRUG	07/14/2023	N/A	NDA	270 TABLET, FILM COATED in 1 BOTTLE (58468-0133-1)
Renvela	58468-0131-2	2400 mg/1	POWDER, FOR SUSPENSION	ORAL	NDA022318	Genzyme Corporation	58468-0131	SEVELAMER CARBONATE	SEVELAMER CARBONATE	HUMAN PRESCRIPTION DRUG	08/12/2009	N/A	NDA	90 PACKET in 1 CARTON (58468-0131-2) / 1 POWDER, FOR SUSPENSION in 1 PACKET (58468-0131-1)
Renvela	58468-0132-2	800 mg/1	POWDER, FOR SUSPENSION	ORAL	NDA022318	Genzyme Corporation	58468-0132	SEVELAMER CARBONATE	SEVELAMER CARBONATE	HUMAN PRESCRIPTION DRUG	08/12/2009	N/A	NDA	90 PACKET in 1 CARTON (58468-0132-2) / 1 POWDER, FOR SUSPENSION in 1 PACKET (58468-0132-1)
Thymoglobulin	58468-0080-1	5 mg/mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	BLA103869	Genzyme Corporation	58468-0080	Anti-thymocyte Globulin (Rabbit)	LAPINE T-LYMPHOCYTE IMMUNE GLOBULIN	HUMAN PRESCRIPTION DRUG	12/30/1998	N/A	BLA	1 VIAL, GLASS in 1 CARTON (58468-0080-1) / 5 mL in 1 VIAL, GLASS
Thyrogen	58468-0030-2	.9 mg/mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAMUSCULAR	BLA020898	Genzyme Corporation	58468-0030	THYROTROPIN ALFA	THYROTROPIN ALFA	HUMAN PRESCRIPTION DRUG	11/30/1998	N/A	BLA	2 VIAL, SINGLE-DOSE in 1 CARTON (58468-0030-2) / 1 mL in 1 VIAL, SINGLE-DOSE (58468-0030-1)
WAYRILZ	58468-0251-5	400 mg/1	TABLET, FILM COATED	ORAL	NDA219685	Genzyme Corporation	58468-0251	rilzabrutinib	RILZABRUTINIB	HUMAN PRESCRIPTION DRUG	08/29/2025	N/A	NDA	2 BLISTER PACK in 1 CARTON (58468-0251-5) / 28 TABLET, FILM COATED in 1 BLISTER PACK (58468-0251-0)
WAYRILZ	58468-0251-6	400 mg/1	TABLET, FILM COATED	ORAL	NDA219685	Genzyme Corporation	58468-0251	rilzabrutinib	RILZABRUTINIB	HUMAN PRESCRIPTION DRUG	08/29/2025	N/A	NDA	1 BOTTLE in 1 CARTON (58468-0251-6) / 60 TABLET, FILM COATED in 1 BOTTLE

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
XENPOZYME	58468-0050-1	20 mg/5.1mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	BLA761261	Genzyme Corporation	58468-0050	olipudase alfa-rpcp	OLIPUDASE ALFA	HUMAN PRESCRIPTION DRUG	08/29/2022	N/A	BLA	1 VIAL in 1 CARTON (58468-0050-1) / 5.1 mL in 1 VIAL
XENPOZYME	58468-0051-1	4 mg/1.1mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	BLA761261	Genzyme Corporation	58468-0051	olipudase alfa-rpcp	OLIPUDASE ALFA	HUMAN PRESCRIPTION DRUG	08/29/2022	N/A	BLA	1 VIAL in 1 CARTON (58468-0051-1) / 1.1 mL in 1 VIAL

Showing 1 to 31 of 31 entries

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Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Attachment E

Corporate Officer Information

Genzyme Corporation

Francois-Xavier M. Dazogbo
Treasurer
% of Ownership: 0

Stephen George Kalinchak
Assistant Secretary
% of Ownership: 0

Attachment A

Nature of Business

Genzyme Corporation (Genzyme) is a biotechnology company and a division of Sanofi, its parent owner. Genzyme is the Specialty Care Global Business Unit of Sanofi, focused on Rare Diseases, Multiple Sclerosis, Oncology, and Immunology.

The Cambridge, MA location never physically handles any of its sample or trade products. The Cambridge location functions as the corporate headquarters and is listed on its product labels.

Genzyme utilizes its affiliated company facilities to warehouse and distribute its trade and sample products. All samples are distributed to licensed healthcare professionals that are authorized to accept prescription drug samples.

Third Party Logistics Providers:

DHL Supply Chain (USA)
1025 Sandhill Road, Reno NV 89521

DHL Supply Chain (USA)
2500 Southpoint Drive, Forest Park GA 30297

Attachment B

Regarding the Reorganization and Organizational Charts

Genzyme Corporation ("Genzyme") was a party to an internal corporate restructuring. The restructuring resulted in a new minority holder of common shares of Genzyme, but had no change to the controlling interest of Genzyme. **In addition, there have been no changes in personnel, FEIN #, or any other information on the face of the license.**

Before the change, Genzyme was 100% wholly-owned by its parent company, Aventis Inc. On December 18, 2025, an affiliated entity, Sanofi Horizon B.V., acquired shares equivalent to 7.835% of Genzyme. Aventis Inc. continues to hold the remaining 92.165% of Genzyme. In addition, the ultimate parent company remains the same. Enclosed please find an organizational chart listing both immediate and ultimate parent and percentages of ownership/equity.

Parent Company Information:

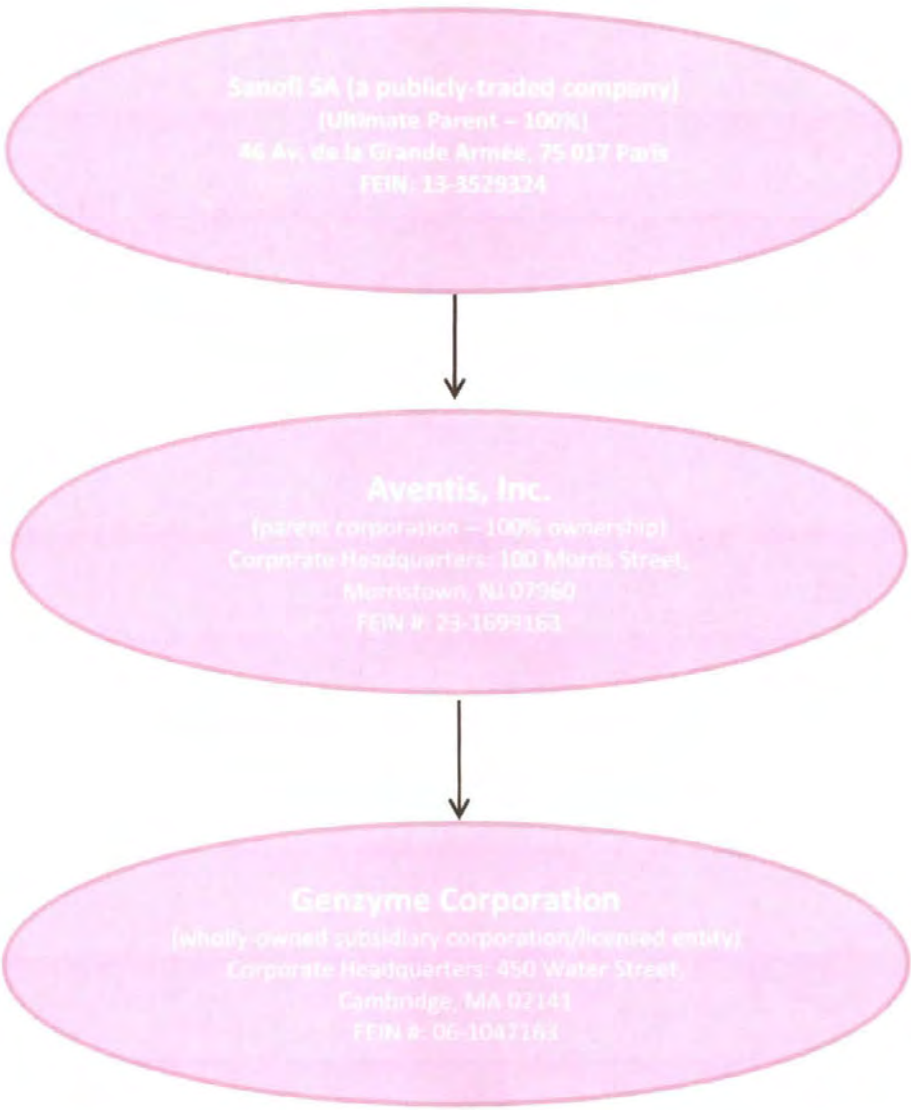
Aventis, Inc.
100 Morris Street, Morristown, NJ 07960
Tax ID #: 23-1699163
Phone: 800-981-2491
% of Ownership: 92.165%

Sanofi Horizon BV
Paasheuvelweg 25, 1105 BP Amsterdam, Netherlands
Phone: +31 20 245 4000
% of Ownership: 7.835%

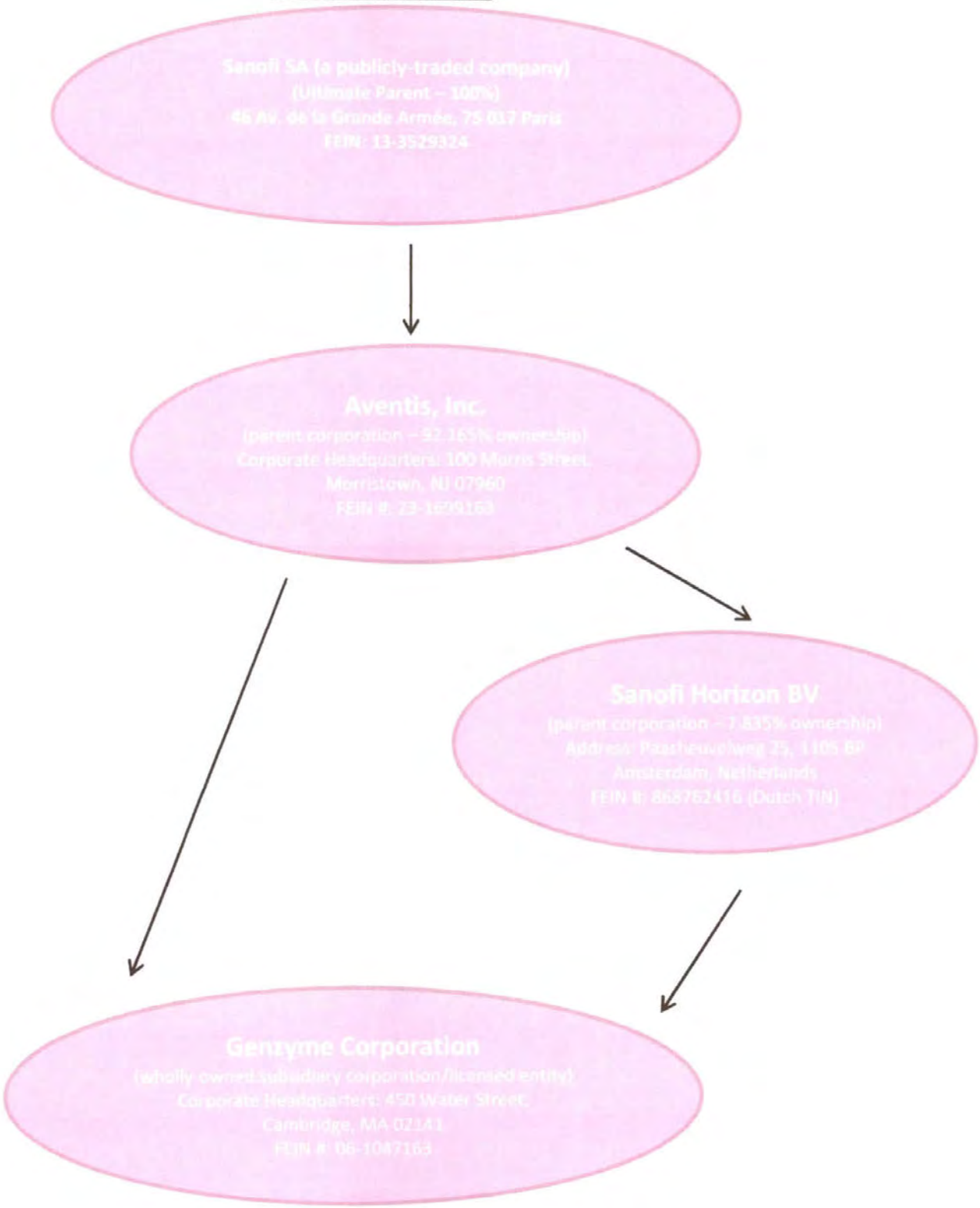
Organizational Chart

Genzyme Corporation

Previous Structure Prior to 12/2025:



New Structure 12/2025:



[redacted]

[redacted]

GENZYME CORPORATION

SUBSCRIPTION AGREEMENT

DECEMBER 18th, 2025

The undersigned, Sanofi Horizon B.V., a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) operating and existing under the laws of the Netherlands, with corporate seat in Amsterdam, the Netherlands, and registered office address at Amsterdam Paasheuvelweg 25, 1105 BP, Amsterdam, the Netherlands, registered with the Dutch Trade Register under number 99040131, hereby subscribes for [redacted] common shares, each with a par value of USD 0.01, (the "**Shares**") of Genzyme Corporation, a Massachusetts corporation (the "**Company**"), for an aggregate purchase price of [redacted].

Sanofi Horizon B.V.

By: [redacted]

Name: [redacted]
Title: Managing Director

Acceptance

This Subscription Agreement regarding the issuance of the Shares is hereby accepted on behalf of the Company.

Genzyme Corporation

By: _____

Name: [redacted]
Title: President

[redacted]

[redacted]

GENZYME CORPORATION

SUBSCRIPTION AGREEMENT

DECEMBER 18th, 2025

The undersigned, Sanofi Horizon B.V., a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) operating and existing under the laws of the Netherlands, with corporate seat in Amsterdam, the Netherlands, and registered office address at Amsterdam Paasheuvelweg 25, 1105 BP, Amsterdam, the Netherlands, registered with the Dutch Trade Register under number 99040131, hereby subscribes for [redacted] common shares, each with a par value of USD 0.01, (the "**Shares**") of Genzyme Corporation, a Massachusetts corporation (the "**Company**"), for an aggregate purchase price of [redacted].

Sanofi Horizon B.V.

By:_____

Name: [redacted]
Title: Managing Director

Acceptance

This Subscription Agreement regarding the issuance of the Shares is hereby accepted on behalf of the Company.

Genzyme Corporation

By: [redacted]

Name: [redacted]
Title: President

The Commonwealth of Massachusetts

Secretary of the Commonwealth

State House, Boston, Massachusetts 02133

William Francis Galvin
Secretary of the
Commonwealth

March 5, 2025

TO WHOM IT MAY CONCERN:

I hereby certify that according to the records of this office,

GENZYME CORPORATION

is a domestic corporation organized on **November 21, 1991**, under the General Laws of the Commonwealth of Massachusetts.

I further certify that there are no proceedings presently pending under the Massachusetts General Laws Chapter 156D section 14.21 for said corporation's dissolution; that articles of dissolution have not been filed by said corporation; that, said corporation has filed all annual reports, and paid all fees with respect to such reports, and so far as appears of record said corporation has legal existence and is in good standing with this office.

In testimony of which,
I have hereunto affixed the
Great Seal of the Commonwealth
on the date first above written.

William Francis Galvin

Secretary of the Commonwealth

Processed By: TAA

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

GENZYME CORPORATION
450 WATER STREET, LOGISTICS OPERATIONS
CAMBRIDGE, MA 02141

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: MA0000973

Type: Virtual Manufacturer

Issue Date: 12/15/2025

Expiration Date: 02/23/2027

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 108102041

Application/License No. WH02560

GENZYME CORPORATION (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 450 Water Street Cambridge, MA 02141 (Address of Applicant/Principal), as PRINCIPAL, and TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square Hartford, CT 06183 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on September 25, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 25th day of September, 2024.

APPLICANT/PRINCIPAL
GENZYME CORPORATION

COMPANY

Authorized Representative

SURETY
TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA

Surety Company's Representative

Wayne G. McVaugh, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Sara Owens

Witness Lori Shelton

Countersigned by:

Nevada Resident Agent Wayne G. McVaugh

Posted February 20, 2020

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Wayne G. McVaugh** of **PHILADELPHIA**, **Pennsylvania**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April**, **2021**.

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **21st** day of **April**, **2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June**, **2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this **25th** day of **September**, **2024**.

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Genzyme Corporation

Pharmacy/Wholesaler License # (if applicable) WH02560

Physical Address 450 Water Street

City Cambridge State MA Zip 02141

Mailing Address (if different from physical address) 100 Morris Street; Attn: Kara McMahon, Manager of State Licensing Operations

City Morristown State NJ Zip 07960

Telephone 617-252-7500 Website www.sanofi.com

Licensing Company Email Kara.McMahon@sanofi.com

Section 2: Personal Information

First Lane Middle Edward Last Wilson

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 100 Morris Street; Attn: Kara McMahon, Manager of State Licensing Operations

City Morristown State NJ Zip 07960

Telephone [redacted] Email Lane.wilson@sanofi.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Arkansas		08/1983 - 05/1987	
Address	**City**	**State**	**Zip**
1002 W Maple Street	Fayetteville	AR	72701
Diploma/Degree obtained, if any			
BSBA			

School Name		From - To (MM/YY – MM/YY)	
Woodlawn High School		08/1979 - 05/1983	
Address	**City**	**State**	**Zip**
6760 US Hwy 63	Rison	AR	71665
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2014 - Present	[redacted]	New Fairfield	CT	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Genzyme Corporation			04/2015 - Present	
Business Address		**City**	**State**	**Zip**
450 Water Street		Cambridge	MA	02141
Phone	**Title**		**Number of Employed Hours**	
617-252-7500	Head Business Operations and Shared Services		40 hours a week	

Description of Duties
Responsible form commercial strategist including market access, commercial structure, operations, product planning and launches Responsible for state licensing distribution requirements and primary contact for Genzyme Corporation including but not limited to development of overall strategy, distribution, full accountably for for business marketing, managed care strategy, and integrated medical strategy

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

I, Lane E. Wilson, **certify that as the designated representative for**

Genzyme Corporation,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. LW I am at least 21 years of age;
3. LW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. LW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. LW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. LW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. LW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Lane E. Wilson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/24/22

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lane E. Wilson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/24/26

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Morris

I, Lane Wilson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/24/26

Date

Subscribed and Sworn to before me this 24th day of January 2026

Kara McMcMahon

Notary Public Signature

KARA MCMAHON
NOTARY PUBLIC
STATE OF NEW JERSEY
MY COMMISSION EXPIRES APRIL 16, 2029
COMMISSION: #2182036
(Seal)

Genzyme Corporation Employee List

Francois-Xavier M. Dazogbo
Treasurer
Business Address: 100 Morris Street, Morristown, NJ 07960
% of Ownership: 0%

Stephen Kalinchak
Secretary
Business Address: 100 Morris Street, Morristown, NJ 07960
% of Ownership: 0%

Designated Representative Information

Name: Lane Wilson
Title: Head Business Operations and Shared Services
Business address: 450 Water Street, Cambridge, MA
Business phone: 908.357.2234
Email address: Lane.wilson@sanofi.com

Residence address: [redacted]
Social Security Number: [redacted]
Driver's License Numbe[redacted]
Date of Birth: [redacted]
Place of birth: [redacted]
[redacted]

Percentage of ownership (officer of the company): 0%

4AA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Safecor Health, LLC

Physical Address: 4951 Hiawatha Drive

City: Rockford State: IL Zip: 61103

Mailing Address (if different from physical address): 4901 Hiawatha Drive

City: Rockford State: I L Zip: 61103

Telephone: 815-654-1201 Website: www.safecorhealth.com

Name of Designated Representative (DR): Valerie Schissel

Licensing Company Email: vschissel@safecorhealth.com DR Email: vschissel@safecorhealth.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	■ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: 3PL

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/16/26
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Mylan Pharmaceuticals Inc.

Address: 3711 Collins Ferry Road City: Morgantown State: WV Zip: 26505

Name: Teva Pharmaceuticals USA

Address: 1090 Horsham Road City: North Wales State: PA Zip: 19454

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): VSCP SH Intermediate, LLC

Corporation/Organization Name: Safecor Health, LLC

Mailing Address: 4060 Business Park Drive

City: Columbus State: OH Zip: 43204

Telephone: 614-351-6117 Email: msaxon@saxon@safecorhealth.com

Contact Person Name: Mark Saxon

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Safecor Health, LLC

Facility Name

Mark Saxon

Print Name of Authorized Person Submitting Application



Original signature of Authorized Person (copies or stamps not accepted)

2/11/2026

Date

Board Use Only	Date Received: 2/26/26	Amount: $1000 CK 1000007585

National Drug Code Directory

Current through March 03, 2026

You have searched Finished drug products

Search Results: *'48433'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marke Date
+ Abacavir Sulfate	48433-001-06	300 mg/1	TABLET, FILM COATED	ORAL	ANDA091294	Safecor Health, LLC	48433-001	abacavir sulfate	ABACAVIR SULFATE	HUMAN PRESCRIPTION DRUG	02/23/2026	N/A
+ Aspirin	48433-129-01	81 mg/1	TABLET	ORAL	M343	Safecor Health, LLC	48433-129	Aspirin 81 mg	ASPIRIN	HUMAN OTC DRUG	11/01/2022	N/A
+ Atenolol	48433-004-20	25 mg/1	TABLET	ORAL	ANDA073457	Safecor Health, LLC	48433-004	atenolol	ATENOLOL	HUMAN PRESCRIPTION DRUG	02/03/2026	N/A
+ Atenolol	48433-005-20	50 mg/1	TABLET	ORAL	ANDA073457	Safecor Health, LLC	48433-005	atenolol	ATENOLOL	HUMAN PRESCRIPTION DRUG	02/03/2026	N/A
+ Atenolol	48433-006-20	100 mg/1	TABLET	ORAL	ANDA073457	Safecor Health, LLC	48433-006	atenolol	ATENOLOL	HUMAN PRESCRIPTION DRUG	02/03/2026	N/A

Top (https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Mark Date
Senna Syrup	48433-219-40	8.8 mg/5mL	LIQUID	ORAL	M334	Safecor Health, LLC	48433-219	Sennosides	SENNOSIDES	HUMAN OTC DRUG	03/01/2020	N/A
Strong Iodine Solution	48433-230-15	700 mg/mL, 1400 mg/mL	SOLUTION/ DROPS	ORAL		Safecor Health, LLC	48433-230	Strong Iodine Solution	IODINE; POTASSIUM IODIDE	HUMAN PRESCRIPTION DRUG	09/20/2008	N/A
Thioridazine Hydrochloride	48433-095-20	10 mg/1	TABLET, FILM COATED	ORAL	ANDA088004	Safecor Health LLC	48433-095	thioridazine hydrochloride	THIORIDAZINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	02/19/2026	N/A
Thioridazine Hydrochloride	48433-096-20	25 mg/1	TABLET, FILM COATED	ORAL	ANDA088004	Safecor Health LLC	48433-096	thioridazine hydrochloride	THIORIDAZINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	02/19/2026	N/A
Thioridazine Hydrochloride	48433-097-20	50 mg/1	TABLET, FILM COATED	ORAL	ANDA088004	Safecor Health LLC	48433-097	thioridazine hydrochloride	THIORIDAZINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	02/19/2026	N/A
Thioridazine Hydrochloride	48433-098-20	100 mg/1	TABLET, FILM COATED	ORAL	ANDA088004	Safecor Health LLC	48433-098	thioridazine hydrochloride	THIORIDAZINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	02/19/2026	N/A

Showing 1 to 45 of 45 entries

Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Top (https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm)

Safecor Health, LLC
List of Owners and Officers

Safecor Health, LLC is 100% owned by VSCP SH Intermediate, LLC

Mark Saxon
CEO
4060 Business Park Drive
Columbus, OH 43204
Phone: 800-447-1006 x 3199

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SAFECOR HEALTH, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF JANUARY, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SAFECOR HEALTH, LLC" WAS FORMED ON THE FIFTEENTH DAY OF FEBRUARY, A.D. 2008.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

4494176 8300

SR# 20260275284

Authentication: 202900880

Date: 01-23-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
004.005565

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
12/31/2026

LICENSED WHOLESALE DRUG DISTRIBUTOR

WHOLESALE DRUG

SAFECOR HEALTH LLC
VALERIE SCHISSEL
4951 HIAWATHA DR
ROCKFORD, IL 61103-1287

MARIO TRETO, JR.
SECRETARY

CAMILE LINDSAY
DIRECTOR

The official status of this license can be verified at IDFPR.illinois.gov

20236218

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 3479268

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
304.008064
004.005565

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
12/31/2026

LICENSED CONTROLLED SUBSTANCE DRUG DIST

III IV V

SAFECOR HEALTH LLC
4951 HIAWATHA DR
ROCKFORD, IL 61103-1287

MARIO TRETO, JR.
SECRETARY

CAMILE LINDSAY
DIRECTOR

The official status of this license can be verified at IDFPR.illinois.gov

20236225

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 3479268

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
278.000274

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
12/31/2026

WHOLESALE DRUG THIRD PARTY
LOGISTICS PROVIDER

SAFECOR HEALTH LLC
VALERIE SCHISSEL
4951 HIAWATHA DR
ROCKFORD, IL 61103-1287

MARIO TRETO, JR.
SECRETARY

CAMILE LINDSAY
DIRECTOR

The official status of this license can be verified at IDFPR.illinois.gov

20603122

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 3479268

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
378.000084
278.000274

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
12/31/2026

WHOLESALE DRUG THIRD PARTY LOGISTICS
PROVIDER CONTROLLED SUBSTANCE

III IV V

SAFECOR HEALTH LLC
4951 HIAWATHA DR
ROCKFORD, IL 61103-1287

MARIO TRETO, JR.
SECRETARY

CAMILE LINDSAY
DIRECTOR

The official status of this license can be verified at IDFPR.illinois.gov

20603123

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 3479268

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RS0704684	02-28-2027	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	01-29-2026

SAFECOR HEALTH LLC
4951 HIAWATHA DR
ROCKFORD, IL 611031287

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RS0704684	02-28-2027	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	01-29-2026

SAFECOR HEALTH LLC
4951 HIAWATHA DR
ROCKFORD, IL 611031287

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RS0704684	02-28-2027	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	01-29-2026

SAFECOR HEALTH LLC
4951 HIAWATHA DR
ROCKFORD, IL 611031287

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions

You have been registered to handle the following chemical/drug codes:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. CIC1960568

Application/License No. _____

SAFECOR HEALTH, LLC
_____, doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
4951 HIAWATHA DRIVE, ROCKFORD, IL 61103-1287
_____, as
Address of Applicant/Principal
PRINCIPAL, and Capitol Indemnity Corporation
_____, a
Surety Company
corporation organized under the laws of the state of Wisconsin
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
1600 Aspen Commons, Suite 300, Middleton, WI 53562
_____ as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 4, 2026
.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 4th day of March, 20 26.

APPLICANT/PRINCIPAL

COMPANY

Mark Sayon
Authorized Representative

SURETY
Capitol Indemnity Corporation

Surety Company's Representative

John Gaffney, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Nicole E Brown
Witness

Samantha Wood
Witness

Countersigned by:

Nevada Resident Agent

CAPITOL INDEMNITY CORPORATION
POWER OF ATTORNEY

CIC1960568
Bond Number

KNOW ALL MEN BY THESE PRESENTS, That the **CAPITOL INDEMNITY CORPORATION**, a corporation of the State of Wisconsin, having its principal offices in the City of Middleton, Wisconsin, does make, constitute and appoint

----------CHERYL TOOTLE, JENNIFER GERHARDT; JOHN P. GAFFNEY----------

its true and lawful Attorney(s)-in-fact, to make, execute, seal and deliver for and on its behalf, as surety, and as its act and deed, any and all bonds, undertakings and contracts of suretyship, provided that no bond or undertaking or contract of suretyship executed under this authority shall exceed in amount the sum of

----------ALL WRITTEN INSTRUMENTS IN AN AMOUNT NOT TO EXCEED: $20,000,000.00----------

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of **CAPITOL INDEMNITY CORPORATION** at a meeting duly called and held on the 15th day of May, 2002.

"**RESOLVED**, that the President, Executive Vice President, Vice President, Secretary or Treasurer, acting individually or otherwise, be and they hereby are granted the power and authorization to appoint by a Power of Attorney for the purposes only of executing and attesting bonds and undertakings, and other writings obligatory in the nature thereof, one or more resident vice-presidents, assistant secretaries and attorney(s)-in-fact, each appointee to have the powers and duties usual to such offices to the business of this company; the signature of such officers and seal of the Company may be affixed to any such power of attorney or to any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signatures or facsimile seal shall be valid and binding upon the Company, and any such power so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking or other writing obligatory in the nature thereof to which it is attached. Any such appointment may be revoked, for cause, or without cause, by any of said officers, at any time."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner – Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

IN WITNESS WHEREOF, the **CAPITOL INDEMNITY CORPORATION** has caused these presents to be signed by its officer undersigned and its corporate seal to be hereto affixed duly attested, this 1st day of September, 2022.

Attest:

Ryan J. Byrnes
Senior Vice President,
Chief Financial Officer and Treasurer

Todd Burrick
Chief Underwriting Officer

CAPITOL INDEMNITY CORPORATION CORPORATE SEAL WISCONSIN

CAPITOL INDEMNITY CORPORATION

Adam L. Sills
Chief Executive Officer and President

STATE OF WISCONSIN
COUNTY OF DANE } S.S.:

On the 1st day of September, 2022 before me personally came Adam L. Sills, to me known, who being by me duly sworn, did depose and say: that he resides in the County of New York, State of New York; that he is Chief Executive Officer and President of **CAPITOL INDEMNITY CORPORATION**, the corporation described in and which executed the above instrument; that he knows the seal of the said corporation; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said corporation and that he signed his name thereto by like order.

DAVID J. REGELE NOTARY PUBLIC STATE OF WISCONSIN

David J. Regele
Notary Public, Dane Co., WI
My Commission Is Permanent

STATE OF WISCONSIN
COUNTY OF DANE } S.S.:

I, the undersigned, duly elected to the office stated below, now the incumbent in **CAPITOL INDEMNITY CORPORATION**, a Wisconsin Corporation, authorized to make this certificate, **DO HEREBY CERTIFY** that the foregoing attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolution of the Board of Directors, set forth in the Power of Attorney is now in force.

Signed and sealed at the City of Middleton, State of Wisconsin this 4TH day of MARCH 20 26

CAPITOL INDEMNITY CORPORATION CORPORATE SEAL WISCONSIN

Suzanne M. Broadbent
Secretary

THIS DOCUMENT HAS BEEN GENERATED FOR A SPECIFIC BOND. IF YOU HAVE ANY QUESTIONS CONCERNING THE AUTHENTICITY OF THIS DOCUMENT CALL 800-475-4450.

CIC-ePOA-M (Rev. 09-2022)

Scott Kipper, Commissioner of Insurance

Non-Resident Producer

Qualification Effective Dates

Casualty	06/30/2025	Health	06/30/2025
Life	06/30/2025	Property	06/30/2025

JOHN GAFFNEY

NPN: 16449770

5905 E GALBRAITH RD STE 9000
CINCINNATI, OHIO 45236-2383

is authorized to transact business as described above

License No: 4125636 Issue Date: 06/30/2025 Expiration Date: 06/30/2028

Generated by Sircon 349225285

Nevada Division of Insurance

THIS IS TO CERTIFY THAT

JOHN GAFFNEY
5905 E GALBRAITH RD STE 9000
CINCINNATI, OHIO 45236-2383

LICENSE NUMBER: 4125636 NPN: 16449770

IS HEREBY AUTHORIZED TO TRANSACT BUSINESS IN ACCORDANCE TO THE LICENSE DESCRIPTION SHOWN BELOW:

Non-Resident Producer

Casualty, Health, Life, Property

Issue Date: 06/30/2025 Expiration Date: 06/30/2028

Generated by Sircon 349225285

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Safecor Health, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 4951 Hiawatha Drive

City Rockford State IL Zip 61103

Mailing Address (if different from physical address) 4901 Hiawatha Drive

City Rockford State IL Zip 61103

Telephone 815-282-1201 Website www.safecorhealth.com

Licensing Company Email vschissel@safecorhealth.com

Section 2: Personal Information

First Valerie Middle _____ Last Schissel

Alias(es, nicknames, name changes, etc.) Valerie Gramzow

Date of Birth [redacted] SSN or ITIN _____ Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Rockford State IL Zip [redacted]

Telephone 815-282-1201 Email vschissel@safecorhealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Boylan Central Catholic High School		08/82-05/86	
Address	**City**	**State**	**Zip**
4000 Saint Francis Drive	Rockford	IL	61103
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/92 - present	[redacted]	Rockford	IL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Safecor Health, LLC			06/2025-Present
Business Address	**City**	**State**	**Zip**
4951 Hiawatha Drive	Rockford	IL	61103
Phone	**Title**	**Number of Employed Hours**	
815-282-1201	Senior Manager QA Receiving/Labeling	1,170	

Description of Duties

Direct, guide, support and coach the QA Receiving, Quality NOR and Hold, Label Control and Label Design Department personnel. Responsible for the direct supervision and activities department staffing, scheduling, work assignments, training, employee development of the Supervisor Receiving and Label Control, Labeling Associate and Labeling Assistant at the Hiawatha facility.

Business Name			From - To (MM/YY – MM/YY)
Mylan Institutional Inc.			01/07-06/2025
Business Address	**City**	**State**	**Zip**
4951 Hiawatha Drive	Rockford	IL	61103
Phone	**Title**	**Number of Employed Hours**	
815-282-1201	Senior Manager QA Receiving/Labeling	36,000	

Description of Duties

Direct, guide, support and coach the QA Receiving, Quality NOR and Hold, Label Control and Label Design Department personnel. Responsible for the direct supervision and activities department staffing, scheduling, work assignments, training, employee development of the Supervisor Receiving and Label Control, Labeling Associate and Labeling Assistant at the Hiawatha facility.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

02-20-2026
Date

I, Valerie Schissel, **certify that as the designated representative for**

Safecor Health, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. VS I am at least 21 years of age;
3. VS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. VS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. VS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. VS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. VS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Valerie Schissel

Print Name (First, Last)

Valerie Schissel

Original Signature (electronic, copies or stamps not accepted)

02/20/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Valerie Schissel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-20-2024

Date

Please have this section completed in the presence of a Notary Public.

State of Illinois, ss. County of Winnebago

I, Valerie Schissel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2-20-2024

Date

Subscribed and Sworn to before me this 20th day of February.

Notary Public Signature

OFFICIAL SEAL
CASEY MARIE WHEELER
Notary Public, State of Illinois
Commission No. 1015993
My Commission Expires August 25, 2029

(Seal)

Safecor Health LLC
4951 Hiawatha Drive
Rockford, IL 61103

List of Employees

DEAN	SHAY	VP of Operations
VALERIE	SCHISSEL	Sr. Manager QA Receiving/Labeling
LIZ	PEREZ	Supervisor QA Receiving and Label Control
TIMOTHY	BENIDT	Supervisor, Labeling and Receiving
KAREN	COY	Sr. Specialist, Labeling
MARY	DAY-TALLEY	Sr. Specialist, Quality Receiving
LESLEY	FRINT	Sr. Specialist, Label Control
KIRT	JOHNSON	Sr. Coordinator, Material Handling
JAIME	LAMER	Sr. Specialist, Labeling
LAINE	OLSON	Sr. Specialist, Printing
LIZBETH	PEREZ-MORALES	Supervisor, Labeling and Receiving
MICHAEL	RODRIGUEZ	Sr. Coordinator, Material Handling
ENES	VREBAC	Sr. Specialist, Label Control

4BB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) * If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Sanofi Vaccines US Inc.

Physical Address: 1 Discovery Drive

City: Swiftwater State: PA Zip: 18370

Mailing Address (if different from physical address): 100 Morris Street, Attn: Kara McMcahon

City: Morristown State: NJ Zip: 07960

Telephone: (570) 839-7187 Website: www.sanofipasteur.us

Name of Designated Representative (DR): Patrick O'Neil

Licensing Company Email: Kara.McMahon@sanofi.com DR Email: Patrick.O'Neil@sanofi.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☑ Pharmacies ☑ Practitioners ☑ Hospitals ☑ Wholesalers ☐ Veterinarians ☐ Others:	☑ Dangerous Drugs ☐ Controlled Substances ☐ [a]Medical devices, equipment, supplies, gases ☐ Others:	☑ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: DHL Supply Chain (USA)
Address: 1025 Sandhill Road City: Reno State: NV Zip: 89521
Name: DHL Supply Chain (USA)
Address: 2500 Southpoint Drive City: Forest Park State: GA Zip: 30297
Name: N/A
Address: City: State: Zip:
Name: N/A
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): N/A - See Attachment C for Ownership Information
Corporation/Organization Name: Sanofi Vaccines US Inc.
Mailing Address: 100 Morris Street, Attn: Kara McMcahon
City: Morristown State: NJ Zip: 07960
Telephone: (570) 839-7187 Email: Kara.McMahon@sanofi.com
Contact Person Name: Kara McMahon

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration See Attachment A 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment B		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment C	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment C		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment D	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment E		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - owned by corporation		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment F	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment G	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: N/A http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Sanofi Vaccines US Inc.

Facility Name

Patrick O'Neil

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

18 Feb 2026

Date

Amanda Loizeaux 18 Feb 2026

Commonwealth of Pennsylvania - Notary Seal
AMANDA LOIZEAUX - Notary Public
Monroe County
My Commission Expires August 14, 2027
Commission Number 1201291

Board Use Only	Date Received: 2/23/26	Amount: $ waive

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (index.cfm)

Search Results for **Sanofi Vaccines**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Sanofi Vaccines US Inc.	2518760	086723285	LABEL; MANUFACTURE; PACK;	1 Discovery Drive, Swiftwater, Pennsylvania (PA) 18370, United States (USA)	12/31/2026

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Tuesday, Jan 13, 2026

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Provided MH 2/23/26

Attachment C

Corporate Officer and Ownership Information

Sanofi Vaccines US Inc.

Ownership:

97.99% owned by :
Merieux US Holdings ULC
Address: PO BOX 49130 2900 - 595 BURRARD STREET VANCOUVER BC V7X 1J5 CANADA

2.01% owned by:
Sanofi Pasteur Participants
Address: 82 AVENUE RASPAIL; GENTILLY; 94250; VAL-DE-MARNE; FRANCE

Corporate Officers:

Matthew H. Farmer
Secretary

Francois-Xavier M. Dazogbo
Treasurer

Stephen Kalinchak
Assistant Secretary

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SANOFI VACCINES US INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTH DAY OF FEBRUARY, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SANOFI VACCINES US INC." WAS INCORPORATED ON THE EIGHTEENTH DAY OF JANUARY, A.D. 1977.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

833607 8300

SR# 20260427868

Authentication: 202996427

Date: 02-04-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

STATE OF NEVADA

FRANCISCO V. AGUILAR
Secretary of State

C. MURPHY HEBERT
Chief Deputy Secretary of State

DEANNA L. REYNOLDS
Deputy Secretary for Commercial Recordings

OFFICE OF THE
SECRETARY OF STATE

Business Entity - Filing Acknowledgement

01/02/2026

Work Order Item Number:	W2026010202063-4950827
Filing Number:	20265418097
Filing Type:	Officer's Statement
Filing Date/Time:	1/2/2026 12:41:00 PM
Filing Page(s):	4

Indexed Entity Information:

Entity ID: C9322-1990 **Entity Name:** SANOFI PASTEUR INC.

Entity Status: Active **Expiration Date:** None

Commercial Registered Agent

CORPORATION SERVICE COMPANY*

112 NORTH CURRY STREET, Carson City, NV 89703, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Commercial Recording

2250 Las Vegas Blvd North
North Las Vegas, NV 89030

401 N. Carson Street
Carson City, NV 89701

1 State of Nevada Way
Las Vegas, NV 89119

Filed in the Office of	Business Number
FHAguilar	C9322-1990
	Filing Number
Secretary of State	20265418097
State Of Nevada	Filed On
	1/2/2026 12:41:00 PM
	Number of Pages
	4

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov

Profit Corporation:

Certificate of Amendment (PURSUANT TO NRS 78.380 & 78.385/78.390)
Certificate to Accompany Restated Articles or Amended and Restated Articles (PURSUANT TO NRS 78.403)
Officer's Statement (PURSUANT TO NRS 80.030)

TYPE OR PRINT - USE DARK INK ONLY - DO NOT HIGHLIGHT

1. Entity information:

Name of entity as on file with the Nevada Secretary of State:
Sanofi Pasteur Inc.

Entity or Nevada Business Identification Number (NVID): C9322-1990

2. Restated or Amended and Restated Articles:
(Select one)

(If amending and restating only, complete section 1,2 3, 5 and 6)

☐ Certificate to Accompany Restated Articles or Amended and Restated Articles
☐ Restated Articles - No amendments; articles are restated only and are signed by an officer of the corporation who has been authorized to execute the certificate by resolution of the board of directors adopted on:
The certificate correctly sets forth the text of the articles or certificate as amended to the date of the certificate.
☐ Amended and Restated Articles
* Restated or Amended and Restated Articles must be included with this filing type.

3. Type of Amendment Filing Being Completed:
(Select only one box)

(If amending, complete section 1, 3, 5 and 6.)

☐ Certificate of Amendment to Articles of Incorporation (Pursuant to NRS 78.380 - Before Issuance of Stock)
The undersigned declare that they constitute at least two-thirds of the following: (Check only one box) ☐ incorporators ☐ board of directors
The undersigned affirmatively declare that to the date of this certificate, no stock of the corporation has been issued

☐ Certificate of Amendment to Articles of Incorporation (Pursuant to NRS 78.385 and 78.390 - After Issuance of Stock)
The vote by which the stockholders holding shares in the corporation entitling them to exercise at least a majority of the voting power, or such greater proportion of the voting power as may be required in the case of a vote by classes or series, or as may be required by the provisions of the articles of incorporation* have voted in favor of the amendment is:
Or ☐ No action by stockholders is required, name change only.

☒ Officer's Statement (foreign qualified entities only) -
Name in home state, if using a modified name in Nevada:

Jurisdiction of formation: Delaware

Changes to takes the following effect:
☒ The entity name has been amended.
☐ The purpose of the entity has been amended.
☐ The authorized shares have been amended.
☐ Other: (specify changes)
Sanofi Vaccines US Inc.

☐ Dissolution
☐ Merger
☐ Conversion

* Officer's Statement must be submitted with either a certified copy of or a certificate evidencing the filing of any document, amendatory or otherwise, relating to the original articles in the place of the corporations creation.

This form must be accompanied by appropriate fees.

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov

Profit Corporation:
Certificate of Amendment (PURSUANT TO NRS 78.380 & 78.385/78.390)
Certificate to Accompany Restated Articles or Amended and Restated Articles (PURSUANT TO NRS 78.403)
Officer's Statement (PURSUANT TO NRS 80.030)

4. Effective Date and Time: (Optional)

Date: Time:

(must not be later than 90 days after the certificate is filed)

5. Information Being Changed: (Domestic corporations only)

Changes to takes the following effect:

The entity name has been amended.

The registered agent has been changed. (attach Certificate of Acceptance from new registered agent)

The purpose of the entity has been amended.

The authorized shares have been amended.

The directors, managers or general partners have been amended.

IRS tax language has been added.

Articles have been added.

Articles have been deleted.

Other.

The articles have been amended as follows: (provide article numbers, if available)

(attach additional page(s) if necessary)

6. Signature: (Required)

X Matthew Farmer Digitally signed by Matthew Farmer Date: 2025.12.03 17:25:39 -05'00' Secretary

Signature of Officer or Authorized Signer Title

X _____

Signature of Officer or Authorized Signer Title

*If any proposed amendment would alter or change any preference or any relative or other right given to any class or series of outstanding shares, then the amendment must be approved by the vote, in addition to the affirmative vote otherwise required, of the holders of shares representing a majority of the voting power of each class or series affected by the amendment regardless to limitations or restrictions on the voting power thereof.

Please include any required or optional information in space below:
(attach additional page(s) if necessary)

This form must be accompanied by appropriate fees.

Certificate of Licensure

Certificate No. 8000000069
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Category:

Wholesaler/Distributor

Drug & Device Registration
Attn: DDC
2525 N. Seventh Street, Suite 210D
Harrisburg, PA 17110
(717) 787-4779

SANOFI VACCINES US INC.
ONE DISCOVERY DRIVE
SWIFTWATER, PA 18370

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Wholesale Prescription Drug License Act, Act #145, approved December 14, 1992.

Issuance Date: September 01, 1994
Expiration Date: The Last Day of February, 2027

Jeanne Parisi
Deputy Secretary for Quality Assurance

Pennsylvania
Department of Health

Debra L. Bogen, MD, FAAP
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

BOND NO. 9366902

RIDER

To be attached to and form a part of Bond No. 9366902

executed by SANOFI PASTEUR, INC. as Principal

and by FIDELITY AND DEPOSIT COMPANY OF MARYLAND as Surety,

in favor of NEVADA STATE BOARD OF PHARMACY,

and effective as of October 19, 2020,

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing Principal Name Change and add additional location

FROM: Principal Name: Sanofi Pasteur, Inc.

TO: Principal Name: Sanofi Vaccines US Inc. - Add location: One Discovery Drive, Swiftwater, PA 18370

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated. This rider is effective on the 3rd day of December, 2025.

Signed and sealed this 12th day of December, 2025.

SANOFI VACCINES US INC.

Principal

BY: Elyda Kolick

FIDELITY AND DEPOSIT COMPANY OF MARYLAND

Surety

BY: Kimberly G. Sherrod

Kimberly G. Sherrod Attorney-in-Fact

ZURICH AMERICAN INSURANCE COMPANY
COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND
POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the ZURICH AMERICAN INSURANCE COMPANY, a corporation of the State of New York, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, a corporation of the State of Illinois, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND a corporation of the State of Illinois (herein collectively called the "Companies"), by Robert D. Murray, Vice President, in pursuance of authority granted by Article V, Section 8, of the By-Laws of said Companies, which are set forth on the reverse side hereof and are hereby certified to be in full force and effect on the date hereof, do hereby nominate, constitute, and **appoint** AnnMarie BREENE, Joanne C. WAGNER, Patricia DORSANEO, Cathy H. HO, Patricia A. RAMBO, Sara OWENS, Kimberly G. SHERROD, Patrick R. BREENE, Babette WARD, Dana DONAHUE, Lori S. SHELTON, Wayne G. MCVAUGH of Philadelphia, Pennsylvania, its true and lawful agent and Attorney-in-Fact, to make, execute, seal and deliver, for, and on its behalf as surety, and as its act and deed: **any and all bonds and undertakings,** and the execution of such bonds or undertakings in pursuance of these presents, shall be as binding upon said Companies, as fully and amply, to all intents and purposes, as if they had been duly executed and acknowledged by the regularly elected officers of the ZURICH AMERICAN INSURANCE COMPANY at its office in New York, New York., the regularly elected officers of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at its office in Owings Mills, Maryland., and the regularly elected officers of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at its office in Owings Mills, Maryland., in their own proper persons.

The said Vice President does hereby certify that the extract set forth on the reverse side hereof is a true copy of Article V, Section 8, of the By-Laws of said Companies, and is now in force.

IN WITNESS WHEREOF, the said Vice-President has hereunto subscribed his/her names and affixed the Corporate Seals of the said **ZURICH AMERICAN INSURANCE COMPANY, COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and FIDELITY AND DEPOSIT COMPANY OF MARYLAND**, this 25th day of February A.D. 2025.

ATTEST:
ZURICH AMERICAN INSURANCE COMPANY
COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND

By: Thomas O. McClennan
Vice President

By: Dawn E. Brown
Secretary

State of Maryland
County of Baltimore

On this 25th day of February, A.D. 2025 before the subscriber, a Notary Public of the State of Maryland, duly commissioned and qualified, **Thomas O. McClellan, Vice President and Dawn E. Brown, Secretary** of the Companies, to me personally known to be the individuals and officers described in and who executed the preceding instrument, and acknowledged the execution of same, and being by me duly sworn, deposeth and saith, that he/she is the said officer of the Company aforesaid, and that the seals affixed to the preceding instrument are the Corporate Seals of said Companies, and that the said Corporate Seals and the signature as such officer were duly affixed and subscribed to the said instrument by the authority and direction of the said Corporations.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal the day and year first above written.

Genevieve M. Maisonneuve
Notary Public
My Commission Expires January 27, 2029

Authenticity of this bond can be confirmed at bondvalidator.zurichna.com or 410-559-8790

EXTRACT FROM BY-LAWS OF THE COMPANIES

"Article V, Section 8, Attorneys-in-Fact. The Chief Executive Officer, the President, or any Executive Vice President or Vice President may, by written instrument under the attested corporate seal, appoint attorneys-in-fact with authority to execute bonds, policies, recognizances, stipulations, undertakings, or other like instruments on behalf of the Company, and may authorize any officer or any such attorney-in-fact to affix the corporate seal thereto; and may with or without cause modify of revoke any such appointment or authority at any time."

CERTIFICATE

I, the undersigned, Vice President of the ZURICH AMERICAN INSURANCE COMPANY, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND, do hereby certify that the foregoing Power of Attorney is still in full force and effect on the date of this certificate; and I do further certify that Article V, Section 8, of the By-Laws of the Companies is still in force.

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the ZURICH AMERICAN INSURANCE COMPANY at a meeting duly called and held on the 15th day of December 1998.

RESOLVED: "That the signature of the President or a Vice President and the attesting signature of a Secretary or an Assistant Secretary and the Seal of the Company may be affixed by facsimile on any Power of Attorney...Any such Power or any certificate thereof bearing such facsimile signature and seal shall be valid and binding on the Company."

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at a meeting duly called and held on the 5th day of May, 1994, and the following resolution of the Board of Directors of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at a meeting duly called and held on the 10th day of May, 1990.

RESOLVED: "That the facsimile or mechanically reproduced seal of the company and facsimile or mechanically reproduced signature of any Vice-President, Secretary, or Assistant Secretary of the Company, whether made heretofore or hereafter, wherever appearing upon a certified copy of any power of attorney issued by the Company, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seals of the said Companies, this 12th day of December, 2025.



Mary Jean Pethick
Vice President

TO REPORT A CLAIM WITH REGARD TO A SURETY BOND, PLEASE SUBMIT A COMPLETE DESCRIPTION OF THE CLAIM INCLUDING THE PRINCIPAL ON THE BOND, THE BOND NUMBER, AND YOUR CONTACT INFORMATION TO:

Zurich Surety Claims
1299 Zurich Way
Schaumburg, IL 60196-1056
reportsfclaims@zurichna.com
800-626-4577

Authenticity of this bond can be confirmed at bondvalidator.zurichna.com or 410-559-8790

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 9366902

Application/License No. _____

Sanofi Pasteur, Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
50 Stauffer Industrial Park, Taylor, PA 18517, as
(Address of Applicant/Principal)
PRINCIPAL, and Fidelity and Deposit Company of Maryland, a
(Surety Company)
corporation organized under the laws of the state of Illinois
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
1299 Zurich Way, Schaumburg IL 60196-1056 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 19, 2020.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 19th day of October, 2020.

Sanofi Pasteur, Inc.
APPLICANT/PRINCIPAL

Authorized Representative

Fidelity and Deposit Company of Maryland
SURETY COMPANY

Surety Company's Representative

Jaquanda Martin, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Sabrina Jackson

Witness Kevin King

Countersigned by:

Nevada Resident Agent

Wayne G. McVaugh, NonRes Agent #500206

ZURICH AMERICAN INSURANCE COMPANY
COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND
POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the ZURICH AMERICAN INSURANCE COMPANY, a corporation of the State of New York, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, a corporation of the State of Illinois, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND a corporation of the State of Illinois (herein collectively called the "Companies"), by **Robert D. Murray, Vice President**, in pursuance of authority granted by Article V, Section 8, of the By-Laws of said Companies, which are set forth on the reverse side hereof and are hereby certified to be in full force and effect on the date hereof, do hereby nominate, constitute, and appoint **Wayne G. MCVAUGH, Elizabeth MARRERO, Patricia A. RAMBO, Sara OWENS, Kimberly G. SHERROD, Joanne C. WAGNER, Vicki JOHNSTON, Cathy H. HO, George GIONIS, Lori SHELTON, Jaquanda MARTIN and Kaitlyn MALKOWSKI all of Philadelphia, Pennsylvania, EACH,** its true and lawful agent and Attorney-in-Fact, to make, execute, seal and deliver, for, and on its behalf as surety, and as its act and deed: **any and all bonds and undertakings,** and the execution of such bonds or undertakings in pursuance of these presents, shall be as binding upon said Companies, as fully and amply, to all intents and purposes, as if they had been duly executed and acknowledged by the regularly elected officers of the ZURICH AMERICAN INSURANCE COMPANY at its office in New York, New York., the regularly elected officers of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at its office in Owings Mills, Maryland., and the regularly elected officers of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at its office in Owings Mills, Maryland., in their own proper persons.

The said Vice President does hereby certify that the extract set forth on the reverse side hereof is a true copy of Article V, Section 8, of the By-Laws of said Companies, and is now in force.

IN WITNESS WHEREOF, the said Vice-President has hereunto subscribed his/her names and affixed the Corporate Seals of the said **ZURICH AMERICAN INSURANCE COMPANY, COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and FIDELITY AND DEPOSIT COMPANY OF MARYLAND,** this 15th day of May, A.D. 2019.

ATTEST:
ZURICH AMERICAN INSURANCE COMPANY
COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND

By: Robert D. Murray
Vice President

By: Dawn E. Brown
Secretary

State of Maryland
County of Baltimore

On this 15th day of May, A.D. 2019, before the subscriber, a Notary Public of the State of Maryland, duly commissioned and qualified, **Robert D. Murray, Vice President and Dawn E. Brown, Secretary** of the Companies, to me personally known to be the individuals and officers described in and who executed the preceding instrument, and acknowledged the execution of same, and being by me duly sworn, deposeth and saith, that he/she is the said officer of the Company aforesaid, and that the seals affixed to the preceding instrument are the Corporate Seals of said Companies, and that the said Corporate Seals and the signature as such officer were duly affixed and subscribed to the said instrument by the authority and direction of the said Corporations.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal the day and year first above written.

Constance A. Dunn, Notary Public
My Commission Expires: July 9, 2019

Barbara D. Richardson, Commissioner of Insurance

Non-Resident Producer

Casualty, Property, Surety

WAYNE G MCVAUGH

335A W JEFFERSON ST
MEDIA, PA 19063-3603

is authorized to transact business as described above

License No: 500206 Issue Date: 08-15-2006 Expiration Date: 09-01-2021

Generated by Sircon 172538174

Nevada Division of Insurance

THIS IS TO CERTIFY THAT

WAYNE G MCVAUGH
335A W JEFFERSON ST, MEDIA, PA 19063-3603

LICENSE NUMBER: 500206

IS HEREBY AUTHORIZED TO TRANSACT BUSINESS IN ACCORDANCE TO THE LICENSE DESCRIPTION SHOWN BELOW:

Non-Resident Producer
Casualty, Property, Surety

Issue Date: 08-15-2006 Expiration Date: 09-01-2021

Generated by Sircon 172538174

THE FIDELITY AND DEPOSIT COMPANY

OF MARYLAND
1299 Zurich Way Schaumburg, IL 60196

Statement of Financial Condition
As Of December 31, 2019

ASSETS

Bonds		$ 255,279,821
Stocks		21,280,401
Cash and Short Term Investments		2,878,421
Reinsurance Recoverable		25,356,035
Federal Income Tax Recoverable		140,480
Other Accounts Receivable		20,383,843
TOTAL ADMITTED ASSETS		$ 325,319,001

LIABILITIES, SURPLUS AND OTHER FUNDS

Reserve for Taxes and Expenses		$ 795,381
Ceded Reinsurance Premiums Payable		43,024,327
Remittances and Items Unallocated		0
Payable to parents, subs and affiliates		0
Securities Lending Collateral Liability		0
TOTAL LIABILITIES		$ 43,819,708
Capital Stock, Paid Up	$ 5,000,000	
Surplus	276,499,293	
Surplus as regards Policyholders		281,499,293
TOTAL		$ 325,319,001

Securities carried at $164,223,431 in the above statement are deposited with various states as required by law.

Securities carried on the basis prescribed by the National Association of Insurance Commissioners. On the basis of market quotations for all bonds and stocks owned, the Company's total admitted assets at December 31, 2019 would be $322,248,132 and surplus as regards policyholders $288,428,424.

I, LAURA J. LAZARCZYK, Corporate Secretary of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND, do hereby certify that the foregoing statement is a correct exhibit of the assets and liabilities of the said Company on the 31st day of December, 2019.

Laura J Lazarczyk
Corporate Secretary

State of Illinois
City of Schaumburg } SS:

Subscribed and sworn to, before me, a Notary Public of the State of Illinois, in the City of Schaumburg, this 25th day of February, 2020.

Daryl Joiner
Notary Public

DARRYL JOINER
OFFICIAL SEAL
Notary Public - State of Illinois
My Commission Expires 2/24/2022

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Sanofi Vaccines US Inc.

Pharmacy/Wholesaler License # (if applicable) Pending

Physical Address 1 Discovery Drive

City Swiftwater State PA Zip 18370

Mailing Address (if different from physical address) 100 Morris Street, Attn: Kara McMcahon

City Morristown State NJ Zip 07960

Telephone (570) 839-7187 Website www.sanofipasteur.us

Licensing Company Email Kara.McMahon@sanofi.com

Section 2: Personal Information

First Patrick Middle Timothy Last O'Neil

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 1 Discovery Drive

City Swiftwater State PA Zip 18370

Telephone [redacted] Email Patrick.O'Neil@sanofi.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Montclair University			From - To (MM/YY – MM/YY): 08/1986 - 05/1990
Address: 1 Normal Ave	City: Montclair	State: NJ	Zip: 07043
Diploma/Degree obtained, if any: BA Political Science			
School Name: Cranford High School			From - To (MM/YY – MM/YY): 09/1979 - 06/1983
Address: 201 W End Pl	City: Cranford	State: NJ	Zip: 07016
Diploma/Degree obtained, if any: High School Diploma			
School Name: N/A			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): - Present	Address: [redacted]	City: Saylorsburg	State: PA	Zip: [redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Sanofi Vaccines US Inc.			04/2022 - Present
Business Address	**City**	**State**	**Zip**
1 Discovery Drive	Swiftwater	PA	18370
Phone	**Title**	**Number of Employed Hours**	
(570) 839-7187	Global Regulatory Lead	40 hours a week	

Description of Duties
Director of regulatory affairs responsible for business-critical regulatory oversight and management of the US licensed product portfolio Responsible for local business functions in order to coordinate and support regulatory requirements.

Business Name			From - To (MM/YY – MM/YY)
Sanofi Pasteur Inc.			04/2013 - 04/2022
Business Address	**City**	**State**	**Zip**
1 Discovery Drive	Swiftwater	PA	18370
Phone	**Title**	**Number of Employed Hours**	
(570) 839-7187	Director - Regulatory Affairs	40 hours a week	

Description of Duties
Responsible for purchasing, project management, contract negotiations, product quality & ensuring regulatory requirements are met for state licensing and FDA requirements.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

I, Patrick O'Neil, **certify that as the designated representative for**

Sanofi Vaccines US Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PO I am at least 21 years of age;
3. PO I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PO I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PO I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PO I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PO I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Patrick O'Neil

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

18 February 2026

Date

Amanda Loizeaux 18 Feb 2026

Commonwealth of Pennsylvania - Notary Seal
AMANDA LOIZEAUX - Notary Public
Monroe County
My Commission Expires August 14, 2027
Commission Number 1201291

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Patrick O'Neil
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

18 February 2026
Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of

I, Patrick O'Neil, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

18 February 2026
Date

Subscribed and Sworn to before me this _____ day of 2026.

Kara McMahon
Notary Public Signature

KARA MCMAHON
NOTARY PUBLIC
STATE OF NEW JERSEY
MY COMMISSION EXPIRES APRIL 16, 2029
COMMISSION: #2182036

(Seal)

Section F:Employee List

Officers / Directors:

FARMER, Matthew Heston
Title: Secretary
Business Address: 450 Water Street, Cambridge MA 02141
Email Address: Matthew.Farmer@sanofi.com
Percentage of Ownership: 0%

KALINCHAK, Stephen George
Title: Assistant Secretary
Business Address: 100 Morris Street, Morristown, NJ 07960
Email Address: stephen.kalinchak@sanofi.com
Percentage of Ownership: 0%

DAZOGBO, Francois-Xavier Medjignon
Title: Treasurer
Business Address: 100 Morris Street, Morristown, NJ 07960
Email Address: francois-xavier.dazogbo@sanofi.com
Percentage of Ownership: 0%

Designated Representative:

O'NEIL, Patrick
Title: Global Regulatory Lead
Business Address: 1 Discovery Drive, Swiftwater, PA 18370
Email Address : Patrick.O'Neil@sanofi.com

Are there any other individuals who have undue influence over the day-to-day operations? No.

4CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ■ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Scioto Pharmaceuticals, LLC

Physical Address: 277 W. Nationwide Blvd., Suite 250

City: Columbus State: Ohio Zip: 43215

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: (855) 702-7452 Website: www.sciotopharma.com

Name of Designated Representative (DR): Michael Plessinger

Licensing Company Email: info@sciotopharma.com DR Email: mike.plessinger@sciotopharma.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	■ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ ³Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

1-27-26
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Yichang Humanwell Oral Solid Dosage Plant
Address: No. 519 Donglin Road City: Yichang, Hubei China State: _____ Zip: 443112

Name: _____
Address: _____ City: _____ State: _____ Zip: _____

Name: _____
Address: _____ City: _____ State: _____ Zip: _____

Name: _____
Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____
Parent Company (if any): _____
Corporation Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____
Parent Company (if any): _____
Corporation/Organization Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: Mike Plessinger
Business Name: Scioto Pharmaceuticals, LLC
Business Address: 277 W. Nationwide Blvd., Suite 250
City: Columbus State: Ohio Zip: 43215
Telephone: (614) 947-7274 Email: mike.plessinger@sciotopharma.com

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification * 3PL - J. Knipper and Company carries VAWD 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓ N/A
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Scioto Pharmaceuticals, LLC

Facility Name

Michael Plessinger

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

01/26/2026

Date

Board Use Only	Date Received: 2/10/26	Amount: $1000 CK# 12635

Drug Establishments Current Registration Site

New Search (index.cfm)

Search Results for **Scioto**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Scioto Pharmaceuticals, LLC	4990095	119460661	MANUFACTURE;	277 W Nationwide Blvd Suite 250, Columbus, Ohio (OH) 43215, United States (USA)	12/31/2026

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Wednesday, Jan 21, 2026

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SCIOTO PHARMACEUTICALS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIRST DAY OF AUGUST, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SCIOTO PHARMACEUTICALS, LLC" WAS FORMED ON THE NINTH DAY OF JULY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

4179277 8300

SR# 20253541871

Authentication: 204360587

Date: 08-01-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

Ohio Board of Pharmacy

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2027.

Scioto Pharmaceuticals, LLC

277 W Nationwide Blvd Ste 250

Columbus, OH 43215-2567

License Number: 0132000204

License Type: Wholesaler - Category 3

Sub-Category: VW – Virtual Wholesaler

Expiration Date: June 30, 2027

Responsible Person – Print, sign, and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
MARISSA CRADDOCK	Marissa L Craddock

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request in eLicense Ohio - elicense.ohio.gov.

Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RJ0504313	12-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	11-19-2025

J. KNIPPER AND COMPANY, INC.
1250 PATROL RD
CHARLESTOWN, IN 471118670

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D C 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RJ0504313	12-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	11-19-2025

J. KNIPPER AND COMPANY, INC.
1250 PATROL RD
CHARLESTOWN, IN 471118670

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RJ0504313	12-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	11-19-2025

J. KNIPPER AND COMPANY, INC.
1250 PATROL RD
CHARLESTOWN, IN 471118670

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 30260726

Application/License No. _____

Scioto Pharmaceuticals, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 277 W. Nationwide Blvd., Suite 260, Columbus, OH 43215 (Address of Applicant/Principal), as PRINCIPAL, and Western Surety Company (Surety Company), a corporation organized under the laws of the state of SD (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 151 N. Franklin St., Chicago, IL 60606 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 1/23/2026 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 23rd day of January, 20 26.

APPLICANT/PRINCIPAL
Scioto Pharmaceuticals, LLC

Authorized Representative

SURETY COMPANY
Western Surety Company

Surety Company's Representative

Austin Jones, Attorney-in-fact
print name

WESTERN SURETY COMPANY CORPORATE SEAL SOUTH DAKOTA

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Kathryn E Ward
Witness

Golda Lindsey
Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

Western Surety Company

POWER OF ATTORNEY APPOINTING INDIVIDUAL ATTORNEY-IN-FACT

Know All Men By These Presents, That WESTERN SURETY COMPANY, a South Dakota corporation, is a duly organized and existing corporation having its principal office in the City of Sioux Falls, and State of South Dakota, and that it does by virtue of the signature and seal herein affixed hereby make, constitute and appoint

Brian F Haughn, Rachel Stone, Chad M Dougherty, Steven Gloeckner, Phillip Rosen, Austin Jones, Eileen Barrett, Individually

of Dublin, OH, its true and lawful Attorney(s)-in-Fact with full power and authority hereby conferred to sign, seal and execute for and on its behalf bonds, undertakings and other obligatory instruments of similar nature

- In Unlimited Amounts -

and to bind it thereby as fully and to the same extent as if such instruments were signed by a duly authorized officer of the corporation and all the acts of said Attorney, pursuant to the authority hereby given, are hereby ratified and confirmed.

This Power of Attorney is made and executed pursuant to and by authority of the Authorizing By-Laws and Resolutions printed at the bottom of this page, duly adopted, as indicated, by the shareholders of the corporation.

In Witness Whereof, WESTERN SURETY COMPANY has caused these presents to be signed by its Vice President and its corporate seal to be hereto affixed on this 14th day of November, 2024.

WESTERN SURETY COMPANY

Larry Kasten, Vice President

State of South Dakota }
County of Minnehaha } ss

On this 14th day of November, 2024, before me personally came Larry Kasten, to me known, who, being by me duly sworn, did depose and say: that he resides in the City of Sioux Falls, State of South Dakota; that he is a Vice President of WESTERN SURETY COMPANY described in and which executed the above instrument; that he knows the seal of said corporation; that the seal affixed to the said instrument is such corporate seal; that it was so affixed pursuant to authority given by the Board of Directors of said corporation and that he signed his name thereto pursuant to like authority, and acknowledges same to be the act and deed of said corporation.

My commission expires

March 2, 2026

M. BENT
NOTARY PUBLIC
SOUTH DAKOTA

M. Bent, Notary Public

CERTIFICATE

I, Paula Kolsrud, Assistant Secretary of WESTERN SURETY COMPANY do hereby certify that the Power of Attorney hereinabove set forth is still in force, and further certify that the By-Law and Resolutions of the corporation printed below this certificate are still in force. In testimony whereof I have hereunto subscribed my name and affixed the seal of the said corporation this 23rd day of January, 2026.

WESTERN SURETY COMPANY

Paula Kolsrud, Assistant Secretary

Authorizing By-Laws and Resolutions

ADOPTED BY THE SHAREHOLDERS OF WESTERN SURETY COMPANY

This Power of Attorney is made and executed pursuant to and by authority of the following By-Law duly adopted by the shareholders of the Company.

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, and Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

This Power of Attorney is signed by Larry Kasten, Vice President, who has been authorized pursuant to the above Bylaw to execute power of attorneys on behalf of Western Surety Company.

This Power of Attorney may be signed by digital signature and sealed by a digital or otherwise electronic-formatted corporate seal under and by the authority of the following Resolution adopted by the Board of Directors of the Company by unanimous written consent dated the 27th day of April, 2022:

"RESOLVED: That it is in the best interest of the Company to periodically ratify and confirm any corporate documents signed by digital signatures and to ratify and confirm the use of a digital or otherwise electronic-formatted corporate seal, each to be considered the act and deed of the Company."

Go to www.cnasurety.com > Owner / Obligee Services > Validate Bond Coverage, if you want to verify bond authenticity.

Form F4280-6-2023

WESTERN SURETY COMPANY
Sioux Falls, South Dakota
Statement of Net Admitted Assets and Liabilities
December 31, 2024

ASSETS

Bonds	$	1,977,426,497
Stocks		14,281,828
Cash, cash equivalents, and short-term investments		55,103,010
Investment income due and accrued		17,819,818
Premiums and considerations		84,144,805
Amounts recoverable from reinsurers		(4,320,189)
Net deferred tax asset		18,694,198
Receivable from parent, subsidiaries, and affiliates		11,631,758
Other assets		580,232
Total Assets	$	2,175,361,957

LIABILITIES AND SURPLUS

Losses	$	264,641,145
Loss adjustment expense		56,935,932
Commissions payable, contingent commissions and other similar charges		13,946,448
Taxes, license and fees (excluding federal and foreign income taxes)		4,432,923
Federal and foreign income taxes payable		711,402
Unearned premiums		339,078,542
Advance premiums		6,415,557
Ceded reinsurance premiums payable (net of ceding commissions)		2,586,994
Amounts withheld or retained by company for account of others		3,710,405
Provision for reinsurance		387,964
Payable to parent, subsidiaries and affiliates		5,975
Other liabilities		31,970
Total Liabilities	$	692,885,257

Surplus Account:			
Common stock	$ 4,000,000		
Gross paid in and contributed surplus	286,896,195		
Unassigned funds	1,191,580,505		
Surplus as regards policyholders		$	1,482,476,700
Total Liabilities and Capital		$	2,175,361,957

I, Julie Lee, Vice President of Western Surety Company hereby certify that the above is an accurate representation of the financial statement of the Company dated December 31, 2024, as filed with the various Insurance Departments and is a true and correct statement of the condition of Western Surety Company as of that date.

WESTERN SURETY COMPANY

By _____
Julie Lee
Vice President, Accounting Policy & External Reporting

Subscribed and sworn to me this 13th day of March, 2025.

My commission expires:

YOLANDA JIMENEZ
OFFICIAL SEAL
Notary Public - State Of Illinois
My Commission Expires
September 24, 2025

By _____
Yolanda Jimenez
Notary Public

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Scioto Pharmaceuticals, LLC

Pharmacy/Wholesaler License # (if applicable): _____

Physical Address: 277 W. Nationwide Blvd., Suite 250

City: Columbus State: Ohio Zip: 43215

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: (855) 702-7452 Website: www.sciotopharm.com

Licensing Company Email: info@sciotopharma.com

Section 2: Personal Information

First: Michael Middle: _____ Last: Plessinger

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 277 W. Nationwide Blvd., Suite 250

City: Columbus State: Ohio Zip: 43215

Telephone: [redacted] Email: mike.plessinger@sciotopharma.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Miami University		08/92-05/96	
Address	City	State	Zip
501 E High Street	Oxford	Ohio	45056
Diploma/Degree obtained, if any			
BS Economics, BS Finance			

School Name		From - To (MM/YY – MM/YY)	
Columbus Academy		08/88-05/92	
Address	City	State	Zip
4300 Cherry Bottom Road	Gahanna	Ohio	43230
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/04-Present	[redacted]	Columbus	Ohio	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Scioto Pharmaceuticals, LLC			07/24-Present
Business Address	**City**	**State**	**Zip**
277 W. Nationwide Blvd., Suite 250	Columbus	Ohio	43215
Phone	**Title**	**Number of Employed Hours**	
(614) 947-7274	CEO and President	3,120	
Description of Duties			
Started company in July 2024. Negotiate with global companies to form marketing partnerships for generic and brand human prescription drug products. Work with third party logistics to distribute human prescription drug products.			

Business Name			From - To (MM/YY – MM/YY)
Slate Run Pharmaceuticals, LLC			03/15-Present
Business Address	**City**	**State**	**Zip**
277 W. Nationwide Blvd., Suite 260	Columbus	Ohio	43215
Phone	**Title**	**Number of Employed Hours**	
(614) 947-7274	CEO and President	22,360	
Description of Duties			
Work with third party logistics to distribute human prescription drug products. Work with investors to ensure company achieves sale and margin targets. Responsible for all aspects of business including $2.5M annual operating budget.			

Business Name			From - To (MM/YY – MM/YY)
Cardinal Health			10/13-03/15
Business Address	**City**	**State**	**Zip**
7000 Cardinal Place	Dublin	Ohio	43017
Phone	**Title**	**Number of Employed Hours**	
(614) 757-5000	Vice President, Generic Sourcing	2,945	
Description of Duties			
Work with senior management as a consultant focused on strategic projects.			

Business Name			From - To (MM/YY – MM/YY)
Roxane Laboratories			01/09-10/13
Business Address	**City**	**State**	**Zip**
1809 Wilson Road	Columbus	Ohio	43228
Phone	**Title**	**Number of Employed Hours**	
(614) 276-4000	Director, Marketing	9,836	
Description of Duties			
Direct and manage launch of 8-10 new generic products per year. Participate in cross functional team responsible for choosing development projects. Member of leadership team responsible for creating and directing company strategy.			

Business Name			From - To (MM/YY – MM/YY)
Cardinal Health			08/07-01/09
Business Address	**City**	**State**	**Zip**
7000 Cardinal Place	Dublin	Ohio	43017
Phone	**Title**	**Number of Employed Hours**	
(614) 757-5000	Vice President, Pharmaceutical Strategic Sourcing	4,160	
Description of Duties			
Led team responsible for negotiations with over 100 manufacturers. Negotiated generic wholesale service agreements with new manufacturers.			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Cardinal Health			01/00-08/07	
Business Address		City	State	Zip
7000 Cardinal Place		Dublin	Ohio	43017
Phone	Title		Number of Employed Hours	
(614) 757-5000	Business Manager and Director, Rx Product Managemen		15,600	
Description of Duties				
Negotiated and maintained contracts with over 40 generic pharmaceutical manufacturers.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:



_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Michael Plessinger, **certify that as the designated representative for**

Scioto Pharmaceuticals, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Plessinger, Michael

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/26/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Plessinger, Michael

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/26/2026

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Mike Plessinger, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/26/26

Date

Subscribed and Sworn to before me this 26th day of 2026.

Notary Public Signature

Jonathan Ha
Notary Public, S
My Commissic
March 20,

(Seal)

Jonathan Harmacek
Notary Public, State of Ohio
My Commission Expires:
March 20, 2027

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Scioto Pharmaceuticals, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 277 W. Nationwide Blvd., Suite 250

City: Columbus State: Ohio Zip: 43215

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: (855) 702-7452 Website: www.sciotopharm.com

Licensing Company Email: info@sciotopharma.com

Section 2: Personal Information

First: Michael Middle: _____ Last: Plessinger

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or IT[redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 277 W. Nationwide Blvd., Suite 250

City: Columbus State: Ohio Zip: 43215

Telephone: [redacted] Email: mike.plessinger@sciotopharma.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Miami University		08/92-05/96	
Address	City	State	Zip
501 E High Street	Oxford	Ohio	45056
Diploma/Degree obtained, if any			
BS Economics, BS Finance			

School Name		From - To (MM/YY – MM/YY)	
Columbus Academy		08/88-05/92	
Address	City	State	Zip
4300 Cherry Bottom Road	Gahanna	Ohio	43230
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/04-Present	[redacted]	Columbus	Ohio	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Scioto Pharmaceuticals, LLC			07/24-Present
Business Address	**City**	**State**	**Zip**
277 W. Nationwide Blvd., Suite 250	Columbus	Ohio	43215
Phone	**Title**		
(614) 947-7274	CEO and President		

Description of Duties

Started company in July 2024. Negotiate with global companies to form marketing partnerships for generic and brand human prescription drug products. Work with third party logistics to distribute human prescription drug products.

Business Name			From - To (MM/YY – MM/YY)
Slate Run Pharmaceuticals, LLC			03/15-Present
Business Address	**City**	**State**	**Zip**
277 W. Nationwide Blvd., Suite 260	Columbus	Ohio	43215
Phone	**Title**		
(614) 947-7274	CEO and President		

Description of Duties

Work with third party logistics to distribute human prescription drug products. Work with investors to ensure company achieves sale and margin targets. Responsible for all aspects of business including $2.5M annual operating budget.

Business Name			From - To (MM/YY – MM/YY)
Cardinal Health			10/13-03/15
Business Address	**City**	**State**	**Zip**
7000 Cardinal Place	Dublin	Ohio	43017
Phone	**Title**		
(614) 757-5000	Vice President, Generic Sourcing		

Description of Duties

Work with senior management as a consultant focused on strategic projects.

Business Name			From - To (MM/YY – MM/YY)
Roxane Laboratories			01/09-10/13
Business Address	**City**	**State**	**Zip**
1809 Wilson Road	Columbus	Ohio	43228
Phone	**Title**		
(614) 276-4000	Director, Marketing		

Description of Duties

Direct and manage launch of 8-10 new generic products per year. Participate in cross functional team responsible for choosing development projects. Member of leadership team responsible for creating and directing company strategy.

Business Name			From - To (MM/YY – MM/YY)
Cardinal Health			08/07-01/09
Business Address	**City**	**State**	**Zip**
7000 Cardinal Place	Dublin	Ohio	43017
Phone	**Title**		
(614) 757-5000	Vice President, Pharmaceutical Strategic Sourcing		

Description of Duties

Led team responsible for negotiations with over 100 manufacturers. Negotiated generic wholesale service agreements with new manufacturers.

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Cardinal Health			01/00-08/07
Business Address	**City**	**State**	**Zip**
7000 Cardinal Place	Dublin	Ohio	43017
Phone	**Title**		
(614) 757-5000	Business Manager and Director, Rx Product Management		
Description of Duties			
Negotiated and maintained contracts with over 40 generic pharmaceutical manufacturers.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Plessinger, Michael

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/26/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin

I, Mike Plessinger, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/26/26

Date

Subscribed and Sworn to before me this 26th day of January.

Notary Public Signature

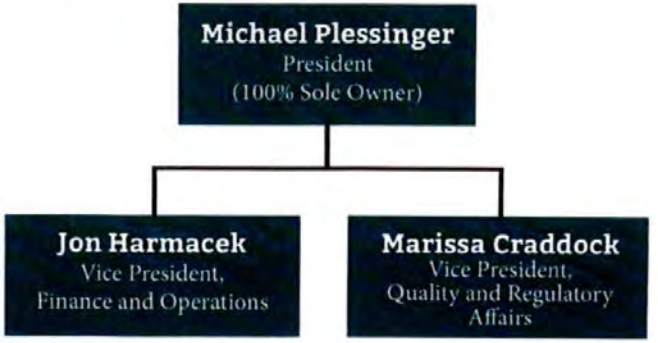
Jonat... Harmacek
Notary ...tate of Ohio
My C... Expires:
Ma... ...027

Jonathan Harmacek
Notary Public, State of Ohio
My Commission Expires:
March 20, 2027

(Seal)

SCIOTO
PHARMACEUTICALS

Organizational Chart



Revised March 31, 2025

4DD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Umedica Laboratories USA Inc.

Physical Address: 6 Century Dr, Suite 350

City: Parsippany State: NJ Zip: 07054

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 973-294-7368 Website: www.umedicalabsusa.com

Name of Designated Representative (DR): Dmitrey Kuznetsov

Licensing Company Email: dmitreykuznetsov@umedicalabs.com DR Email: dmitreykuznetsov@umedicalabs.com

Entities the Wholesaler will Serve (✓all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others: Prescription Drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*: N/A

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Umedica Laboratories Private Limited, Plot No.221 and 221/1, GIDC, Vapi, Gujarat 396195, India

Corporation/Organization Name: Umedica Laboratories USA Inc.

Mailing Address: 6 Century Drive, Suite 350

City: Parsippany State: NJ Zip: 07054

Telephone: 973-294-7368 Email: dmitreykuznetsov@umedicalabs.com

Contact Person Name: Dmitrey Kuznetsov

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration Labeler Code information attached 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✔" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✔	✔		
• **List the top four corporation shareholders and their percent ownership.**	✔			
• **List of all corporation shareholders and their percent ownership.**		✔		
• **List of all partners and their percent ownership.**			✔	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✔	✔	✔	✔
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✔	✔	✔
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✔	✔	✔
• **Copy of DEA certificate if handling controlled substances**	✔	✔	✔	✔
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✔			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✔	✔	✔	✔
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✔	✔	✔	✔
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✔	✔	✔	✔
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✔	✔	✔	✔
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8) N/A				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✔	✔	✔
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✔	✔	✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Umedica Laboratories USA Inc.

Facility Name

Dmitrey Kuznetsov

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

1/8/26

Date

Board Use Only	Date Received: _____	Amount: $1000 CHECK #1019

fyi

From: edrls@fda.hhs.gov [mailto:edrls@fda.hhs.gov]
Sent: Friday, August 09, 2013 8:12 PM
To: arunava@umedicalabs.com
Subject: Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 08/09/2013
Labeler DUNS: 650219934
Labeler Name: Umedica Laboratories Pvt Ltd
Labeler Code: 60290

The Food and Drug Administration (FDA) has assigned the above Labeler Code Number to your firm. Please resubmit your Labeler Code Request SPL with the assigned number above to complete the assignment.

This Labeler Code should be used on all forms related to drug establishment registration and/or drug product listing. Per Title 21, Part 207 of the Code of Federal Regulations (CFR), owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

UMEDICA
LABORATORIES USA INC

Ownership Details:

S. No.	Name	Address	Number of Equity Shares	Percentage of Holding
01.	Umedica Laboratories Private Limited	Plot No. 221 and 221/1, GIDC, IInd Phase Vapi – 396195, Gujarat, India	1,00,000	100 %

Name of Officers:

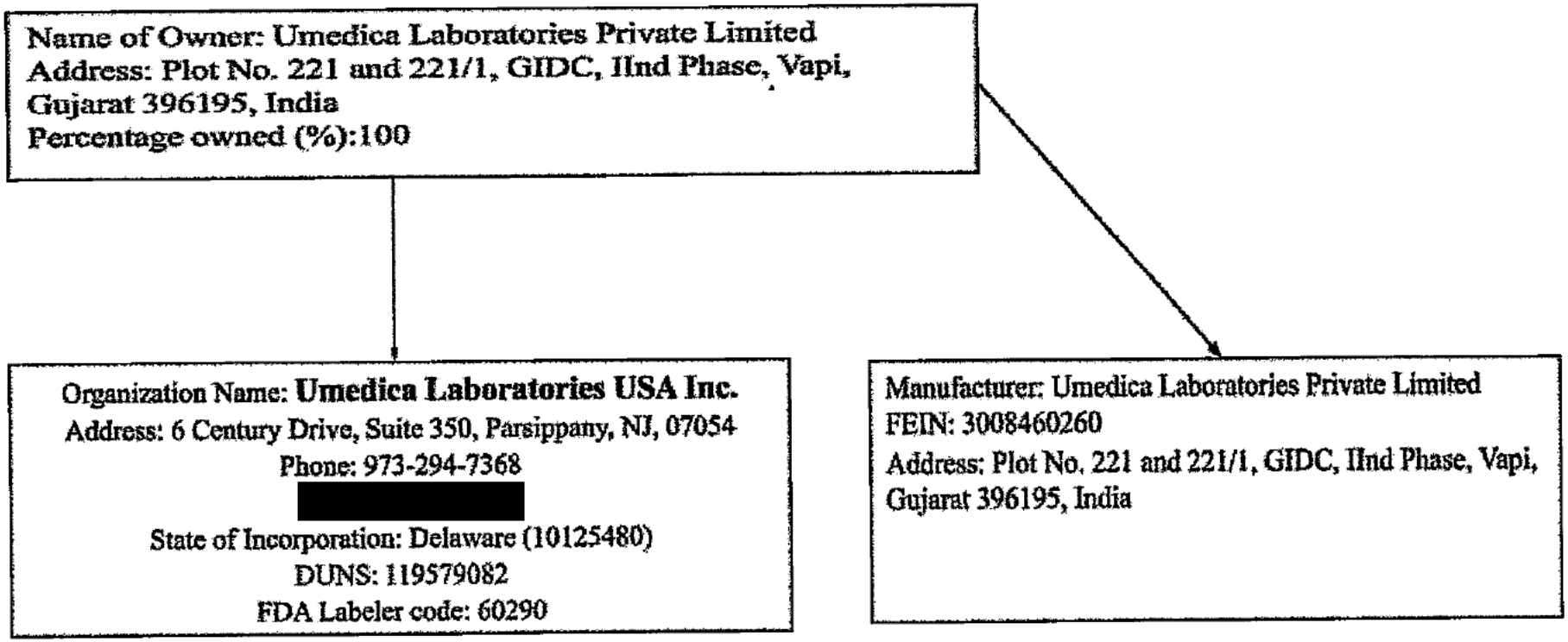
S. No	Officer Name	Date of Birth	Home Address & Contact Information	Designation
1.	Dmitrey Kuznetsov	[redacted]	[redacted] Email: dmitreykuznetsov@umedicalabs.com Phone: [redacted]	President

Name of Directors:

S. No	DIRECTORS Officer Name	Date of Birth	Home Address & Contact Information	Designation
1.	Dmitrey Kuznetsov	[redacted]	[redacted] Email: dmitreykuznetsov@umedicalabs.com Phone: [redacted]	President/Director
2.	Pratik Kothari	[redacted]	[redacted] Email: pratik.kothari@umedicalabs.com Phone: [redacted]	Director

UMEDICA
LABORATORIES USA INC

OWNERSHIP ORGANOGRAM



UMEDICA
LABORATORIES USA INC

Nature of Business

Umedica Laboratories USA Inc.("ULUI") is a virtual prescription drug manufacturer with assigned Dun & Bradstreet (DUNS) number 119579082 and FDA Labeler code 60290. As a newly established entity, ULUI is currently pursuing licensure with relevant state agencies prior to initiating virtual manufacturer/distributor activities. A contract manufacturer will be used to manufacture the product(s) that company intends to sell, and a third-party logistics provider (3PL) will handle receipt, storage and distribution activities. No product will be handled at ULUI's business office. ULUI will sell prescription drugs for which its co-Licensing partner/Affiliate holds FDA approval. Provided below are the details of the product(s) the company intends to sell, the contract manufacturing facility and the third-party logistics provider.

Contract Manufacturer & Product Details:

CMO Details	Product(s)	ANDA	Dosage Form	Strength	NDC
Umedica Laboratories Private Limited Plot No. 221 and 221/1, GIDC, IInd Phase, Vapi, Gujarat 396195, India FDA Establishment Number: 3008460260	Celecoxib	210628	Capsule	100 mg	60290-017-03
	Celecoxib	210628	Capsule	200mg	60290-018-02 60290-018-03
	Rosuvastatin Calcium	207626	Tablet	5mg	60290-043-02 60290-043-03 60290-043-05
	Rosuvastatin Calcium	207626	Tablet	10 mg	60290-044-02 60290-044-03 60290-044-05
	Rosuvastatin	207626	Tablet	20 mg	60290-045-02

UNEDICA
LABORATORIES USA INC

	Calcium				60290-045-03 60290-045-05
	Rosuvastatin Calcium	207626	Tablet	40 mg	60290-046-01 60290-046-03 60290-046-05
	Diclofenac Potassium	215750	Tablet, Film Coated	25mg	60290-088-05
	Diclofenac Potassium	215750	Tablet, Film Coated	50 mg	60290-057-01 60290-057-02 60290-057-03
	Diclofenac Potassium	215750	Tablet, Film Coated	25 mg	60290-088-01 60290-088-02 60290-088-03 60290-088-04

Third Party Logistics Provider:
Integrated Commercialization Solutions, LLC
167 International Blvd., Suite A, Brooks, KY 40109
Nevada Permit# WH03155

UMEDICA
LABORATORIES USA INC

A list of all licenses and permits issued to the applicant by any other state under which the applicant is permitted to purchase or possess prescription drugs:

Firm Name	Registered as	State	Issue Date	Expiration Date	Registration Number
Umedica Laboratories USA Inc.	Manufacturer. Distributor	NJ	11/06/2025	1/31/2027	7202637
Umedica Laboratories USA Inc.	Manufacturer Not NYS	NY	12/22/2025	11/30/2028	042285
Umedica Laboratories USA Inc.	Manufacturer of Drugs (Out of State)	CT	01/08/2026	N/A	CSM.0003258-OOS
Umedica Laboratories USA Inc.	Manufacturer (Non-Resident)	WV	01/05/2026	06/30/2026	MR0552802
Umedica Laboratories USA Inc.	Non-Resident Manufacturer	VT	01/09/2026	07/31/2027	163.0001115
Umedica Laboratories USA Inc.	Wholesale Distributor (Non-Resident)	AR	01/06/2026	12/31/2026	WD06252
Umedica Laboratories USA Inc.	Virtual Manufacturer	NM	01/15/2026	12/31/2027	WD20220469

Active Product List:
The details of all the active product list which intended to be distributed by Umedica Laboratories USA Inc. are provided in Table 1 below:

Table 1: Active Product List

S. No	NDC code	Product Name & Dosage form	Strength	Pack Size	Applicant	Contract Manufacturer	Labeler
1	60290-017-03	Celecoxib Capsules	100 mg	500	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc.
2	60290-018-02	Celecoxib Capsules	200 mg	100	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc
3	60290-018-03	Celecoxib Capsules	200 mg	500	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc.
4	60290-043-02	Rosuvastatin Calcium Tablets, USP	5 mg	90	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc
5	60290-043-03	Rosuvastatin Calcium Tablets, USP	5 mg	500	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc.
6	60290-043-05	Rosuvastatin Calcium Tablets, USP	5 mg	1000	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc
7	60290-044-02	Rosuvastatin Calcium Tablets, USP	10 mg	90	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc.
8	60290-044-03	Rosuvastatin Calcium Tablets, USP	10 mg	500	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc
9	60290-044-05	Rosuvastatin Calcium Tablets, USP	10 mg	1000	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc.

10	60290-045-02	Rosuvastatin Calcium Tablets, USP	20 mg	90	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc
11	60290-045-03	Rosuvastatin Calcium Tablets, USP	20 mg	500	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc.
12	60290-045-05	Rosuvastatin Calcium Tablets, USP	20 mg	1000	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc
13	60290-046-01	Rosuvastatin Calcium Tablets, USP	40 mg	30	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc.
14	60290-046-03	Rosuvastatin Calcium Tablets, USP	40 mg	500	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc
15	60290-046-05	Rosuvastatin Calcium Tablets, USP	40 mg	1000	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc
16	60290-088-0	Diclofenac Potassium Film Coated Tablet	25 mg	60	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc
17	60290-057-01	Diclofenac Potassium Film Coated Tablet	50 mg	100	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc
18	60290-057-02	Diclofenac Potassium Film Coated Tablet	50 mg	1000	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc
19	60290-057-03	Diclofenac Potassium Film Coated Tablet	50 mg	500	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc
20	60290-088-01	Diclofenac Potassium Film Coated Tablet	25 mg	30	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc
21	60290-088-02	Diclofenac Potassium Film Coated Tablet	25 mg	100	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc

22	60290-088-03	Diclofenac Potassium Film Coated Tablet	25 mg	500	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc
23	60290-088-04	Diclofenac Potassium Film Coated Tablet	25 mg	1000	Umedica Laboratories Private Limited	Umedica Laboratories Private Limited	Umedica Laboratories USA Inc

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "UMEDICA LABORATORIES USA INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SECOND DAY OF DECEMBER, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "UMEDICA LABORATORIES USA INC." WAS INCORPORATED ON THE TENTH DAY OF MARCH, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL FRANCHISE TAXES HAVE BEEN ASSESSED TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

10125480 8300

SR# 20254952973

Authentication: 205688115

Date: 12-22-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES

SHORT FORM STANDING

UMEDICA LABORATORIES USA INC.
0451397072

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named Delaware Foreign For-Profit Corporation was registered by this office on Monday, January 12, 2026.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and registered office are:

DMITREY KUZNETSOV
6 CENTURY DR, STE 350
PARSIPPANY, NEW JERSEY 07054

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal 12th day of January, 2026

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 4305096035
Verify this certificate online at https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

Registration Number: 7202637 **Registered As:** Manufacturer,Distributor

Information Recorded in the System as of 01/16/2026

Name: Umedica Laboratories USA Inc.

New Jersey Department of Health

DBA:

Address: 6 Century DR STE 350 PARSIPPANY, NJ 07054

Original Issue Date: **Expiration Date:** 01/31/2027

Current Issue Date: 11/06/2025

Disciplines: No

Permit Status: Active

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0022556

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written noticeprior to the change of the address of such new location and the name and address of the individual to be in charge thereof.A fee of $20.00 shall accompanying such notification."

Registered as: ☑ Manufacturer ☑ Distributor which conducts business at the following locations:

Reg. No.:
7202637

Umedica Laboratories USA Inc.
6 Century DR STE 350
PARSIPPANY, NJ 07054

ISSUED PURSUANT TO:
N.J.S.A. 24:6B
EXPIRES: January 31, 2027

Establishment Copy

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. AM3192989

Application/License No. .

Umedica Labs USA Inc (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 8 Century Dr. Suite 350 Parsippany NJ 07054 (Address of Applicant/Principal), as PRINCIPAL, and Capitol Indemnity Corporation (Surety Company), a corporation organized under the laws of the state of WI (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1600 Aspen Commons Ste. 300 Middleton WI 53562 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 11/21/2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 21st day of November, 20 25.

APPLICANT/PRINCIPAL
Umedica Labs USA Inc

Authorized Representative

SURETY COMPANY
Capitol Indemnity Corporation

Surety Company's Representative

Steve Shike, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

CAPITOL INDEMNITY CORPORATION
POWER OF ATTORNEY

AM3192989
Bond Number

KNOW ALL MEN BY THESE PRESENTS, That the CAPITOL INDEMNITY CORPORATION, a corporation of the State of Wisconsin, having its principal offices in the City of Middleton, Wisconsin, does make, constitute and appoint

Steve Shike
Name of Individual

its true and lawful Attorney(s)-in-fact, to make, execute, seal and deliver for and on its behalf, as surety, and as its act and deed, any and all bonds, undertakings and contracts of suretyship, provided that no bond or undertaking or contract of suretyship executed under this authority shall exceed in amount the sum of

$ 25,000.00 (Bond Amount) for AM3192989 (Bond Number) on behalf of Umedica Labs USA Inc (Principal)

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of CAPITOL INDEMNITY CORPORATION at a meeting duly called and held on the 15th day of May, 2002.

"RESOLVED, that the President, Executive Vice President, Vice President, Secretary or Treasurer, acting individually or otherwise, be and they hereby are granted the power and authorization to appoint by a Power of Attorney for the purposes only of executing and attesting bonds and undertakings, and other writings obligatory in the nature thereof, one or more resident vice-presidents, assistant secretaries and attorney(s)-in-fact, each appointee to have the powers and duties usual to such offices to the business of this company; the signature of such officers and seal of the Company may be affixed to any such power of attorney or to any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signatures or facsimile seal shall be valid and binding upon the Company, and any such power so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking or other writing obligatory in the nature thereof to which it is attached. Any such appointment may be revoked, for cause, or without cause, by any of said officers, at any time."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner – Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

IN WITNESS WHEREOF, the CAPITOL INDEMNITY CORPORATION has caused these presents to be signed by its officer undersigned and its corporate seal to be hereto affixed duly attested, this 1st day of September, 2022.

Attest:

Ryan J. Byrnes
Senior Vice President,
Chief Financial Officer and Treasurer

Todd Burrick
Chief Underwriting Officer

CAPITOL INDEMNITY CORPORATION

Adam L. Sills
Chief Executive Officer and President

STATE OF WISCONSIN
COUNTY OF DANE } S.S.:

On the 1st day of September, 2022 before me personally came Adam L. Sills, to me known, who being by me duly sworn, did depose and say: that he resides in the County of New York, State of New York; that he is Chief Executive Officer and President of CAPITOL INDEMNITY CORPORATION, the corporation described in and which executed the above instrument; that he knows the seal of the said corporation; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said corporation and that he signed his name thereto by like order.

David J. Regele
Notary Public, Dane Co., WI
My Commission Is Permanent

STATE OF WISCONSIN
COUNTY OF DANE } S.S.:

I, the undersigned, duly elected to the office stated below, now the incumbent in CAPITOL INDEMNITY CORPORATION, a Wisconsin Corporation, authorized to make this certificate, DO HEREBY CERTIFY that the foregoing attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolution of the Board of Directors, set forth in the Power of Attorney is now in force.

Signed and sealed at the City of Middleton, State of Wisconsin this 21st day of November, 2025.

Suzanne M. Broadbent
Secretary

THIS DOCUMENT HAS BEEN GENERATED FOR A SPECIFIC BOND. IF YOU HAVE ANY QUESTIONS CONCERNING THE AUTHENTICITY OF THIS DOCUMENT CALL [illegible]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Umedica Laboratories USA Inc.

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 6 Century Drive, Suite 350

City: Parsippany State: NJ Zip: 07054

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 973-294-7368 Website: www.umedicalabsusa.com

Licensing Company Email: dmitreykuznetsov@umedicalabs.com

Section 2: Personal Information

First: Dmitrey Middle: Last: Kuznetsov

Alias(es, nicknames, name changes, etc.): NA

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: East Rutherford State: NJ Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Parkway North High School			09/86-06/89	
Address		City	State	Zip
12860 Fee Fee Rd		Saint Louis	MO	63146
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
St. Louis College of Pharmacy (renamed to University of Health Sciences & Pharmacy)			09/89- 06/94	
Address		City	State	Zip
1 Pharmacy Place		Saint Louis	MO	63110
Diploma/Degree obtained, if any				
BS in Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/25- Present	[redacted]	East Rutherford	NJ	[redacted]
From - To (MM/YY – MM/YY)		City	State	
04/21- 08/24		Wallington	NJ	
From - To (MM/YY – MM/YY)		City	State	
12/12- Present		Saint Louis	MO	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Umedica Laboratories USA Inc.			05/25- Present	
Business Address		City	State	Zip
6 Century Drive, Suite 350		Parsippany	NJ	07054
Phone	Title		Number of Employed Hours	
973-294-7368	President (Designated Representative)		1200	
Description of Duties				
As Designated Representative: Plan, Execute , Control and direct Strategic Initiatives in the area of company's overall business including Quality, Compliance, Record keeping and Logistics Management				

Business Name			From - To (MM/YY – MM/YY)	
Glenmark Pharmaceuticals Inc.			10/20-08/24	
Business Address		City	State	Zip
750 Corporate Drive		Mahwah	NJ	07430
Phone	Title		Number of Employed Hours	
201-684-8000	Senior Vice President, Commercialization		5760	
Description of Duties				
As Designated Representative: Plan, Execute , Control and direct Strategic Initiatives in the area of company's overall business including Quality, Compliance, Record keeping and Logistics Management				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Dmitrey Kuznetsov, **certify that as the designated representative for**

Umedica Laboratories USA Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DK I am at least 21 years of age;
3. DK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Dmitrey Kuznetsov

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/8/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dmitrey Kuznetsov

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/8/26

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Morris

I, Dmitrey Kuznetsov, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/8/26

Date

Subscribed and Sworn to before me this 8 day of January.

Notary Public Signature

FREDDY BENITEZ JR
NOTARY PUBLIC
STATE OF NEW JERSEY
MY COMMISSION EXPIRES April 17 2030

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Umedica Laboratories USA Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 6 Century Drive, Suite 350

City: Parsippany State: NJ Zip: 07054

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 973-294-7368 Website: www.umedicalabsusa.com

Licensing Company Email: dmitreykuznetsov@umedicalabs.com

Section 2: Personal Information

First: Dmitrey Middle: _____ Last: Kuznetsov

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: East Rutherford State: NJ Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Parkway North High School		09/86-06/89	
Address	**City**	**State**	**Zip**
12860 Fee Fee Rd	Saint Louis	MO	63146
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
St. Louis College of Pharmacy (renamed to University of Health Sciences & Pharmacy)		09/89- 06/94	
Address	**City**	**State**	**Zip**
1 Pharmacy Place	Saint Louis	MO	63110
Diploma/Degree obtained, if any			
BS in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/25- Present	[redacted]	East Rutherford	NJ	[redacted]
04/21- 08/24		Wallington	NJ	
08/12- Present		Saint Louis	MO	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Umedica Laboratories USA Inc.			05/25- Present
Business Address	**City**	**State**	**Zip**
6 Century Drive, Suite 350	Parsippany	NJ	07054
Phone	**Title**		
973-294-7368	President (Designated Representative)		

Description of Duties

As Designated Representative: Plan, Execute , Control and direct Strategic Initiatives in the area of company's overall business including Quality, Compliance, Record keeping and Logistics Management

Business Name			From - To (MM/YY – MM/YY)
Complete Pharma Consulting			09/24-04/25
Business Address	**City**	**State**	**Zip**
	St. Louis	MO	63141
Phone	**Title**		
201-341-7145	President		

Description of Duties

Strategic advisor to pharmaceutical companies, developing and executing solutions that solve complex business challenges, streamline operations, and accelerate growth.

Business Name			From - To (MM/YY – MM/YY)
Glenmark Pharmaceuticals Inc.			10/20-08/24
Business Address	**City**	**State**	**Zip**
750 Corporate Drive	Mahwah	NJ	07430
Phone	**Title**		
201-684-8000	Senior Vice President, Commercialization		

Description of Duties

As Designated Representative: Plan, Execute , Control and direct Strategic Initiatives in the area of company's overall business including Quality, Compliance, Record keeping and Logistics Management

Business Name			From - To (MM/YY – MM/YY)
Sun Pharma			07/17-09/20
Business Address	**City**	**State**	**Zip**
2 Independence Way	Princeton	NJ	08540
Phone	**Title**		
609-720-9200	Vice-President, Sales and Marketing Generics		

Description of Duties

Drove retail business revenue beyond targets by forging strategic customer partnerships, Managed and audited third-party logistics (3PL) providers, wholesalers, and distribution partners to confirm compliance with licensing

Business Name			From - To (MM/YY – MM/YY)
H D Smith			12/12-03/17
Business Address	**City**	**State**	**Zip**
4650 Industrial Drive	Springfield	IL	62703
Phone	**Title**		
217-529-0211	Senior Vice-President, Strategic Sourcing ; Vice President, Generic Pharmaceuticals		

Description of Duties

Led the transformation of the generics strategy to enhance customer alignment and drive contract compliance. Enabled cross-functional execution that optimized generics category performance across sales, supply, and product

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dmitrey Kuznetsov

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/8/26

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Morris

I, Dmitrey Kuznetsov, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/8/26

Date

Subscribed and Sworn to before me this 8 day of January.

Notary Public Signature

FREDDY BENITEZ JR
NOTARY PUBLIC
STATE OF NEW JERSEY
MY COMMISSION EXPIRES April 17 2030

(Seal)

UMEDICA
LABORATORIES USA INC

List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant:

Employees of Umedica Laboratories USA Inc:

1. Dmitrey Kuznetsov, President

Holder of Indebtedness:

Umedica Laboratories Private Limited
Plot No. 221, 221/1, GIDC, Vapi, Valsad,
Pardi, 96195, Gujarat, India

4EE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ■ Location Change* (in-state only)	* If making a change, provide current license number: WH 01184	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Upsher-Smith Laboratories, LLC

Physical Address: 6701 Evenstad Drive Ste 300

City: Maple Grove State: MN Zip: 55369

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 763-315-2000 Website: https://www.upsher-smith.com/

Name of Designated Representative (DR): James Maahs

Licensing Company Email: statelicensing@upsher-smith.com DR Email: jim.maahs@upsher-smith.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Upsher-Smith Laboratories, LLC has voluntarily surrendered some licenses. Please see the attached list of licenses and their reason for surrender.

Original Signature (electronic, copies or stamps not accepted)

10/14/2025
Date

Upsher-Smith Laboratories, LLC

6701 Evenstad Dr N, Maple Grove, MN 55369

FEIN: 41-0969017

Upsher-Smith Laboratories, LLC has permanently closed their manufacturing and packaging plant in Plymouth, Minnesota. All business operations at this facility have been completed. Due to this, Upsher-Smith has surrendered these licenses for this location as they are no longer needed.

State	License Type	License Number	Expiration
ME	Manufacturer	MF30001737	Surrender in Process
MN	Manufacturer	461254	Surrendered
MS	Non-Resident Manufacturer	16049	Surrendered
NH	Man/Dist/Whole/Broker	0017	Surrendered
OK	Manufacturer	88-M-5181	Surrendered
OR	Manufacturer	M-0001306	Surrendered
OR	Controlled Substance	M-0001306-CS	Surrendered
RI	Manufacturer – Out of State	DIS03058	Surrendered
RI	Controlled Substance	CDIS03058	Surrendered

Upsher-Smith has also surrendered the licenses below because they were no longer needed. They do not distribute samples and do not ship CS into NY.

State	License Type	License Number	Expiration
FL	Non-resident Manufacturer	261885	Closed
FL	Comp Drug Distributor	40748	Surrendered
NY CS	Controlled Substance	02A0960	Surrender in Process
WA	Drug Sample Distributor	461254	Surrendered

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Bora Pharmaceuticals Inc.

Address: 6701 Evenstad Drive N City: Maple Grove State: MN Zip: 55369

Name: Eversana Life Science Services

Address: 4580 Mendenhall Road City: Memphis State: TN Zip: 38141

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota

Parent Company (if any): Bora Pharmaceutical Holdings, LLC

Corporation/Organization Name: Upsher-Smith Laboratories, LLC

Mailing Address: 6701 Evenstad Drive Ste 300

City: Maple Grove State: MN Zip: 55369

Telephone: 763-315-2000 Email: statelicensing@upsher-smith.com

Contact Person Name: James Maahs

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: 3032948549	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Upsher-Smith Laboratories, LLC
Facility Name

James Maahs
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/14/2025
Date

Board Use Only	Date Received: 12/1/25	Amount: $1000ch 010404

Upsher-Smith Laboratories, LLC
Maple Grove, MN 55369
763-315-2000
State of Incorporation: Minnesota
FEIN: 41-0969017

Ownership Information

Bora Pharmaceutical Holdings, LLC – 100% Ownership
State of Incorporation: Delaware
FEIN: 35-2843957

Upsher-Smith Laboratories, LLC
Maple Grove, MN 55369
763-315-2000

FDA Registration

Search Result

FEI Number	Firm Name
3032948549	Upsher-Smith LLC

Physical Address

Line 1 Address:	6701 Evenstad Dr N Ste 300
Line 2 Address:	
City:	Maple Grove
State:	MN - MINNESOTA
Province:	
Zip/Mail Code:	55369-6013
Country:	US - UNITED STATES OF AMERICA

Mailing Address

Line 1 Address:	6701 Evenstad Dr N Ste 300
Line 2 Address:	
City:	Maple Grove
State:	MN - MINNESOTA
Province:	
Zip/Mail Code:	55369-6013
Country:	US - UNITED STATES OF AMERICA

Labeler Verified ✓ M.H 12/3/25

Upsher-Smith Laboratories, LLC
Maple Grove, MN 55369
763-315-2000
State of Incorporation: Minnesota
FEIN: 41-0969017

Officer List

Pao Shi, Sheng, Chairman + President

DOB: [redacted]

Address: [redacted] Neihu Dist., Taipei City [redacted]

Phone # [redacted]

Jim Maahs, Head of Commercial

DOB: [redacted]

Address: [redacted] Maple Grove, MN [redacted]

Phone #: [redacted]

Dan Bruno, CFO

DOB: [redacted]

Address: [redacted] Maple Grove, MN [redacted]

Phone #: [redacted]

Nien-Hua Liu, President, TWi Pharma (Subsidiary of Bora)

DOB: [redacted]

Address: [redacted] Neihu District, Taipei City, [redacted]

Phone: [redacted]

Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Upsher-Smith Laboratories, LLC
Date Filed:	05/30/2017
File Number:	952258200089
Minnesota Statutes, Chapter:	322C
Home Jurisdiction:	Minnesota
This certificate has been issued on:	06/02/2025

Steve Simon
Secretary of State
State of Minnesota

State of Minnesota

Minnesota Board of Pharmacy
St. Paul, MN 55102

HAS ISSUED

Manufacturer
License Number 462718

To: Upsher-Smith Laboratories, LLC
6701 Evenstad Drive
Ste 300
Maple Grove, MN 55369

EFFECTIVE DATE
12/18/25

EXPIRATION DATE
5/31/26

State of Minnesota

Minnesota Board of Pharmacy
St. Paul, MN 55102

HAS ISSUED

Manufacturer
License Number 462718

To: Upsher-Smith Laboratories, LLC

EFFECTIVE DATE
12/18/25

EXPIRATION DATE
5/31/26

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RU0247343	05-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,3,3N, 4,5	DISTRIBUTOR	04-18-2025

UPSHER-SMITH LABORATORIES LLC
6701 EVENSTAD DR N
MAPLE GROVE, MN 553696026

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RU0247343	05-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,3,3N, 4,5	DISTRIBUTOR	04-18-2025

UPSHER-SMITH LABORATORIES LLC
6701 EVENSTAD DR N
MAPLE GROVE, MN 553696026

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RU0247343	05-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,3,3N, 4,5	DISTRIBUTOR	04-18-2025

UPSHER-SMITH LABORATORIES LLC
6701 EVENSTAD DR N
MAPLE GROVE, MN 553696026

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Liberty Mutual SURETY

BOND RIDER

To be attached to and form a part of :

Bond No.: **190015626**

Cross Ref Bond No.: _____

Type of Bond: Wholesale Pharmaceutical bond

Dated effective: October 17, 2006

Executed by: Upsher-Smith Laboratories, LLC

_____, as Principal,

And by: Liberty Mutual Insurance Company , as Surety,

In favor of: Nevada Board of Pharmacy

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to:

Changing: Principal Name and/or Address

From: Upsher-Smith Laboratories, LLC
6701 Evenstad Dr., Maple Grove, MN 55369

To: Upsher-Smith Laboratories, LLC
6701 Evenstad Dr., Suite #300, Maple Grove, MN 55369

Address Change Applies to: Billing, Legal / Physical & Mailing Address

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

The Principal as changed by this Rider is the Principal as if it had been initially named the Principal when the bond was issued. The former Principal is hereby released and has no obligations with respect to the bond.

This rider is effective: February 11, 2026

Signed and Sealed on: February 11, 2026

Principal Name: Upsher-Smith Laboratories, LLC

By: _____

Surety Name: Liberty Mutual Insurance Company

By: _____

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

Agency Name: RJF, a Marsh & McLennan Agency LLC Company

Agency Address: 6160 Golden Hills Drive, Minneapolis, MN 55416

Liberty Mutual Surety Claims • P.O. Box 34526, Seattle, WA 98124 • Phone: 206-473-6700 • Fax: 866-442-4060
Email: HOSCL@libertymutual.com • https://claims-intake.libertymutualsurety.com

POWER OF ATTORNEY

Liberty Mutual Insurance Company

Principal: Upsher-Smith Laboratories, LLC
Agency Name: RJF, a Marsh & McLennan Agency LLC Company Bond Number: 190015626
Obligee: Nevada Board of Pharmacy
Bond Amount: ($100,000.00) One Hundred Thousand Dollars And Zero Cents

KNOW ALL PERSONS BY THESE PRESENTS: that Liberty Mutual Insurance Company, a corporation duly organized under the laws of the State of Massachusetts (herein collectively called the "Company"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint **Carolyn Banks** in the city and state of **Seattle, WA**, each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Company in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Company and the corporate seal of the Company has been affixed thereto this 11th day of February, 2026.

Liberty Mutual Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA
COUNTY OF MONTGOMERY ss

On this 11th day of February, 2026, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-law and Authorizations of Liberty Mutual Insurance Company, which is now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature or electronic signatures of any assistant secretary of the Company or facsimile or mechanically reproduced or electronic seal of the Company, wherever appearing upon a certified copy of any power of attorney or bond issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company do hereby certify that this power of attorney executed by said Company is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Company this 11th day of February, 2026.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Upsher-Smith Laboratories, LLC

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 6701 Evenstad Drive Ste 300

City Maple Grove State MN Zip 55369

Mailing Address (if different from physical address) N/A

City _____ State _____ Zip _____

Telephone 763-315-2000 Website https://www.upsher-smith.com/

Licensing Company Email statelicensing@upsher-smith.com

Section 2: Personal Information

First James Middle Eldon Last Maahs

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 6701 Evenstad Drive, Suite 300

City Maple Grove State MN Zip 55369

Telephone [redacted] Email jim.maahs@upsher-smith.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Iowa State University		08/82 - 05-86	
Address	City	State	Zip
2167 Union Dr	Ames	IA	50011
Diploma/Degree obtained, if any			
B.S., Business Administration			

School Name		From - To (MM/YY – MM/YY)	
University of Saint Thomas		09/97 - 05-03	
Address	City	State	Zip
2115 Summit Ave	St. Paul	MN	55105
Diploma/Degree obtained, if any			
M.B.A., Healthcare Management			

School Name		From - To (MM/YY – MM/YY)	
Algona High School		08/77 - 05/81	
Address	City	State	Zip
600 S Hale St	Algona	IA	50511
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/98 - Present	[redacted]	St. Paul	MN	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Upsher-Smith Laboratories, LLC			
Business Address	**City**	**State**	**Zip**
6701 Evenstad Drive	Maple Grove	MN	55369
Phone	**Title**	**Number of Employed Hours**	
763-315-2000	Current title: SVP, Head of Commercial (see resume for previous titles)	06/2003 - Present	
Description of Duties			
See attached resume for list of duties.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

JIM MAAHS

[redacted]

QUALIFICATIONS

Results driven pharmaceutical executive with extensive experience and strong track record of leading teams to achieve P&L targets with revenue greater than $400M. Well respected leader who develops talent and builds highly effective and engaged teams.

- Currently responsible for P&L, commercial and SG&A functions: Legal, Supply Chain, Project Management, Marketing, Trade, Sales, Medical Affairs, HR, Specialty
- Performed roles and lead teams across all commercial functions, including:
  - Marketing, Sales, Trade, Market Access, Pricing, Contracts, Advocacy, Patient Access
- Developed strategy for integrating and maximizing value of company acquisition valued >$50M.
- Commercialized 8-505B2 that generated total $350M annual peak revenue (IQVIA).
- Lead cross functional team responsible for developing pipeline strategy for Rare Disease portfolio.
- Launched Upsher-Smith's first field sales team and all commercial operations functions.
- Significant experience with brands, branded-generics, generics, and lifecycle management strategies.
- Key leader in organization that has grown >40x in my tenure.
- Multiple disease states: Cardiology, Neurology, Dermatology, Women's Health

Guiding Values: integrity, respect, commitment, persistence, learning, work-ethic

EXPERTISE

- Organizational Effectiveness
- Innovative Commercial Strategies
- Developing and Leading Teams
- Executive Leadership
- Gross to Net
- Mergers & Acquisition
- Rare Disease
- Limited Distribution
- Developing Talent
- Business Development

PROFESSIONAL EXPERIENCE

UPSHER-SMITH LABORATORIES, INC, Minneapolis, MN

SVP, Head of Upsher-Smith Commercial, February 2025-Present

- Responsible for P&L and leading all SG&A functions with >$450M revenue.
- Lead company through successful integration with Bora Pharmaceuticals.
- Developed and implemented reorganization to reduce OpEx and improve profitability.
- Lead team through multiple product launches and company acquisition valued >$50M.
- Commercial team recognized by industry partners receiving 15 HDA DIANA Awards.

Vice President, Head of Commercial, May 2024-February 2025

- Responsible for all functions related to commercializing brands USL portfolio.
- Lead cross-functional team to identify, evaluate and add 2 products to pipeline.
- Launched Rare Disease drug and achieved annual revenue objectives.
- Key leader on Executive Team responsible for selling the company.

Vice President, Marketing & Market Access, July 2015-May 2024

- Increased revenue for CNS brand by >500% during 4-year period
- Lead and launched and directed strategies for specialty brand to achieve >$80M in annual sales.
- Led cross-functional team to create new pipeline strategy; currently includes 7 products.
- Developed limited distribution model to drive lower patient acquisition cost & improved compliance.
- Partnered with Business Development to acquire and launch two 505B2 brands.
- Led Market Access team to achieve access of >80% of commercial and government lives.

Senior Director, Marketing-Product Portfolio Management, July 2014-June 2015

- Responsible for portfolio of brands, generic drugs, and OTC's.
- Key commercial leader on team that achieved record company sales >$500M during this period.
- Lead a cross-functional commercial team to execute a CNS patient-centric sales & marketing plan.
- Prepared framework for customer segmentation, sales force targeting and integration with CRM.
- Direct activities for first-ever national consumer marketing campaign for Amlactin® Lotion & Cream

Senior Director, Commercial Operations, 2010 – June 2014.

- Consistently achieved annual financial targets, including revenue growth of 190% and gross margins more than industry standards
- Chief role in leading the organization through a period of nine consecutive years of record revenue and profits.
- Headed the Trade team through an unprecedented number of industry leading awards from the Healthcare Distributors Management Association (HDMA Diana Award): Best Overall Small Consumer Products Company in 2012 and First Merit in 2013; Best Small Branded Pharmaceutical Company in 2010, 2011, 2013. In addition, all NAM's received Rep of the Year Award from their top customers
- Launched multiple new generic products and achieved #1 or #2 market share in over 80% of generic SKUs, while growing revenue by 180% from 2010-2013.

Director, Sales, Marketing & Commercial Operations, 2008 - 2009

- Responsible for developing and executing all trade account, marketing, pricing, channel, and product strategies to achieve revenue targets.
- Developed cross-functional Pricing Committee for over 150 generic SKU's that resulted in improving margins.
- Chief role in negotiating wholesaler fee for service contracts that were more favorable than industry benchmark
- Directed advertising and communications agency to create a business building program for Independent Pharmacy that provided digital and social media marketing tools for ~2,000 independent pharmacies
- Led cross functional Generic Portfolio Team to review 100% of SKU's annually and implement supply chain, operation or commercial changes that generated financial benefit of over $25M.

Director of Marketing, 11/2006-12/2007

- Responsible for directing all marketing activities, including strategy, commercial launch plans, market research, and directing product managers and all advertising and promotion partner activities.
- Chief role in driving strategy, commercial launch activities and forecast for Divigel® (estradiol gel) that resulted in achieving #1 market share in the category.
- Directed all cross-functional brand team and market research activities to reposition Women's Health products that resulted in achieving market share leader position for two key products
- Selected by Executive Team to be on Continuous Improvement (CI) Steering Committee that developed & implemented enterprise-wide CI processes & systems that generated ~$7M in financial benefits

Director of Sales, 2006

- Lead national account team to generate sales growth of 12% without new products, while keeping expenses under approved budget
- Selected by Executive Leadership Team to be a key member of team that developed initial Corporate Code of Business Conduct

National Sales Manager, 06/2003 – 12/2005

- Lead a sales force expansion that included adding 50 sales reps and 5 District Managers
- Directed the results of 3 Regional Managers, 10 District Managers and 135 Sales Reps to meet or exceed sales targets for $100M branded product portfolio
- Successfully launched two new products into market leader positions in both dermatology and cardiology while operating within $25M expense budget
- Lead the cross-functional team that developed a commercial launch plan for a Women's Health product that achieved market leader position in year #1, achieving *President's Club* for results.
- Developed and implemented multiple National Sales Meetings & POA's to inspire and engage sales force

ADDITIONAL ROLES AT UPSHER-SMITH LABORATORIES, LLC

Group Product Manager, Marketing

- Provided direction and coaching to 6 product managers to develop strategies and implement tactics for a $175M product portfolio of brands, generics, and consumer products.

Product Manager, Marketing

- Develop business plan for two cardiology brands that generated over 50% of corporate profits

National Account Manager-Trade

- Awarded "Branded Supplier of the Year" by Bergen Brunswig Drug Company
- Lead West Region to achieve 110% of Sales Goals

Manager, Health Systems Sales & Government Contracts

- Managed Contract Administration staff to effectively implement over 250 contracts
- Negotiated FSS agreement and GPO contracts that increased institutional sales by 96%

National Account Manager, Managed Care

- Developed very first Managed Care commercial plan, including identify accounts, objectives & strategies.
- Initiated and developed new relationships with key PBM's & HMO's that grew market share by 300%

Territory Sales Representative

- Consistently achieved 110% of sales goals and ranked in top of department.

BOSTON-SCIENTIFIC, INC, Maple Grove, MN
Product Manager-Cardiology Guide Wires

- Managed interventional guidewire franchise with $40M annual revenue, achieving 10% growth.
- Lead the successful commercialization of specialty device, Forte' Guidewire, including all strategy, forecasting, promotion, and sales training; exceeded forecast by 70%.

PFIZER LABORATORIES, INC, New York, NY
Sales Representative

- Grew Southwest Minnesota/ Northwest Iowa territory sales by 10% in one year

THETA CHI FRATERNITY, Indianapolis, IN
Leadership & Education Consultant

- Provided consulting and leadership training to officers and members of 50 Theta Chi chapters in 5 states.

EDUCATION

B.S., Business Administration
Iowa State University, Ames, IA
M.B.A., Healthcare Management
University of Saint Thomas, St. Paul, MN

OTHER ACTIVITIES

Member of Upsher-Smith Leadership Council, Operating Team & Other
Active member of community, including church council & youth sports coach
Guest lecturer & Adjunct Professor, St. Catherine's University
Volunteer

Upsher-Smith Laboratories, LLC

Maple Grove, MN 55369

FEIN: 41-0969017

Upsher-Smith Laboratories, LLC has permanently closed their manufacturing and packaging plant in Plymouth, Minnesota. All business operations at this facility have been completed. Due to this, Upsher-Smith has surrendered these licenses for this location as they are no longer needed.

State	License Type	License Number	Expiration
ME	Manufacturer	MF30001737	Surrendered
MN	Manufacturer	461254	Surrendered
MS	Non-Resident Manufacturer	16049	Surrendered
NH	Man/Dist/Whole/Broker	0017	Surrendered
OK	Manufacturer	88-M-5181	Surrendered
OR	Manufacturer	M-0001306	Surrendered
OR	Controlled Substance	M-0001306-CS	Surrendered
RI	Manufacturer – Out of State	DIS03058	Surrendered
RI	Controlled Substance	CDIS03058	Surrendered

Upsher-Smith has also surrendered the licenses below because they were no longer needed. They do not distribute samples and do not ship CS into NY.

State	License Type	License Number	Expiration
FL	Non-resident Manufacturer	261885	Closed
FL	Comp Drug Distributor	40748	Surrendered
NY CS	Controlled Substance	02A0960	Surrendered
WA	Drug Sample Distributor	461254	Surrendered

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section B: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	X	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Upsher-Smith Laboratories, LLC has voluntarily surrendered some licenses. Please see the attached list of licenses and their reason for surrender.

Original Signature (electronic, copies or stamps not accepted)

11/13/2025
Date

I, James Maahs, **certify that as the designated representative for**

Upsher-Smith Laboratories, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JM I am at least 21 years of age;
3. JM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

James Maahs

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/24/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James Maahs

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/13/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Minnesota, ss. County of Hennepin

I, James Maahs, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/13/2025

Date

Subscribed and Sworn to before me this 13 day of November.

Notary Public Signature

Tammy Lucille Groene
Notary Public
Minnesota
My Commission Expires Jan. 31, 2030

(Seal)

Employee ID	Legal Name in General Display Format	Job Title	Cost Center	Worker Type
001269	Jonathan G Krinke	Sr Scientist - Technical Services	B6450 Technical Services	Employee
001312	Jeffrey A Larsen	Sr Supervisor Maintenance	B2750 Maintenance - Maple Grove	Employee
007348	Ann C Roberts	Associate Director Benefits and HR Systems	C1410 Human Resources	Employee
009821	Leah M Schneider	Head of HR US	C1410 Human Resources	Employee
009897	Thu T Pham	Chemist II - QC	B6710 Quality Control - Maple Grove	Employee
009908	Stephen D Harrington	Sr Lead Facilities Technician	B7830 Facilities - Maple Grove	Employee
009951	Sharon M Swentkofske	Sr SAP Business Analyst	C1610 Information Technology	Employee
009973	Daniel E Wick	Computerized Systems Validation Specialist	C1610 Information Technology	Employee
010066	Leon E Meemken	Director Metrology	B6770 Metrology	Employee
010103	Michelle T Christy	Principal Procurement Specialist	B2610 Materials Management	Employee
010223	Mark W Rohmann	Sr Master Planner	C4410 National Accounts	Employee
010311	James E Maahs	Senior Vice President/Head of Upsher-Smith Commercial	C4110 Head of Commercial	Employee
010331	Solomon O Tewolde	Line Lead Chemical Process Manufacturing Technician	B2230 Manufacturing - Maple Grove	Employee
010332	Ketsana Inthichack	Line Lead	B2230 Manufacturing - Maple Grove	Employee
010346	Michelle B Zachman	Medical Affairs Director	C6160 Medical Affairs	Employee
010358	Patrick F Condon	Manager Warehouse and Inventory Control	B7110 Distribution	Employee
010384	Jean L Thielen	Sr Chargeback Coordinator	C1510 Commercial Finance	Employee
010389	Rebecca A Jansen	AVP Manufacturing and Technical Services	B6450 Technical Services	Employee
010458	Greg E Lamphere	Manager Manufacturing & Packaging Operations	B2230 Manufacturing - Maple Grove	Employee
010459	Molly E Popowski	Sr Director Quality	B6210 Quality Assurance	Employee
010468	Ramin Rigi	Director Human Resources	C1410 Human Resources	Employee
010472	Ryan W Urbach	Director IT Infrastructure & Enterprise Security	C1610 Information Technology	Employee
010474	Michelle Brassington	National Accounts Director	C4410 National Accounts	Employee
010490	Thung M Nguyen	Supervisor Material Handling	B7110 Distribution	Employee
010532	Kyle J Anderson	Associate Director Facilities Services	B7830 Facilities - Maple Grove	Employee
010543	Dawn R Ekwall	Customer Relations Specialist	C4410 National Accounts	Employee
010567	Jonas R Skjei	Associate Director Quality Compliance & CSV	B6210 Quality Assurance	Employee
010596	Miguel Hernandez Viveros	Sr Material Handler	B7110 Distribution	Employee
010615	Andrew S Thayer	Associate Director Quality Control	B6710 Quality Control - Maple Grove	Employee
010651	Bee J Yang	Sr Line Lead	B2230 Manufacturing - Maple Grove	Employee
010655	Jerusha R Thompson	Associate Director PMO	C1210 Project Management	Employee
010672	Stephanie R Fleitman	Director National Sales	C4220 Marketing	Employee
010690	Clinton V Stewart	Sr Line Lead	B2230 Manufacturing - Maple Grove	Employee
010694	Gregory P Wedin	Pharmacovigilance and Risk Management Sr Director	C6120 Regulatory Affairs	Employee
010696	Rhonda N Turner	Project Coordinator	C1210 Project Management	Employee
010699	Greg D Elfering	Line Lead	B2230 Manufacturing - Maple Grove	Employee
010726	Amy L Dearborn	Director Customer Relations and Order Management	C4410 National Accounts	Employee
010810	Robert J Hoffman	Principal Procurement Specialist	B2610 Materials Management	Employee
010829	Robert J Marek	Supervisor Shipping and Receiving	B7110 Distribution	Employee
010858	Paul B Buck	Principal External Quality Management Specialist	B6210 Quality Assurance	Employee
010882	Laura L Hoag	Associate Director Marketing Operations	C4220 Marketing	Employee
010903	Matthew J Olsen	Sr Material Handler	B7110 Distribution	Employee
010911	Husnija Begic	Analyst - QC	B6710 Quality Control - Maple Grove	Employee

010913	Danielle M Jungroth	Sr External Product Quality Specialist	C6210 Commercial Quality Assurance	Employee
010977	Arvid J Green	Sr Material Handler	B7110 Distribution	Employee
011036	Sarah Shannon	Associate Vice President Generic Sales and Marketing Operations	C4410 National Accounts	Employee
011058	Kou Yang	Sr Line Lead	B2340 Packaging - Maple Grove	Employee
011062	Benjamin L Sanders	Supervisor Laboratory Support	B6710 Quality Control - Maple Grove	Employee
011067	Derek K Weber	Sr Chemist - QC	B6710 Quality Control - Maple Grove	Employee
011072	Katie L Joslyn	Design Manager	C4220 Marketing	Employee
011109	Stephanie C Gibson	Procedural & Technical Writer	B2230 Manufacturing - Maple Grove	Employee
011138	Stephanie L Myhervold	Marketing Coordinator	C4220 Marketing	Employee
011169	Faraz A Shaukat	Enterprise Client Solutions Principal	C1610 Information Technology	Employee
011171	Curt J Adams	Line Lead	B2340 Packaging - Maple Grove	Employee
011175	Matthew L Baumgartner	Sr Line Lead	B2340 Packaging - Maple Grove	Employee
011192	Daniel L Stephenson	Line Lead	B2340 Packaging - Maple Grove	Employee
011216	Suzannabeth Mua	Sr Line Lead	B2340 Packaging - Maple Grove	Employee
011239	Ryan C Baker	Director Regulatory Affairs - CMC	C6120 Regulatory Affairs	Employee
011261	Carlotta K Rosebrock	Labeling Graphics Specialist	C6120 Regulatory Affairs	Employee
011265	Dustin S Seagren	Principal Infrastructure Engineer	C1610 Information Technology	Employee
011274	Robert J Green	Sr Director Engineering	B2720 Engineering - MN	Employee
011288	Jonathan R Koppin	Commercial Analytics Principal Business Analyst	C4410 National Accounts	Employee
011294	Wesley Dybedahl	Product Quality Specialist	B6210 Quality Assurance	Employee
011295	Bridget R Newman	Project Manager II	B6450 Technical Services	Employee
011326	Duane C Koshiol	Principal SAP Business Analyst	C1610 Information Technology	Employee
011328	Irada Rybak	Sr Scientist - Technical Services	B6450 Technical Services	Employee
011356	Ryan W Lancour	Computer Systems Validation Associate II	B6210 Quality Assurance	Employee
011364	Jamie L Overman	Medical & Scientific Affairs Operations Manager	C6140 Clinical Operations	Employee
011374	Jeremy L Minner	Help Desk Supervisor	C1610 Information Technology	Employee
011382	Nicholas J Helland	Associate Scientist II - Tech Services	B6450 Technical Services	Employee
011399	Jovanny Roldan	Manufacturing Tech III	B2230 Manufacturing - Maple Grove	Employee
011406	Ka Y Lo	Sr Regulatory Affairs CMC Specialist	C6120 Regulatory Affairs	Employee
011411	Brian C Hamsmith	Line Lead	B2340 Packaging - Maple Grove	Employee
011451	Andrew J Hoganson	Associate Manager Quality Control	B6710 Quality Control - Maple Grove	Employee
011454	Justin R Hanna	Manager IT Infrastructure Operations	C1610 Information Technology	Employee
011471	Derek D Johnson	Operations Trainer	B6210 Quality Assurance	Employee
011494	Jennifer L McCray	Sr Labeling Specialist	C6120 Regulatory Affairs	Employee
011507	Eric J Johnson	Manager Equipment Validation	B6450 Technical Services	Employee
011516	Katharine A Jackson Huebsch	Associate General Counsel Intellectual Property	C1320 Legal Affairs	Employee
011528	Kelli N Flanders	Sr Product Quality Specialist	B6210 Quality Assurance	Employee
011541	Lucy D Gary	Associate Director Regulatory Affairs Labeling	C6120 Regulatory Affairs	Employee
011581	Laura C Cavataio	Sr Data Reviewer - Analytical Development	B6740 Pharmaceutical Development Solutions	Employee
011666	Randall G Staffanson	Sr Metrologist II	B6770 Metrology	Employee
011667	Angela J Leadens	Chemist II - QC	B6710 Quality Control - Maple Grove	Employee
011702	Da Thao	Warehouse Lead	B7110 Distribution	Employee
011705	Shannon L Klick	Talent Acquisition Specialist	C1410 Human Resources	Employee
011709	Kristine K Veches	Project Manager II	C1210 Project Management	Employee
011712	Nicole R Bakker	Sr Supply Chain Data Analyst	B7110 Distribution	Employee
011721	Emily D Weckman	Sr Product Quality Specialist	B6210 Quality Assurance	Employee

011755	Amanda K Hough	Corporate Controller	C1510 Commercial Finance	Employee
011796	Jason E Lofsness	Sr Material Handler	B7110 Distribution	Employee
011805	Megan A Levis	Sr External Product Quality Specialist	C6210 Commercial Quality Assurance	Employee
011806	Raymond J Ehmiller	Network Support Analyst II	C1610 Information Technology	Employee
011830	Kevin Timm	Principal Manufacturing Engineer	B2720 Engineering - MN	Employee
011863	Brenda S Crawford	Procurement Specialist	B2610 Materials Management	Employee
011865	Ann M Mrozek	Sr Quality Systems Specialist	B6210 Quality Assurance	Employee
011866	Stephanie J Hoffman	Sr Metrology Coordinator	B6770 Metrology	Employee
011872	Eric E Barnes	Chemist II - QC	B6710 Quality Control - Maple Grove	Employee
011886	Herbert B Miller IV	Director Supply Chain	B7110 Distribution	Employee
011888	Amy R Sharp	Manager Quality Control	B6710 Quality Control - Maple Grove	Employee
011903	Shannon L Guarneri	Sr Procurement Specialist	C4410 National Accounts	Employee
011939	Jack E Brady	Manager Technical Services	B6450 Technical Services	Employee
011945	Travis R Rivard	Sr Data Reviewer I	B6710 Quality Control - Maple Grove	Employee
011947	Vang Yang	Line Lead	B2230 Manufacturing - Maple Grove	Employee
011987	Daniel J Stupca	Sales Operations and Analytics Specialist	C4220 Marketing	Employee
012002	Tracy S Hean	Sr Packaging Tech II	B2340 Packaging - Maple Grove	Employee
012010	Chee Xiong	Line Lead	B2340 Packaging - Maple Grove	Employee
012030	Natalie J Lange	Manufacturing Support Specialist	B2230 Manufacturing - Maple Grove	Employee
012062	Teri E Tanquist	Director Operational Excellence	C4110 Head of Commercial	Employee
012063	Joseph R Volk	Enterprise Applications Analyst III	C1610 Information Technology	Employee
012077	Anthony J LaSota	Sr SAP Business Analyst	C1610 Information Technology	Employee
012078	Katelyn J Futel	Key Account Manager	C4320 Specialty Sales	Employee
012089	Der Yang	Supervisor Operations	B2230 Manufacturing - Maple Grove	Employee
012097	Alicia D Pueringer	Sr Scientist - Technical Services	B6450 Technical Services	Employee
012121	Christina R Nohava	Sr Accounts Receivable Coordinator	C1510 Commercial Finance	Employee
012124	Irina Kotkova	Principal Regulatory Operations Specialist	C6120 Regulatory Affairs	Employee
012183	Kenneth N Daniels	Metrologist	B6770 Metrology	Employee
012185	Dennis W Hall	Vice President and General Manager	B2110 Manufacturing Management	Employee
012204	Bridget S Holmes	Chemist - Analytical Development	B6740 Pharmaceutical Development Solutions	Employee
012208	Kevin E Korpi	Lead HVAC/Plant Technician	B2750 Maintenance - Maple Grove	Employee
012219	Houa Her	Line Lead	B2340 Packaging - Maple Grove	Employee
012234	Kriti Kumar Gregory	Associate Director Corporate Accounting	C1510 Commercial Finance	Employee
012236	Timothy J Donelon	Director IT Business Solutions	C1610 Information Technology	Employee
012241	Megan A Gustafson	Associate Director Environmental Health and Safety	B2720 Engineering - MN	Employee
012253	Deborah L Drummer	Medicaid Rebates Analyst	C1510 Commercial Finance	Employee
012266	Gary Mackinnon	Sr Director External Quality	C6210 Commercial Quality Assurance	Employee
012267	Connor B Bruder	Sr Line Lead	B2230 Manufacturing - Maple Grove	Employee
012277	Donald F Stille	Sr Lead Technician	B2750 Maintenance - Maple Grove	Employee
012316	Sierra E Orth	Sr Operations Trainer	B6210 Quality Assurance	Employee
012320	Yer K Keith	Quality Associate	B6210 Quality Assurance	Employee
012336	Pamela S Barckett	Sr External Product Quality Specialist	C6210 Commercial Quality Assurance	Employee
012347	Stephanie R Leonard	Laboratory Support Technician	B6710 Quality Control - Maple Grove	Employee
012361	Michael J Whebbe	Sr Quality Systems Specialist	B6210 Quality Assurance	Employee
012389	Hiral Patel	Sr External Product Quality Specialist	C6210 Commercial Quality Assurance	Employee
012390	Kimberly A Dupuis	Manager Operations Quality	B6210 Quality Assurance	Employee
012391	Blake W Johnson	Principal Chemist - Analytical Development	B6740 Pharmaceutical Development Solutions	Employee
012393	Henry E Hernandez	Line Lead	B2230 Manufacturing - Maple Grove	Employee

012406	Stefan S Sauer	Sr Financial Analyst	C1510 Commercial Finance	Employee
012441	Skip T Buckmiller	Principal Procurement Specialist	C4410 National Accounts	Employee
012446	Ysania Eldred	Principal Regulatory CMC Specialist	C6120 Regulatory Affairs	Employee
012465	Andrew W Stolba	Master Data Specialist	B2610 Materials Management	Employee
012481	Erik T Johnson	Quality Systems Specialist	B6210 Quality Assurance	Employee
012496	Anthony J Bellotte	Director Procurement and Planning	C4410 National Accounts	Employee
012499	Lori D Riggs	Sr Procurement Specialist	C4410 National Accounts	Employee
012521	Pheng Lor	Chemical Process Manufacturing Technician	B2230 Manufacturing - Maple Grove	Employee
012535	Nancy K Thao	Manufacturing Tech III	B2230 Manufacturing - Maple Grove	Employee
012537	Pao Yang	Manufacturing Tech II	B2230 Manufacturing - Maple Grove	Employee
012542	Brittany J Wolters	Manager Finance Shared Services	C1510 Commercial Finance	Employee
012546	Rachel A Hopps	Associate Chemist - QC	B6710 Quality Control - Maple Grove	Employee
012548	Alisa M Abrams	Principal External Quality Management Specialist	C6210 Commercial Quality Assurance	Employee
012549	James Yang	Sr Material Handler	B7110 Distribution	Employee
012551	Allison M Hall	Associate Chemist - QC	B6710 Quality Control - Maple Grove	Employee
012552	Kaylyn E Leonard	Associate Chemist - QC	B6710 Quality Control - Maple Grove	Employee
012553	Timothy X Yang	Material Handler II	B7110 Distribution	Employee
012556	Moses M Zodua	Line Lead	B2230 Manufacturing - Maple Grove	Employee
012571	Timothy J Clifford	Associate Chemist - QC	B6710 Quality Control - Maple Grove	Employee
012572	Joseph M Mohar	Principal Procurement Leader	C4410 National Accounts	Employee
012580	Shelly M Schewe	Sr Revenue Accountant	C1510 Commercial Finance	Employee
012588	Amy A Wolbert	Benefits Specialist	C1410 Human Resources	Employee
012603	Jessica L Wise	Manager Pricing & Contracts	C4410 National Accounts	Employee
012610	Luis C Uz	Metrologist	B6770 Metrology	Employee
012623	Jennifer Kay Heichert	Payroll Administrator	C1510 Commercial Finance	Employee
012633	Fat'hi I Mohamed	Help Desk Analyst I	C1610 Information Technology	Employee
012647	Timothy L Ramey Jr	Lead Technician	B2750 Maintenance - Maple Grove	Employee
012652	Deshaun Thao	Material Handler II	B7110 Distribution	Employee
012653	Victor Hernandez-Vergara	Manufacturing Tech II	B2230 Manufacturing - Maple Grove	Employee
012668	Thomas V Le	Analyst - QC	B6710 Quality Control - Maple Grove	Employee
012669	Geoffrey J Rajotte	Chemical Process Manufacturing Technician	B2230 Manufacturing - Maple Grove	Employee
012675	Sandra A Wiskocil	Sr Quality Associate	B6210 Quality Assurance	Employee
012678	Jason Christopher	Chemical Process Manufacturing Technician	B2230 Manufacturing - Maple Grove	Employee
012698	Steven L Miller	Metrologist	B6770 Metrology	Employee
012709	Rachel M Bauer	Commercial Coordinator	C4220 Marketing	Employee
012712	Loren D Jorgensen	Data Integration Analyst	C1610 Information Technology	Employee
012727	Matthew A Wolney	Sr Facilities Technician	B7830 Facilities - Maple Grove	Employee
012735	Kayla M Helmberger	Sr Chemist - QC	B6710 Quality Control - Maple Grove	Employee
012737	Yoko R Bautista	Press Operator II	B2230 Manufacturing - Maple Grove	Employee
012747	Cha Vang	Manufacturing Tech II	B2230 Manufacturing - Maple Grove	Employee
012773	Benhur M Solomon	Associate Scientist I - Technical Services	B6450 Technical Services	Employee
012784	Darius M Roberson	Key Account Manager	C4320 Specialty Sales	Employee
012806	Linda B Nesbitt	Principal Procurement Specialist	C4410 National Accounts	Employee
013231	Vaishnavi Chelikam	Sr SAP Business Analyst	C1610 Information Technology	Employee
013234	Julie A Lynch	Key Account Manager	C4320 Specialty Sales	Employee
013235	Kerri L Romagna	Key Account Manager	C4320 Specialty Sales	Employee
013236	Robert D McGovern	Key Account Manager	C4320 Specialty Sales	Employee
013238	Kris M Whittington	Key Account Manager	C4320 Specialty Sales	Employee
013239	Michelle Kochan	Key Account Manager	C4320 Specialty Sales	Employee
013240	Thomas J McCrink	Key Account Manager	C4320 Specialty Sales	Employee
013242	Molly A Phillips	Key Account Manager	C4320 Specialty Sales	Employee
013243	Cheryl L Poole Ramirez	Key Account Manager	C4320 Specialty Sales	Employee
013244	Brian J Townsend	Director KOL Engagement	C4320 Specialty Sales	Employee
013246	Benjamin J Marx	HVAC/Plant Technician	B7830 Facilities - Maple Grove	Employee
013247	Sarah A Volovick	Associate Director Meetings & Events	C4220 Marketing	Employee
013248	Sarah A Maxey	Associate Director Patient Services and Analytics	C4220 Marketing	Employee
013250	Patrick J Moty	Sr Director National Accounts & Health Policy	C4220 Marketing	Employee

013251	Andrew J Tamulevich	VP Sales	C4320 Specialty Sales	Employee
013252	Raenel V Gibson	Associate Vice President Regulatory Affairs	C6120 Regulatory Affairs	Employee
013264	Jaclyn M Kobienia	Associate Director Marketing Execution	C4220 Marketing	Employee
013272	Timothy J Smith	Pharmacovigilance and Risk Management Director	C6120 Regulatory Affairs	Employee
013274	Daniel J Bruno	Division CFO Commercial	C1510 Commercial Finance	Employee
013277	Dominique E Hetrick	Sr. Regulatory Licensing and Registration Specialist	C6120 Regulatory Affairs	Employee
013280	Kristen L Stott	Key Account Manager	C4320 Specialty Sales	Employee
013296	Maulik K Panchal	Principal Scientist - Process	B6450 Technical Services	Employee
013297	Joaquin Lugo Pagán	Principal Scientist - Process	B6450 Technical Services	Employee
013299	Brooklynn R Nagpal	Legal Intern	C1320 Legal Affairs	Employee
013305	Marco F Polizzi	Vice President Pharmacy Commercialization	C4410 National Accounts	Employee
013309	Jerel D Smith	Director Integrity and Compliance / USL Commercial Chief Compliance Officer	C4220 Marketing	Employee
013311	Jeanne A Stafki	Receptionist	B7830 Facilities - Maple Grove	Employee
013313	Todd M Engle	National Accounts Associate Vice President	C4410 National Accounts	Employee
013315	Christy S Cardelli	Director Human Resources	B2110 Manufacturing Management	Employee
013319	Richard M Dudek	VP Commercial Operations, Rare Disease	C4220 Marketing	Employee
013323	Sarah M Magnuson	Sr Business Analyst - Pricing, Contracts & Analysis	C4410 National Accounts	Employee
013324	Jon T Dever	Revenue Accountant	C1510 Commercial Finance	Employee
013325	Tammy L Groene	Executive Assistant	C4110 Head of Commercial	Employee
013327	Matthew S Green	Associate Vice President Finance	C1510 Commercial Finance	Employee
013339	Kathryn E Kraemer	Customer Relations Specialist	C4410 National Accounts	Employee
013343	Garrett J Stoddard	Manager Analytical Development	B6740 Pharmaceutical Development Solutions	Employee
013345	CeCelia Williams	Sr Payroll Analyst	C1410 Human Resources	Employee
900209	Julie J Wang	Patent Paralegal	C1320 Legal Affairs	Contingent Worker
901008	Daniel Norat	Microbiologist	B6710 Quality Control - Maple Grove	Contingent Worker
901025	Yves Gauthier	SAP ABAP Consultant	C1610 Information Technology	Contingent Worker
901029	Mitch Cleveland	Excel Energy Consultant	B2720 Engineering - MN	Contingent Worker
901043	Amy Todd	Telephony Contractor - HaigTodd	C1610 Information Technology	Contingent Worker
901066	Jed Peterson	Excel Engineering Consultant	B2720 Engineering - MN	Contingent Worker
901080	Ryan J Smetak	ECSI contractor	B7830 Facilities - Maple Grove	Contingent Worker
901084	Angelina Martinez	Cleaning Consultant	B7830 Facilities - Maple Grove	Contingent Worker
901166	Yer A Vang	Contingent Worker	B6710 Quality Control - Maple Grove	Contingent Worker
901244	Amanda R Williams	Payroll Administrator	C1410 Human Resources	Contingent Worker
901248	Ethan J Henseler	Associate Scientist II	B6710 Quality Control - Maple Grove	Contingent Worker
901251	Jackie Bazata	Advertising & Promotion Director	C6120 Regulatory Affairs	Contingent Worker
901252	Michael J Bibeau	Lab Tech	B6710 Quality Control - Maple Grove	Contingent Worker
901253	Abigail J Afryl	Sr Corporate Accountant	C1510 Commercial Finance	Contingent Worker
901261	Sarah M Brouillard	Independent Consultant	C4110 Head of Commercial	Contingent Worker
901262	Carol L Staffenhagen	Independent Consultant	C1320 Legal Affairs	Contingent Worker
901263	April D Robbins	Accounts Payable Coordinator	C1510 Commercial Finance	Contingent Worker
901264	Kenton J Yoder	Chemist Analytical Development	B6740 Pharmaceutical Development Solutions	Contingent Worker
901265	Andre Brouwers	Engineering Contractor	2720 Engineering - MN	Contingent Worker
901266	Robert J Wilson	Chemist Analytical Development	B6740 Pharmaceutical Development Solutions	Contingent Worker
901267	Michael K Tesfu	Principal Chemist	B6740 Pharmaceutical Development Solutions	Contingent Worker
901270	Benjamin T Waldusky	Sr Cost Accountant	1510 Finance & Strategic Planning	Contingent Worker
901271	Laurie P Smith	Sr. Business Analyst, Pricing & Contracts	C4410 National Accounts	Contingent Worker
901272	Colleen Lutz	Sr Data Reviewer	B6710 Quality Control - Maple Grove	Contingent Worker
901273	Glen G Itskovich	Project Manager	2720 Engineering - MN	Contingent Worker

901274	Gavin S Wightman	Associate Scientist	B6710 Quality Control - Maple Grove	Contingent Worker
901275	Ryan J Lester	Associate Scientist	B6710 Quality Control - Maple Grove	Contingent Worker
901276	Collin J Carlson	Lab Technician	B6710 Quality Control - Maple Grove	Contingent Worker
901277	Efrain Romero	Cleaning Consultant	B7830 Facilities - Maple Grove	Contingent Worker
901278	Teresa Lema	Cleaning Consultant	B7830 Facilities - Maple Grove	Contingent Worker
901279	Maria Tirado	Cleaning Consultant	B7830 Facilities - Maple Grove	Contingent Worker

4FF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 02899	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Clinical Solutions Wholesale, LLC

Physical Address: 416 Mary Lindsay Polk Drive, Ste 519

City: Franklin State: TN Zip: 37067

Mailing Address (if different from physical address): 416 Mary Lindsay Polk Drive, Ste 515

City: Franklin State: TN Zip: 37067

Telephone: 877-826-5488 Website: N/A

Name of Designated Representative (DR): Christi Throneberry

Licensing Company Email: compliance@cspmeds.com DR Email: christi@cspmeds.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	■ Controlled Substances	■ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Clinics		■ Others: Distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/25/2026
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: TopRx, LLC
Address: 2950 Brother Blvd City: Bartlett State: TN Zip: 38133

Name: AmerisourceBergen
Address: 12577 Stateline Rd. City: Olive Branch State: MS Zip: 38654

Name: Smith Drug Company
Address: 1104 Jones Rd. City: Paragould State: AR Zip: 72450

Name: N/A
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Tennessee
Parent Company (if any): CS Solutions Intermediate Holdings, LLC
Corporation/Organization Name: Clinical Solutions Wholesale, LLC
Mailing Address: 416 Mary Lindsay Polk Drive, Ste 519
City: Franklin State: TN Zip: 37067
Telephone: 877-826-5488 Email: compliance@cspmeds.com
Contact Person Name: Amanda Ramzy

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Clinical Solutions Wholesale, LLC

Facility Name

Christi Throneberry

Print Name of Authorized Person Submitting Application

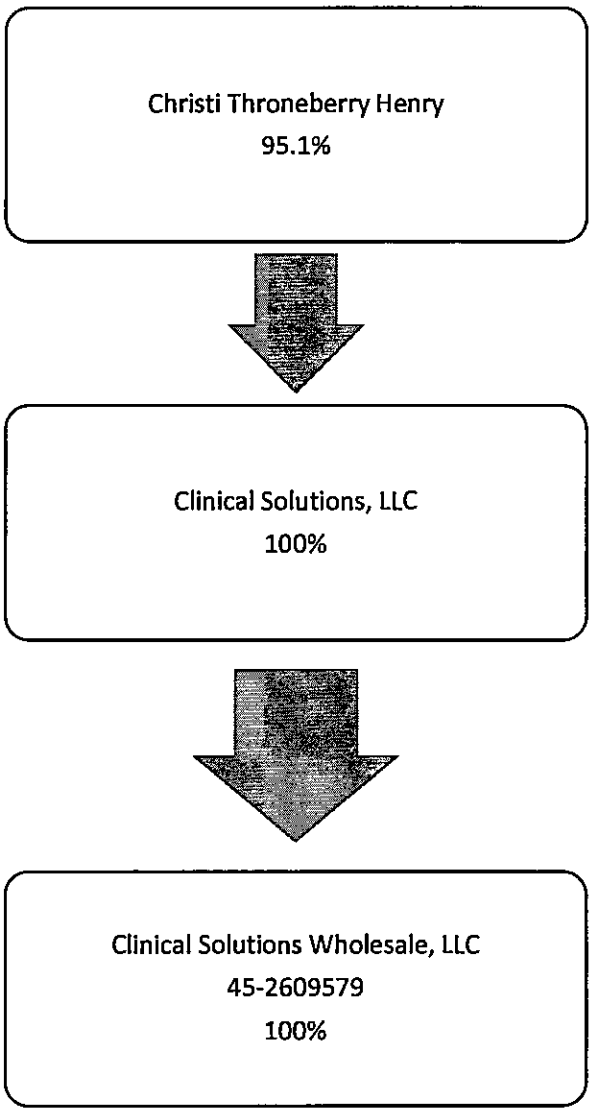
Original signature of Authorized Person (copies or stamps not accepted)

2/25/2026

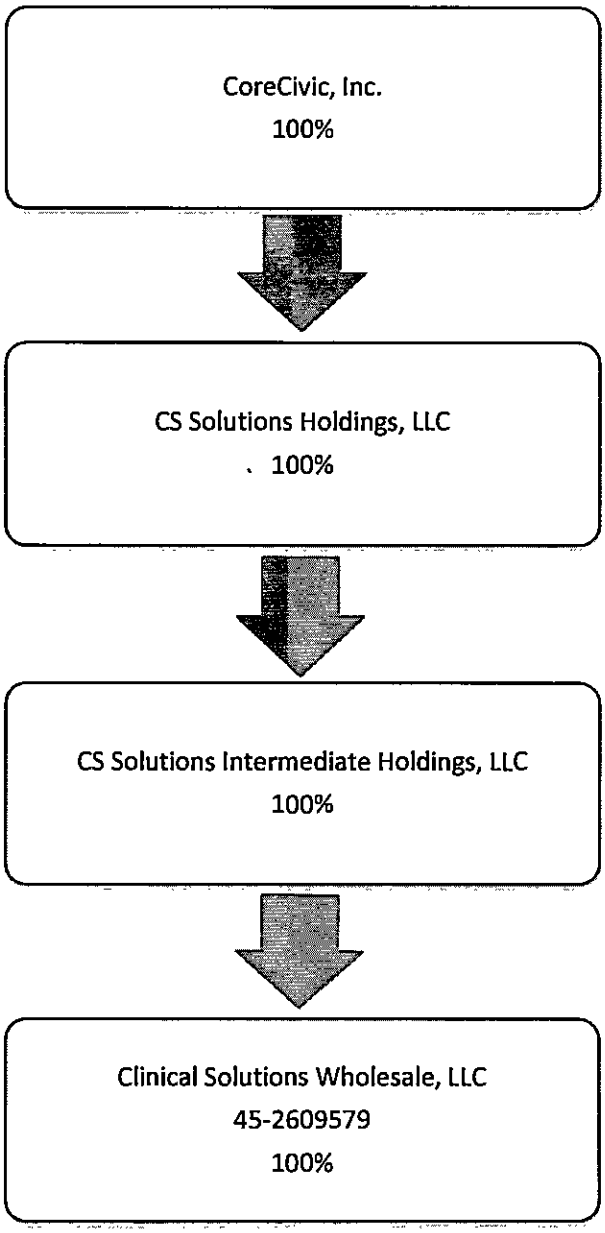
Date

Board Use Only	Date Received: 3/2/26	Amount: $1000 ck 955936

Pre-Close



Post-Close



Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (index.cfm)

Search Results for **CLINICAL SOLUTIONS WHOLESALE, LLC**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
CLINICAL SOLUTIONS WHOLESALE, LLC	3010191394	078710347	REPACK;	416 Mary Lindsay Polk Dr Ste 519, Franklin, Tennessee (TN) 37067, United States (USA)	12/31/2026

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Wednesday, Nov 12, 2025

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

NABP ACCREDITED
DRUG DISTRIBUTOR

Clinical Solutions Wholesale LLC

located at

416 Mary Lindsay Polk Dr, Ste 519 Franklin, TN, 37067

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

Accredited Drug Distributors

Find an Accredited Drug Distributor

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

1 2 3 4 5 Next >>

Name	Address	Accreditation Date
AnovoRx Distribution, LLC	1710 N Shelby Oaks Dr, Ste 6 Memphis, TN 38134	05/09/23
Aphena Pharma Solutions - Tennessee, LLC dba Aphena Pharma Solutions	1976 Chocolate Dr Cookeville, TN 38506	Reaccreditation in process
Associated Pharmacies, Inc dba API: APIRX	5375 Mineral Wells Rd Memphis, TN 38141	07/10/25
Cardinal Health 105, LLC dba Specialty Pharmaceutical Services	15 Ingram Blvd LaVergne, TN 37086	04/26/25
Cardinal Health 105, LLC dba Specialty Pharmaceutical Services	501 Mason Road, Ste 200 LaVergne, TN 37086	02/18/25
Cardinal Health 108, LLC dba Cardinal Health; Metro Medical Supply	233 Mason Rd LaVergne, TN 37086	03/17/23
Cardinal Health 110, LLC	2512 Westcott Boulevard Knoxville, TN 37931	09/11/23
Cardinal Health 110, LLC dba Parmed Pharmaceuticals	5960 E Shelby Dr, Ste 100 Memphis, TN 38141	09/30/25
Cardinal Health Packaging Solutions	339 Mason Road LaVergne, TN 37086	12/21/23
Clinical Solutions Wholesale LLC	416 Mary Lindsay Polk Dr, Ste 519 Franklin, TN 37067	10/07/25

1 2 3 4 5 Next >>

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Clinical Solutions Wholesale, LLC

Franklin, TN

Officer and Ownership Information

Name	Title	Address
Christi Throneberry	Officer and Designated Representative	416 Mary Lindsay Polk Drive, Suite 519 Franklin, TN 37067

The facility is wholly owned by:
Clinical Solutions Wholesale, LLC
FEIN: 73-1704205
416 Mary Lindsay Polk Drive
Suite 519
Franklin, TN 37067

Clinical Solutions Wholesale, LLC is wholly owned by:
CS Solutions Intermediate Holdings, LLC
FEIN: 41-3908543
416 Mary Lindsay Polk Drive
Suite 519
Franklin, TN 37067

Division of Business and Charitable Organizations
Department of State
State of Tennessee
312 Rosa L. Parks Avenue, 6th Floor
Nashville, Tennessee 37243
Phone: 615-741-2286
sos.tn.gov/

Tre Hargett
Secretary of State

CHRISTI THRONEBERRY
416 MARY LINDSAY POLK DR. STE 515
FRANKLIN, TN 37067, USA

12/10/2025

Request Type: Certificate of Existence/Authorization

Issuance Date: 12/10/2025

Request #: C2025109455

Document Receipt

Order Number: C2025109455

Verification #: 4549EC6E

Receipt #: 2025-811872

Filing Fee: $20.00

Payment: Credit Card - [redacted] $20.00

Entity Name:	CLINICAL SOLUTIONS WHOLESALE, LLC		
SOS Control #:	000661662	Initial Filing Date:	06/27/2011
Entity Type:	Limited Liability Company (LLC)	Formation Locale:	TENNESSEE
Status:	Active	Duration Term:	Perpetual
Fiscal Year Close:	December	Annual Report Due:	04/01/2026
Business County:	WILLIAMSON		
Managed By:	Manager Managed		
Obligated Member Entity:	No		

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

CLINICAL SOLUTIONS WHOLESALE, LLC

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;
* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;
* has filed the most recent annual report required with this office;
* has appointed a registered agent and registered office in this State;
* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Verification #: 4549EC6E

13838503

34742

State of Tennessee
Department of Health

BOARD OF PHARMACY
WHOLESALE/DISTRIBUTOR
CLINICAL SOLUTIONS WHOLESALE, LLC
416 MARY LINDSAY POLK DR.
SUITE 519
FRANKLIN TN 37067

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000003566
EXPIRATION DATE: 08/31/2026

CONTROLLED SUBSTANCE REGISTRATION

Jennifer L. Rotramel Esq
ASSISTANT COMMISSIONER, HEALTH LICENSURE & REGULATION

COMMISSIONER, DEPARTMENT OF HEALTH

DCF171

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	08-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	07-02-2025

CLINICAL SOLUTIONS WHOLESALE, LLC
CLINICAL SOLUTIONS
416 MARY LINDSAY POLK DR STE 519
FRANKLIN, TN 370672681

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	08-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	07-02-2025

CLINICAL SOLUTIONS WHOLESALE, LLC
CLINICAL SOLUTIONS
416 MARY LINDSAY POLK DR STE 519
FRANKLIN, TN 370672681

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	08-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	07-02-2025

CLINICAL SOLUTIONS WHOLESALE, LLC
CLINICAL SOLUTIONS
416 MARY LINDSAY POLK DR STE 519
FRANKLIN, TN 370672681

CONTROLLED SUBSTANCE/REGULATED CHEMICAL REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. B150069555

Application/License No. _____

Clinical Solutions Wholesale, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 416 Mary Lindsay Polk Dr Ste 519, Franklin, TN 37067-2681 (Address of Applicant/Principal), as PRINCIPAL, and Old Republic Surety Company (Surety Company), a corporation organized under the laws of the state of Wisconsin (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 18500 W Corporate Dr, Ste 170, Brookfield, WI 53045 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 3/13/2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 27th day of March, 20 25.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Val W. Morton, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Amanda Ray
Witness

Witness

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

OLD REPUBLIC SURETY COMPANY

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That OLD REPUBLIC SURETY COMPANY, a Wisconsin stock insurance corporation, does make, constitute and appoint:

Val Morton Of ALGONA, Iowa

its true and lawful Attorney(s)-in-Fact, with full power and authority, not exceeding $10,000,000, for and on behalf of the company as surety, to execute and deliver and affix the seal of the company thereto (if a seal is required), bonds, undertakings, recognizances or other written obligations in the nature thereof, ***(other than bail bonds, bank depository bonds, mortgage deficiency bonds, mortgage guaranty bonds, guarantees of installment paper and note guaranty bonds, self-insurance workers compensation bonds guaranteeing payment of benefits, waste management bonds, hazardous waste remediation bonds or black lung bonds),*** as follows:

Effective Date: 03/13/2025

Bond Number: B150069555 Bond Amount: Twenty-Five Thousand Dollars $ 25,000.00

Principal Name: Clinical Solutions Wholesale, LLC

Obligee Name: NV State Board of Pharmacy, Nevada

and to bind OLD REPUBLIC SURETY COMPANY thereby, and all of the acts of said Attorneys-in-Fact, pursuant to these presents, are ratified and confirmed. This appointment is made under and by authority of the board of directors at a special meeting held on February 18, 1982.

This Power of Attorney is signed and sealed by facsimile under and by the authority of the following resolutions adopted by the board of directors of the OLD REPUBLIC SURETY COMPANY on February 18,1982.

RESOLVED that the president, any vice president or assistant vice president, in conjunction with the secretary or any assistant secretary, may appoint attorneys-in-fact or agents with authority as defined or limited in the instrument evidencing the appointment in each case, for and on behalf of the company to execute and deliver and affix the seal of the company to bonds, undertakings, recognizances, and suretyship obligations of all kinds; and said officers may remove any such attorney-in-fact or agent and revoke any Power of Attorney previously granted to such person.

RESOLVED FURTHER that any bond, undertaking, recognizance, or suretyship obligation shall be valid and binding upon the Company

(i) when signed by the president, any vice president or assistant vice president, and attested and sealed (if a seal be required) by any secretary or assistant secretary; or

(ii) when signed by the president, any vice president or assistant vice president, secretary or assistant secretary, and countersigned and sealed (if a seal be required) by a duly authorized attorney-in-fact or agent; or

(iii) when duly executed and sealed (if a seal be required) by one or more attorneys-in-fact or agents pursuant to and within the limits of the authority evidenced by the Power of Attorney issued by the company to such person or persons.

RESOLVED FURTHER that the signature of any authorized officer and the seal of the company may be affixed by facsimile to any Power of Attorney or certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the company; and such signature and seal when so used shall have the same force and effect as though manually affixed.

IN WITNESS WHEREOF, OLD REPUBLIC SURETY COMPANY has caused these presents to be signed by its proper officer, and its corporate seal to be affixed this 27th day of March, 2025

OLD REPUBLIC SURETY COMPANY

Assistant Secretary

President

STATE OF WISCONSIN, COUNTY OF WAUKESHA - SS

On this 27th day of March, 2025, personally came before me, Alan Pavlic and Kevin J. Abitz, to me known to be the individuals and officers of the OLD REPUBLIC SURETY COMPANY who executed the above instrument, and they each acknowledged the execution of the same, and being by me duly sworn, did severally depose and say: that they are the said officers of the corporation aforesaid, and that the seal affixed to the above instrument is the seal of the corporation, and that said corporate seal and their signatures as such officers were duly affixed and subscribed to the said instrument by the authority of the board of directors of said corporation.

Notary Public

My Commission Expires: 09/28/2026

(Expiration of notary's commission does not invalidate this instrument)

CERTIFICATE

I, the undersigned, assistant secretary of the OLD REPUBLIC SURETY COMPANY, a Wisconsin corporation, CERTIFY that the foregoing and attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolutions of the board of directors set forth in the Power of Attorney, are now in force.

0400134

Signed and sealed at the City of Brookfield, WI this 27th day of March, 2025

Assistant Secretary

ORSC 22262 (3-06)

PMC ADVANTAGE INS SERVICES INC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Clinical Solutions Wholesale, LLC

Pharmacy/Wholesaler License # (if applicable): WH02899

Physical Address: 416 Mary Lindsay Polk Drive, Ste 519

City: Franklin State: TN Zip: 37067

Mailing Address (if different from physical address): 416 Mary Lindsay Polk Drive, Ste 515

City: Franklin State: TN Zip: 37067

Telephone: 877-826-5488 Website: N/A

Licensing Company Email: compliance@cspmeds.com

Section 2: Personal Information

First: Christi Middle: Anne Last: Throneberry

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: 416 Mary Lindsay Polk Drive, Ste 515

City: Franklin State: TN Zip: 37067

Telephone: [redacted] Email: christi@cspmeds.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Cullman High School		08/1992-05/1996	
Address	City	State	Zip
510 13th Street NE	Cullman	AL	35055
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Samford University		Graduated 05/2002	
Address	City	State	Zip
800 Lakeshore Drive	Birmingham	AL	35229
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2024-present	[redacted]	Nashville	TN	[redacted]
From - To (MM/YY – MM/YY)		City	State	
2015-2024		Nashville	TN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Clinical Solutions Wholesale, LLC			2011-present	
Business Address		**City**	**State**	**Zip**
416 Mary Lindsay Polk Drive, Ste 519		Franklin	TN	37067
Phone	**Title**		**Number of Employed Hours**	
877-826-5488	Designated Representative		6,000+	
Description of Duties				
Manage the day-to-day operations of distribution and FDA repackaging. Hire, Train, and supervise staff. Develop policies. Ensure the GMP practices are followed. Ensure adherence to FDA, DEA & State regulations. Maintain proper licensure.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

4/25/2024
Date

I, Christi Throneberry, **certify that as the designated representative for**

Clinical Solutions Wholesale, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CT I am at least 21 years of age;
3. CT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christi Throneberry

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/25/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christi Throneberry

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/25/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Williamson

I, Christi Throneberry, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/25/2026

Date

Subscribed and Sworn to before me this 25th day of February 2026

Amanda Ray

Notary Public Signature

Amanda Ray
STATE OF TENNESSEE NOTARY PUBLIC
County of Williamson

(Seal)

Clinical Solutions Wholesale, LLC

Franklin, TN

Employee List

Employee Name
Christi Throneberry
Amanda Ramzy
Judie Summarell
Nina Onxayvieng
Johnathan Bell
Ferman Hasan
Dwight Isaac
Christal Jackson
Norah de Skipper
Andre'a Pardue

4GG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: enableCV, LLC

Physical Address: 6644 W 2100 S, Suite D

City: West Valley City State: UT Zip: 84128

Mailing Address (if different from physical address): 6967 S. River Gate Dr., Suite 104

City: Midvale State: UT Zip: 84047

Telephone: (817) 991-9215 Website: https://www.enablecv.com/

Name of Designated Representative (DR): Robert Lerma

Licensing Company Email: statelicenses@enableCV.com DR Email: Robert.Lerma@enableCV.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others: 3PLs, Clinics, Gov't		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Edwards Lifesciences, LLC

Address: One Edwards Way City: Irvine State: CA Zip: 92614

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): WSHP Cottonwood Buyer, LLC

Corporation/Organization Name: enableCV, LLC

Mailing Address: 6967 S. River Gate Dr., Suite 104

City: Midvale State: UT Zip: 84047

Telephone: (817) 991-9215 Email: statelicenses@enableCV.com

Contact Person Name: Jason Bailey

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

enableCV

Facility Name

Jason Bailey

Print Name of Authorized Person Submitting Application

Jason Bailey

Original signature of Authorized Person (copies or stamps not accepted)

11/18/25

Date

Board Use Only	Date Received: 12/22/25	Amount: $1000 - CK 38055888

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search ack To Searc Results

Establishment:
ENABLECV INC.
6967 S River Gate Dr. Ste 104
Midvale, UT 84047
Registration Number: 3031571797
FEI Number*: 3031571797
Status: Active
Date Of Registration Status: 2025

Owner/Operator:
EnableCV Inc.[6]
6967 S River Gate Dr. Ste 104
Midvale, UT US 84047
Owner/Operator Number: 10092279[7]

Official Correspondent:
Peter L Lindwall
6967 S River Gate Dr. Ste 104
Midvale, UT 84047
Phone: 1-949-7018980

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10092279&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10092279&OwnerOperatc

Page Last Updated: 11/03/2025

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
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Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of **Health & Human Services**

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10092279&OwnerOperatc

Name	Title
Rich Lunsford	Chief Executive Officer
Jason Bailey	Chief Financial Officer

Name	Percent Ownership
WSHP Cottonwood Buyer, LLC	100%

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ENABLECV, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SEVENTH DAY OF OCTOBER, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

7440624 8300

SR# 20254377584

Authentication: 205142510

Date: 10-27-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LICENSE

enableCV, LLC

EFFECTIVE
11/04/2025

EXPIRATION
05/04/2026

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

14255437-1710 Pharmacy - Class C

Manufacturer
Wholesaler

DBA:

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

ENABLECV, LLC
6644 WEST 2100 SOUTH, STE D
WEST VALLEY CITY UT 84128

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE
DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING
ACTIVE LICENSE

EFFECTIVE DATE: **11/04/2025**

EXPIRATION DATE: **05/04/2026**

ISSUED TO: **enableCV, LLC**
6644 West 2100 South, Ste D
West Valley City UT 84128

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

14255437-1710 **Pharmacy - Class C**

Manufacturer
Wholesaler

DBA:

Form #1

BOND NO. 810029274

RIDER

To be attached to and form a part of Bond No. 810029274

executed by ENABLECV, LLC, as Principal

and by ATLANTIC SPECIALTY INSURANCE COMPANY as Surety,

in favor of THE NEVADA STATE BOARD OF PHARMACY,

and effective as of November 18, 2025,

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing Principal Address Change

FROM: 6967 S River Gate Dr, 104, Midvale, Utah 84047-1574, United States

TO: 6644 W 2100 S., West Valley City, UT 84128

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated. This rider is effective on the 18th day of November, 2025.

Signed and sealed this 21st day of January, 2026.

ENABLECV, LLC

Principal

BY: Jason Z Bailey

ATLANTIC SPECIALTY INSURANCE COMPANY

Surety

BY: Kimberly G. Sherrod

Kimberly G. Sherrod Attorney-in-Fact

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Annmarie Breene, Babette Ward, Cathy H. Ho, Dana Donahue, Joanne C. Wagner, Kimberly G. Sherrod, Lori S. Shelton, Patricia A. Rambo, Patricia Dorsaneo, Patrick Breene, Sara Owens, Wayne G. McVaugh**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON D. NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2030

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 21st day of January, 2026.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2030

_____
Kara L.B. Barrow, Secretary

Please direct bond verifications to surety@intactinsurance.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 810029274

Application/License No. _____

enableCV, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 6967 S River Gate Dr, 104, Midvale, Utah 84047-1574, United States (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of New York (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One State Street Plaza, 31st Floor, New York, NY 10004 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on November 18, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 24th day of November, 2025.

APPLICANT/PRINCIPAL

enableCV, LLC

Authorized Representative

SURETY COMPANY

Atlantic Specialty Insurance Company

Surety Company's Representative

Sara Owens, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

Scott Kipper, Commissioner of Insurance

Non-Resident Producer

Qualification Effective Dates

Casualty 06/12/2019 Property 06/12/2019

SARA P OWENS

NPN: 16281042

100 N 18TH ST FL 16

PHILADELPHIA, PA 19103-2707

is authorized to transact business as described above

License No: 3447025 Issue Date: 06/12/2019 Expiration Date: 06/30/2028

Generated by Sircon 344307262

Nevada Division of Insurance

THIS IS TO CERTIFY THAT

SARA P OWENS

100 N 18TH ST FL 16

PHILADELPHIA, PA 19103-2707

LICENSE NUMBER: 3447025 NPN: 16281042

IS HEREBY AUTHORIZED TO TRANSACT BUSINESS IN ACCORDANCE TO THE LICENSE DESCRIPTION SHOWN BELOW:

Non-Resident Producer

Casualty, Property

Issue Date: 06/12/2019 Expiration Date: 06/30/2028

Generated by Sircon 344307262

intact INSURANCE

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Annmarie Breene, Babette Ward, Cathy H. Ho, Dana Donahue, Joanne C. Wagner, Kimberly G. Sherrod, Lori S. Shelton, Patricia A. Rambo, Patricia Dorsaneo, Patrick Breene, Sara Owens, Wayne G. McVaugh**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

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Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

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IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

THE GREAT SEAL OF THE STATE OF MINNESOTA
ALISON D. NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2030

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated twenty-fourth day of November, 2025.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

_____
Kara L.B. Barrow, Secretary

This Power of Attorney expires
January 31, 2030

intact specialty solutions

Atlantic Specialty Insurance Company

Period Ended 12/31/2024

Dollars displayed in thousands

Admitted Assets	
Investments	
Bonds	$ 2,884,084
Preferred Stocks	-
Common Stocks	987,702
Mortgage Loans	-
Real Estate	-
Contract Loans	-
Derivatives	-
Cash, Cash Equivalents & Short Term Investments	383,175
Other Investments	36,178
Total Cash & Investments	4,301,149
Premiums and Considerations Due	350,792
Reinsurance Recoverable	60,063
Receivable from Parent, Subsidiary or Affiliates	11,764
All Other Admitted Assets	94,008
Total Admitted Assets	4,817,776

Liabilities and Surplus	
Liabilities	
Loss Reserves	$ 1,264,802
Loss Adjustment Expense Reserves	423,323
Total Loss & LAE Reserves	1,688,125
Unearned Premium Reserve	811,551
Total Reinsurance Liabilities	64,571
Commissions, Other Expenses, and Taxes due	75,922
Derivatives	-
Payable to Parent, Subs or Affiliates	-
All Other Liabilities	1,121,125
Total Liabilities	3,761,294
Capital and Surplus	
Common Capital Stock	9,001
Preferred Capital Stock	-
Surplus Notes	-
Unassigned Surplus	476,697
Other Including Gross Contributed	570,784
Capital & Surplus	1,056,482
Total Liabilities and C&S	4,817,776

State of Minnesota
County of Hennepin

I, Kara Barrow, Secretary of Atlantic Specialty Insurance Company do hereby certify that the foregoing statement is a correct exhibit of the assets and liabilities of the said Company, on the 31st day of December, 2024, according to the best of my information, knowledge and belief.

Secretary

Subscribed and sworn to, before me, a Notary Public of the State of Minnesota on this 10th day of March, 2025.

Notary Public

KERRI RIECHERS
NOTARY PUBLIC
MINNESOTA
My Commission Expires Jan. 31, 2030

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 1/29/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Arthur J. Gallagher Risk Management Services, LLC 2850 Golf Rd Rolling Meadows IL 60008 License#: 0D69293	CONTACT NAME: Zaria Syfu PHONE (A/C, No, Ext): 630-285-3499 FAX (A/C, No): E-MAIL ADDRESS: Zaria_Syfu@ajg.com
INSURED enableCV, LLC 6967 S River Gate Dr, Ste 104 Midvale UT 84047 COTTHOL-02	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : National Fire Insurance Co of Hartford — 20478 INSURER B : Valley Forge Insurance Company — 20508 INSURER C : Continental Insurance Company — 35289 INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 670744859 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:	Y	Y	8033393312	12/18/2025	12/18/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 100,000 $ 15,000 $ 1,000,000 $ 2,000,000 $ Excluded $
B	AUTOMOBILE LIABILITY X ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			8033393293	12/18/2025	12/18/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ 1,000,000 $ $ $ $
C	X UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED [X] RETENTION $ $10,000	Y	Y	8033393309	12/18/2025	12/18/2026	EACH OCCURRENCE AGGREGATE $	$ 5,000,000 $ 5,000,000 $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A					PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: 6644 West 2100 South, Suite D, West Valley City, Utah, 84128

CheckerProp Utah 6620 West 2100 South, LLC and their lender(s) are shown as Additional Insureds solely with respect to the General Liability coverage as evidenced herein on a primary/non-contributory basis as required by written contract with respect to the premises leased by the Named Insured. NOTE: 10 Day Notice of Cancellation for nonpayment of premium and 30 Day Notice of Cancellation (other than for nonpayment of premium) applies.

CERTIFICATE HOLDER

CheckerProp Utah 6620 West 2100 South, LLC
380 Ocean Ave
Laguna Beach CA 92651

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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EVIDENCE OF COMMERCIAL PROPERTY INSURANCE

DATE (MM/DD/YYYY): 1/29/2026

THIS EVIDENCE OF COMMERCIAL PROPERTY INSURANCE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE ADDITIONAL INTEREST NAMED BELOW. THIS EVIDENCE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS EVIDENCE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE ADDITIONAL INTEREST.

PRODUCER NAME, CONTACT PERSON AND ADDRESS	PHONE (A/C, No, Ext):	COMPANY NAME AND ADDRESS	NAIC NO:
Arthur J. Gallagher Risk Management Services, LLC 2850 Golf Rd Rolling Meadows, IL 60008 License#: 0D69293	630-285-3499	National Fire Insurance Co of Hartford 333 South Wabash Avenue Chicago, IL 60604	20478
FAX (A/C, No):	E-MAIL ADDRESS: Zaria_Syfu@ajg.com	IF MULTIPLE COMPANIES, COMPLETE SEPARATE FORM FOR EACH	
CODE:	SUB CODE:	POLICY TYPE	
AGENCY CUSTOMER ID #: COTTHOL-02			
NAMED INSURED AND ADDRESS enableCV, LLC 6967 S River Gate Dr, Ste 104 Midvale UT 84047		LOAN NUMBER	POLICY NUMBER: 8033393312
		EFFECTIVE DATE: 12/18/2025	EXPIRATION DATE: 12/18/2026
		☐ CONTINUED UNTIL TERMINATED IF CHECKED	
ADDITIONAL NAMED INSURED(S)		THIS REPLACES PRIOR EVIDENCE DATED:	

PROPERTY INFORMATION (ACORD 101 may be attached if more space is required) ☐ BUILDING OR ☒ BUSINESS PERSONAL PROPERTY

LOCATION / DESCRIPTION

THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS EVIDENCE OF PROPERTY INSURANCE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

COVERAGE INFORMATION PERILS INSURED: BASIC ☐ BROAD ☐ SPECIAL ☒

COMMERCIAL PROPERTY COVERAGE AMOUNT OF INSURANCE: $ SEE BELOW — DED: $10,000

	YES	NO	N/A		
☒ BUSINESS INCOME ☐ RENTAL VALUE	X			If YES, LIMIT: SEE BELOW	Actual Loss Sustained; # of months:
BLANKET COVERAGE		X		If YES, indicate value(s) reported on property identified above: $	
TERRORISM COVERAGE	X			Attach Disclosure Notice / DEC	
IS THERE A TERRORISM-SPECIFIC EXCLUSION?		X			
IS DOMESTIC TERRORISM EXCLUDED?		X			
LIMITED FUNGUS COVERAGE	X			If YES, LIMIT: $50,000	DED: $10,000
FUNGUS EXCLUSION (If "YES", specify organization's form used)		X			
REPLACEMENT COST	X				
AGREED VALUE		X			
COINSURANCE		X		If YES, %	
EQUIPMENT BREAKDOWN (If Applicable)	X			If YES, LIMIT: Included	DED: $10,000
ORDINANCE OR LAW - Coverage for loss to undamaged portion of bldg	X			If YES, LIMIT: Included	DED: $10,000
- Demolition Costs	X			If YES, LIMIT: $500,000	DED: $10,000
- Incr. Cost of Construction	X			If YES, LIMIT: Included	DED: $10,000
EARTH MOVEMENT (If Applicable)	X			If YES, LIMIT: $5,000,000	DED: $50,000
FLOOD (If Applicable)	X			If YES, LIMIT: $5,000,000	DED: $50,000
WIND / HAIL INCL ☐ YES ☒ NO Subject to Different Provisions:			X	If YES, LIMIT:	DED:
NAMED STORM INCL ☐ YES ☒ NO Subject to Different Provisions:			X	If YES, LIMIT:	DED:
PERMISSION TO WAIVE SUBROGATION IN FAVOR OF MORTGAGE HOLDER PRIOR TO LOSS			X		

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

ADDITIONAL INTEREST

☐ CONTRACT OF SALE ☐ LENDER'S LOSS PAYABLE ☒ LOSS PAYEE ☐ MORTGAGEE

NAME AND ADDRESS

CheckerProp Utah 6620 West 2100 South, LLC
380 Ocean Ave
Laguna Beach, CA 92651
United States

LENDER SERVICING AGENT NAME AND ADDRESS

AUTHORIZED REPRESENTATIVE

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AGENCY CUSTOMER ID: _____

LOC #: _____

ADDITIONAL REMARKS SCHEDULE

AGENCY Arthur J. Gallagher Risk Management Services, LLC	NAMED INSURED enableCV, LLC 6967 S River Gate Dr, Ste 104 Midvale UT 84047
POLICY NUMBER 8033393312	
CARRIER National Fire Insurance Co of Hartford — NAIC CODE: 20478	EFFECTIVE DATE: 12/18/2025

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 28 **FORM TITLE:** EVIDENCE OF COMMERCIAL PROPERTY INSURANCE

REMARKS:

6967 S River Gate Dr, Suite 100 and 104, Midvale, UT 84047
Personal Property: $2,029,000
Business Income and Extra Expense - $450,000

6644 2100 S Fwy, Ste D, West Valley City, UT 84128
Personal Property: $12,600,000
Business Income and Extra Expense - $1,000,000

RE: 6644 West 2100 South, Suite D, West Valley City, Utah, 84128

CheckerProp Utah 6620 West 2100 South, LLC is shown as a Loss Payee solely with respect to property coverage as evidenced herein as required by written contract with respect to the above listed location leased by the Named Insured. NOTE: 10 Day Notice of Cancellation for nonpayment of premium and 30 Day Notice of Cancellation (other than for nonpayment of premium) applies.

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: enable CV, LLC — MDEG License # (if applicable): _____

Physical Address: 6644 W 2100 S, Suite D

City: West Valley City — State: UT — Zip: 84128

Mailing Address (if different from physical address): 6967 S. River Gate Dr., Suite 104

City: Midvale — State: UT — Zip: 84047

Telephone: (817) 991-9215 — Website: https://enablecv.com

Licensing Company Email: statelicenses@enableCV.com

Section 2: Personal Information

First: Robert — Middle: _____ — Last: Lerma

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: 6644 W 2100 S, Suite D

City: West Valley City — State: UT — Zip: 84128

Telephone: [redacted] — Email: Robert.Lerma@enableCV.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		N/A

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Moorpark High School		08/1990-05/1994	
Address	City	State	Zip
4500 Tierra Rejada Rd	Moorpark	CA	93021
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2021 - Present	[redacted]	Tooele	UT	
05/2023 - 10/2021	[redacted]	Tooele	UT	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
enableCV, LLC			02/2025–Present	
Business Address		**City**	**State**	**Zip**
6644 W 2100 S, Suite D		West Valley City	UT	84128
Phone	**Title**		**Number of Employed Hours**	
(817) 991-9215	Global Manager-Distribution		1,333	
Description of Duties				
Manage the facility and all day-to-day operations, including the employees.				

Business Name			From - To (MM/YY – MM/YY)	
Edwards Lifesciences, LLC			06/2017–02/2025	
Business Address		**City**	**State**	**Zip**
12050 Lone Peak Parkway		Draper	UT	84020
Phone	**Title**		**Number of Employed Hours**	
(801) 565-5200	Quality Assurance Superintendent		15,000	
Description of Duties				
Quality Assurance Superintendent (Management) overseeing all incoming QA inspection of raw materials for production. Managed a team of 77 employees over two shifts that included SEE, SNE, and HNE personnel.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
2000		CA		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
DUI				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

In 2000, Robert Lerma was convicted of a driving under the influence ("DUI") charge in California. He has not had any criminal history (including arrests, convictions, citations, or tickets of any kind) otherwise.

Given that twenty-five years have passed since this incident, Robert Lerma does not have and is unable to provide any related court documentation or specific details.

Original Signature (electronic, copies or stamps not accepted)

11-14-2025
Date

I, Robert Lerma, **certify that as the MDEG Administrator for**

enableCV, LLC,

that I (initial that you have read and meet the following requirements):

1. RL Have a high school diploma or its equivalent;
2. RL Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RL Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RL Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Lerma

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-14-2025

Date

Board Use Only	Date Received: 12/22/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: enableCV, LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 6644 W 2100 S, Suite D

City: West Valley City State: UT Zip: 84128

Mailing Address (if different from physical address): 6967 S. River Gate Dr., Suite 104

City: Midvale State: UT Zip: 84047

Telephone: (817) 991-9215 Website: https://www.enablecv.com/

Licensing Company Email: statelicenses@enableCV.com

Section 2: Personal Information

First: Robert Middle: Last: Lerma

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 6644 W 2100 S, Suite D

City: West Valley City State: UT Zip: 84128

Telephone: [redacted] Email: Robert.Lerma@enableCV.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		N/A

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Moorpark High School			08/1990-05/1994	
Address		City	State	Zip
4500 Tierra Rejada Rd		Moorpark	CA	93021
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2021 - Present	[redacted]	Tooele	UT	[redacted]
From - To (MM/YY – MM/YY)		City	State	
05/2013 - 10/2021		Tooele	UT	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
enableCV, LLC			02/2025–Present	
Business Address		**City**	**State**	**Zip**
6644 W 2100 S, Suite D		West Valley City	UT	84128
Phone	**Title**		**Number of Employed Hours**	
(817) 991-9215	Global Manager-Distribution		1,333	
Description of Duties				
Manage the facility and all day-to-day operations, including the employees.				

Business Name			From - To (MM/YY – MM/YY)	
Edwards Lifesciences, LLC			06/2017–02/2025	
Business Address		**City**	**State**	**Zip**
12050 Lone Peak Parkway		Draper	UT	84020
Phone	**Title**		**Number of Employed Hours**	
(801) 565-5200	Quality Assurance Superintendent		15,000	
Description of Duties				
Quality Assurance Superintendent (Management) overseeing all incoming QA inspection of raw materials for production. Managed a team of 77 employees over two shifts that included SEE, SNE, and HNE personnel.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Robert Lerma, **certify that as the designated representative for**

enableCV, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RL I am at least 21 years of age;
3. RL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Robert Lerma

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-22-26

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
2000		CA		
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge DUI				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity				

Provide explanation below:

In 2000, Robert Lerma was convicted of a driving under the influence ("DUI") charge in California. He has not had any criminal history (including arrests, convictions, citations, or tickets of any kind) otherwise.

Given that twenty-five years have passed since this incident, Robert Lerma does not have and is unable to provide any related court documentation or specific details.

Original Signature (electronic, copies or stamps not accepted)

11-14-2025
Date

I, Robert Lerma, **certify that as the designated representative for**

enableCV, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RL I am at least 21 years of age;
3. RL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Robert Lerma

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-14-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert LERMA

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-14-2025

Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Salt Lake City

I, Shilo Maxwell, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11-14-2025

Date

Subscribed and Sworn to before me this 14 day of November.

Shilo Maxwell

Notary Public Signature

SHILO MAXWELL
Notary Public State of Utah
My Commission Expires on:
February 09, 2027
Comm. Number: 729336

(Seal)

Attachment: Owner Personal History Application

enableCV is 100% wholly owned by WSHP Cottonwood Buyer, LLC rather than a natural person.

Attachment: List Containing Each Employee, Agent, IC, Consultant, Guardian, Personal Representative, Lender or Holder of Indebtedness to Applicant

Dannette Crooms - VP Quality Assurance Quality and Regulatory

Robert Lerma - Global Warehouse Distribution Manager

Vantha Klodt - Quality Assurance Specialist

Martha Baca - Senior Quality Assurance Specialist

Alisha Johnson - Warehouse Coordinator Distribution

Dylan Smith - Warehouse Coordinator Distribution

4HH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Sequel Med Tech, LLC

Physical Address: 50 Commercial Street, Floor 3

City: Manchester State: NH Zip: 03101

Mailing Address (if different from physical address): 50 Commercial Street, Floor 3

City: Manchester State: NH Zip: 03101

Telephone: 877-489-4478 Website: https://sequelmedtech.com/

Name of Designated Representative (DR): Simona Jantz

Licensing Company Email: statelicensing@sequelmedtech.com DR Email: sjantz@sequelmedtech.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☒ Others: Virtual manufacturer

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attached

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Sequel OpCo LLC

Corporation/Organization Name: Sequel Med Tech, LLC

Mailing Address: 50 Commercial Street, Floor 3

City: Manchester State: NH Zip: 03101

Telephone: 888-673-7835 Email: dmcaloon@sequelmedtech.com

Contact Person Name: David McAloon

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Sequel Med Tech, LLC

Facility Name

Alan Lotvin, MD

Print Name of Authorized Person Submitting Application

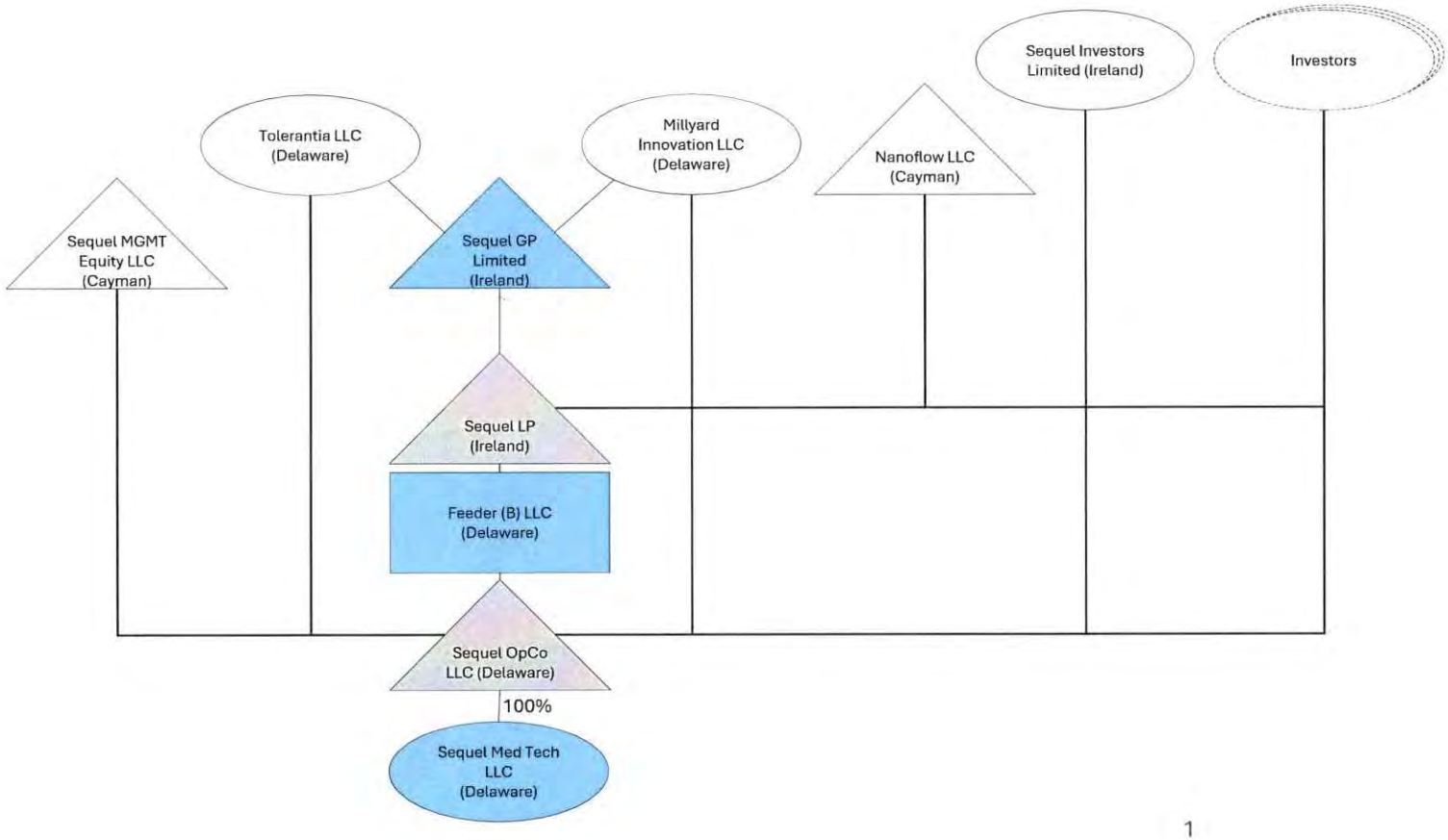
Original signature of Authorized Person (copies or stamps not accepted)

30 May 2025

Date

Board Use Only	Date Received: 9/2/25	Amount: $1000 ck 4289

Sequel Structure Chart



1

Company Information

Company Name: Sequel Med Tech, LLC
Address: 50 Commercial Street, Floor 3
City, State, Zip: Manchester, NH 03101
Phone: 877-489-4478
Website: https://sequelmedtech.com/
E-mail: statelicensing@sequelmedtech.com

[redacted]
State of Formation: Delaware
Date Incorporated: 06/26/2023
File Number: 7526891

Ownership Information

Sequel Med Tech, LLC is 100% owned by Sequel LP.

Parent Company Address: 110 East 59th Street, Suite 2800, New York, NY 10022
Parent Company Phone: 212-883-2274
Parent Company FEIN: 98-1651605

Officer

Alan Lotvin, MD, Chief Executive Officer & Co-Founder
Business Address: 50 Commercial Street, Floor 3, Manchester, NH 03101
Phone: [redacted]
Ownership %: 0%

Sequel

Description of Operations

Sequel Med Tech LLC (Sequel) is a Virtual Manufacturer of Rx medical devices with no drug component. DEKA Research & Development (DEKA) is the innovator and owner of the 510(k). DEKA has a contractual agreement with Millyard Advanced Medical Products LLC (Millyard) for the rights to manufacture the product. Millyard, acting as a virtual manufacturer, has a contractual agreement with Merrimack Manufacturing LLC to physically manufacture the product. Sequel has a contractual agreement with Millyard for the rights to market and distribute the product with Sequel on the product label.

Sequel's product will be distributed to Wholesalers by their Third-Party Logistics Provider, Cardinal Health 105 LLC dba Specialty Pharmaceutical , who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer Information:
The following contract manufacturer will produce our product:

Merrimack Manufacturing LLC
540 Commercial Street, STE 100
Manchester, NH 03101
FDA Establishment Number: 3015192982

Contact Person: Blake W Hughlock
Contact Number: 603-703-2302

Merrimack Manufacturing LLC manufactures Sequel's product and packages finished product. At no time does Merrimack Manufacturing LLC own the product, contract with Sequel's customers, invoice, nor sell a Sequel product. Sequel's products are not Controlled Substances.

Third Party Logistic information:
For distribution into the commercial supply channels, Cardinal Health 105 LLC dba Specialty Pharmaceutical acts as Sequel's Third Party Logistics (3PL) provider to manage the storage and distribution of Sequel's product throughout the United States. Cardinal Health 105 LLC dba Specialty Pharmaceutical Services' address is:

Cardinal Health 105 LLC dba Specialty Pharmaceutical
501 Mason Road, Suite 200, LaVergne TN 37086

Jason Cook, 615-213-1321

Sequel's hours of operation are 8:30 am – 5:30pm Monday through Friday.

Sequel's facility is 9580 square feet.

Sequel's records are stored at Cardinal SPS.

Sequel Med Tech, LLC has 42 employees.

Sequel

Product List

Twiist AID (automated insulin delivery system) Starter Kit

Twiist AID Refill Kit #1

Twiist AID Refill Kit #2

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SEQUEL MED TECH, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF MAY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SEQUEL MED TECH, LLC" WAS FORMED ON THE TWENTY-SIXTH DAY OF JUNE, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203644253

Date: 05-08-25

7526891 8300

SR# 20252128777

You may verify this certificate online at corp.delaware.gov/authver.shtml



nh.gov Licensing Home

Person Information

DBA: Sequel Med Tech, LLC
Name: Sequel LP

Address

Line 1: 50 Commercial Street
Line 2: Floor 3
City: Manchester
County: Hillsborough
Zip: 03101
State: NH

License Information

Profession: Pharmacy
License No: 07981
License Type: MAN/DIST/WHOLE/BROKER
License Status: Active
Issue Date: 1/29/2024
Expiration Date: 1/29/2028

No Related Documents

Board Disciplinary Documents (If Licensee Disciplined)

Disclaimer: The New Hampshire Office of Professional Licensure and Certification considers the information contained in this website to constitute primary source verification. The information viewed here is reflective of current records in our licensing database.

NH.Gov | Privacy Policy | Accessibility Policy | Contact Us Form

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 12/4/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Arthur J. Gallagher Risk Management Services, LLC 300 Madison Avenue, 28th Floor New York NY 10017	CONTACT NAME: PHONE (A/C, No, Ext): 212-994-7100 FAX (A/C, No): 212-994-7047 E-MAIL ADDRESS:
INSURED SEQUMED-03 Sequel Med Tech, LLC 50 Commercial Street, 3rd Floor Manchester NH 03101	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Federal Insurance Company — 20281 INSURER B : Atlantic Specialty Insurance Company — 27154 INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 1720594462 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY			711-01-82-67-0001	12/1/2025	12/1/2026	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 15,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	X POLICY [ ] PRO-JECT [ ] LOC						PRODUCTS - COMP/OP AGG	$ Excluded
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory In NH)	N/A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Products Liability Claims-Made Coverage			36086644	12/1/2025	12/1/2026	Occurrence/ Aggregate	$10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Errors & Omissions
Carrier: Federal Insurance Company
Policy # 36086644
Effective/Expiration Dates: 12/1/2025 - 12/1/2026
Limit: $1,000,000

CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 800024437

Application/License No. _____

Sequel Med Tech, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 50 Commercial Street, Manchester NH 03101 Floor 3 (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of New York (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 605 Highway 169 North, Suite 900, Plymouth. MN 55441 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 22, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 22nd day of July, 2025.

APPLICANT/PRINCIPAL
Sequel Med Tech, LLC

Authorized Representative

SURETY COMPANY
Atlantic Specialty Insurance Company

Surety Company's Representative

Jaymie P. Columbus, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Kayley Klinkel

Witness Kimberly A. Ritchie

Countersigned by:

N/A
Nevada Resident Agent

SURETY

STATE OF NEW YORK
COUNTY OF ALBANY } ss

I, Kayley Klinkel Notary Public of Schenectady County, in the State of New York do hereby certify that Jaymie P. Columbus Attorney-in-Fact, of the Atlantic Specialty Insurance Company, who is personally known to me to be the same person whose name is subscribed to the foregoing instrument, appeared before me this day in person, and acknowledged that he/she signed, sealed and delivered said instrument, for and on behalf of the Atlantic Specialty Insurance Company, for the uses and purposes therein set forth.

Given under my hand and notarial seal at my office in the City of Latham in said County, this 22nd day of July, A.D. 2025.

Notary Public

Kayley Klinkel
Notary Public, State of New York
Reg. No. 01KL0014828
Qualified in Schenectady County
Commission Expires 10/24/2027

intact INSURANCE specialty solutions

Atlantic Specialty Insurance Company

Period Ended 12/31/2023

Dollars displayed in thousands

Admitted Assets	
Investments:	
Bonds	$ 2,666,141
Preferred Stocks	-
Common Stocks	765,847
Mortgage Loans	-
Real Estate	-
Contract Loans	-
Derivatives	-
Cash, Cash Equivalents & Short Term Investments	194,124
Other Investments	9,571
Total Cash & Investments	3,635,684
Premiums and Considerations Due	338,312
Reinsurance Recoverable	127,403
Receivable from Parent, Subsidiary or Affiliates	17,691
All Other Admitted Assets	93,457
Total Admitted Assets	4,212,546

Liabilities and Surplus	
Liabilities	
Loss Reserves	$ 1,191,377
Loss Adjustment Expense Reserves	401,505
Total Loss & LAE Reserves	1,592,881
Unearned Premium Reserve	806,718
Total Reinsurance Liabilities	45,997
Commissions, Other Expenses, and Taxes due	78,425
Derivatives	-
Payable to Parent, Subs or Affiliates	-
All Other Liabilities	810,774
Total Liabilities	3,334,795
Capital and Surplus	
Common Capital Stock	9,001
Preferred Capital Stock	-
Surplus Notes	-
Unassigned Surplus	251,805
Other Including Gross Contributed	616,946
Capital & Surplus	877,751
Total Liabilities and C&S	4,212,546

State of Minnesota
County of Hennepin

I, Kara Barrow, Secretary of Atlantic Specialty Insurance Company do hereby certify that the foregoing statement is a correct exhibit of the assets and liabilities of the said Company, on the 31st day of December, 2023, according to the best of my information, knowledge and belief.

Secretary

Subscribed and sworn to, before me, a Notary Public of the State of Minnesota on this 19th day of March, 2024.

Notary Public

KERRI RIECHERS
Notary Public
Minnesota
My Commission Expires January 31, 2025

intact INSURANCE

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Jaymie P. Columbus, Kimberly A. Ritchie**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON D. NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2030

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 22nd day of July, 2025.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2030

_____
Kara L.B. Barrow, Secretary

Please direct bond verifications to surety@intactinsurance.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Sequel Med Tech, LLC — MDEG License # (if applicable): _____

Physical Address: 50 Commercial Street, Floor 3

City: Manchester — State: NH — Zip: 03101

Mailing Address (if different from physical address): 50 Commercial Street, Floor 3

City: Manchester — State: NH — Zip: 03101

Telephone: 877-489-4478 — Website: https://sequelmedtech.com/

Licensing Company Email: statelicensing@sequelmedtech.com

Section 2: Personal Information

First: Simona — Middle: _____ — Last: Jantz

Alias(es, nicknames, name changes, etc.): Simona Markovik

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X

Mailing Address: 50 Commercial Street, Floor 3

City: Manchester — State: NH — Zip: 03101

Telephone: 877-489-4478 — Email: statelicensing@sequelmedtech.com

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		x

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)		
Queens University	09/2009 - 06/2013		
Address	**City**	**State**	**Zip**
99 University Ave	Kingston	ON	K7L 3N6
Diploma/Degree obtained, if any			
Masters of Science, Neuroscience			
School Name	**From - To (MM/YY – MM/YY)**		
York University	09/2004-06/2008		
Address	**City**	**State**	**Zip**
4700 Keele St	North York	ON	M3J 1P3
Diploma/Degree obtained, if any			
High School Diploma			
School Name	**From - To (MM/YY – MM/YY)**		
Ljupco Santov	09/1998 - 05/2002		
Address	**City**	**State**	**Zip**
	Kocani	North Macedonia	
Diploma/Degree obtained, if any			
High School Diploma			
School Name	**From - To (MM/YY – MM/YY)**		
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name	**From - To (MM/YY – MM/YY**		
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/07/2023 Current	[redacted]	Merrimack	NH	[redacted]
01/28/202 02/07/202	[redacted]	Ayer	MA	
02/01/2020 01/28/202	[redacted]	Westford	MA	
05/18/2018 02/01/20	[redacted]	Acton	MA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Sequel Med Tech, LLC			From - To (MM/YY – MM/YY): 08/2023 - Present
Business Address: 50 Commercial Street, Floor 3	City: Manchester	State: NH	Zip: 03101
Phone: 877-489-4478	Title: VP, Quality	Number of Employed Hours: 3840	
Description of Duties: See attached resume			

Business Name: Getinge - Atrium Medical			From - To (MM/YY – MM/YY): 03/2022-08/2023
Business Address: 40 Continental Blvd	City: Merrimack	State: NH	Zip: 03054
Phone: 603-880-1433	Title: Head of Quality, Director of Quality, Regulatory and	Number of Employed Hours: 6400	
Description of Duties: See attached resume			

Business Name: Insulet Corporation			From - To (MM/YY – MM/YY): 06/2020-03/2022
Business Address: 100 Nagog Park	City: Acton	State: MA	Zip: 01720
Phone: 978-600-7000	Title: Sr. Continuous Improvement Manager	Number of Employed Hours: 3680	
Description of Duties: See attached resume			

Business Name: Insulet Corporation			From - To (MM/YY – MM/YY): 04/2018-08/2023
Business Address: 100 Nagog Park	City: Acton	State: MA	Zip: 01720
Phone: 978-600-7000	Title: Sr. QA Plant Manager, USA Operations	Number of Employed Hours: 3840	
Description of Duties: See attached resume			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:	Number of Employed Hours:	
Description of Duties:			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		x
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		x

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Simona Jantz, **certify that as the MDEG Administrator for**

Sequel Med Tech, LLC,

that I (initial that you have read and meet the following requirements):

1. SJ Have a high school diploma or its equivalent;
2. SJ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SJ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SJ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Simona Jantz

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/26/2025

Date

Board Use Only	Date Received: 9/2/25

Simona Jantz

[redacted]

EXPERIENCE

Sequel Med Tech

Head of Quality, Vice President, Quality, Manchester, NH August 2023 – Present

- Built Sequel's Quality function from the ground up — architected and launched a company-wide QMS that was fully operational within 12 months.
- Defined the strategic vision for Quality, translating it into scalable systems, processes, and tools that enabled rapid growth and compliance.
- Instilled a proactive quality mindset across the organization, shifting the culture from reactive compliance to strategic, quality-first thinking.
- Drove the evaluation and implementation of enterprise platforms to support digital QMS transformation and long-term scalability.
- Acted as a trusted partner to internal stakeholders and external collaborators, aligning quality practices across the product and partner ecosystem.

GETINGE – Atrium Medical

Head of Quality, Director of Quality, Regulatory and Compliance, Merrimack, NH March 2022 – August 2023

- Accountable for the Quality, Regulatory and compliance for Vascular Systems for Getinge
- Management Representative for the FDA
- Person Responsible for Regulatory Compliance (PRRC) for EU Medical Device Regulation
- Responsible for managing a team of 70+ employees (directors, managers and engineers) across 8 departments of Quality Operations, Design Quality Assurance, Regulatory, Supplier Quality, Compliance, Complaints, Training and Continuous Improvement.
- Set the Vision for the site and developed a 3-year quality strategy.
- In charge of Remediation Strategy for the site to facilitate with Consent Decree exit strategy and activities.
- Developed and implemented best practices for elements from the entire lifecycle of the product (improved operational efficiency by reducing engineering efforts by 56% and reducing turn-around time for non-conformance paperwork by 63%).
- Successfully remediated the areas of Non-conformances for the site in less than 12 months (95% reduction in backlog), while developing a state-of-the-art method, that is currently being shared as best practice with 150+ individuals across global Getinge sites.
- In the process of developing a program for the organization to improve Root Cause Analysis while moving the organization towards Data Based Decision making process (rolling out training of 200+ employees on Statistical Methods and Problem Solving).
- Act as a change management agent while influencing the quality culture for the entire site of 500+ employees by embedding the quality culture within the organization as a proactive element and way of working.
- Addressed staff issues at all levels to improve overall moral and work performance while supporting the needs of the senior stakeholders and board of directors.

Insulet Corporation

Sr. Continuous Improvement Manager, Acton, MA June 2020 – March 2022

- Accountable for driving Continuous Improvement initiatives across the organization.
- Key Player in establishing the Operational Excellence department for Insulet.
- Completed Training of first waves of Lean Program for the organization
- Established Lean Training Roadmap and playbook for the organization.
- Acted as a SME in Six Sigma and Lean methodologies. Mentored 30+ Lean Candidates across the organization
- Established Lean/Project Management Playbook for the organization
- Contributed to 3.1 million dollars savings for the organization within one year.

Sr. QA Plant Manager, USA Operations, Acton, MA April 2018 –June 2020

- Accountable for operations quality strategy, buildout, and scale-up of a $200MM greenfield manufacturing facility (13,000 sf ft ISO 8 class Cleanroom) in Acton, MA.
- Validated twelve (12) fully automated and state-of-the-art custom production cells including nearly three hundred (300) transformation stations and thirty (30) vision systems in under six (6) months.

- Hired and trained the first phase of employees (50 + personnel) to support 24/5 operations in under 11 months exceeding goal of 17 months.
- Established the Incoming, In-Process and Outgoing Inspection for components, subassemblies and finished product for the Manufacturing Process. Implemented highly efficient valid Statistical Sampling Plans for Components at Incoming Inspection (ANSI Z1.4-2003 and Z1.9)
- Expanded the existing QMS systems from a contract manufacturing structure to direct manufacturer.
- Supported Operations to achieve 106% of target volume expectations in the first two months of production through the implementation of effective quality metrics, key performance indicators and performance scorecards.
- Extensive decision-making experience in change management, 21 CFR 820 quality management systems, CAPA (corrective and preventative action), personnel and conflict resolution, market health hazard assessments and process validations.
- Acted as the FDA representative for the manufacturing site.

Quality Engineering Manager, Global Supplier Quality, Billerica, MA June 2016 – April 2018

- Established and managed a highly effective and compliant world class Supplier Quality Program for the organization
- Developed and managed Statistical Techniques training program for the entire organization (1000+ employees)
- Led the Supplier Audits for the organization by performing 50+ audits per year
- Oversaw the incoming inspection process at the CM to collaboratively resolve issues and drive improvements with suppliers
- Drove continues improvement for incoming parts/materials – Sampling Plans, Visual Aids, Supplier CAPA, Non-Conformances
- Collaborated with Supplier Engineering and raised the bar for supplier qualifications through application of statistical methods to improve supplier performance, productivity, and equipment validation practices (Cpk/Ppk, SPC, Sampling Plans, TMV)

Medtronic (formerly known as Covidien)

Quality Manager, Global (9 locations across North America) July 2015 – June 2016

- Managed the activities of the supplier quality program for 9 manufacturing plants by prioritizing objectives, developing project plans, assembling the necessary resources, executing supplier selection, evaluation, audits, qualification and monitoring activities and regular assessing the team's progress to improve quality and customer satisfaction
- Directly supported 9 Quality Engineers and 9 Plant Quality Managers with supply chain activities
- Analyzed supplier process capability and made recommendations for improvements/ corrective actions
- Developed and implemented continuous improvement projects of supplier quality
- responsibility for compliance to 21 CFR 820 and ISO 13485.
- Significantly Improved Key Performance Indicators for Supplier Quality activities for 9 manufacturing sites within one year

Operations Quality Engineer, Gananoque, ON Canada August 2013 – July 2015

- Managed manufacturing site supplier quality related activities: supplier CAPAs, external audits, internal audits, supplier evaluation and approval, supplier risk assessment, supplier audit schedule, non-conformities, supplier quality agreements, supplier performance, customer complaints, process and test method validations.
- Supported Class III product transition – plant readiness activities for the new AED PMA requirements
- Demonstrated 72% improvement of RM Non-conformities (NCR) Turn-Around-Time (TAT), 57% reduction of RM NCRs raised at manufacturing site; demonstrated 45% drop in the complaint rate overall, and 75% drop in confirmed complaints within one year

Quality Engineer, In-Process Manufacturing, Gananoque, ON Canada May 2012 – August 2013

- Developed Non-Conforming process for a manufacturing site and deployed as best practice to other manufacturing sites.
- Significantly improved (73%) TAT for departmental finished product NCRs (<30 days).
- Reduced Overdue Supplier related actions (both external and internal) by 60%.

EDUCATION/TRAINING

Masters of Science, Neuroscience, Summa Cum Laude, Queen's University
Bachelor of Science, Neuroscience, Cum Laude, York University
DMAIC Six Sigma Green Belt, Medtronic
Six sigma black belt professional – MSI
Six sigma lean professional - MSI
Sampling Plans - Subject Matter Expertise – Covidien
External/Internal Lead Auditor – Covidien
Project Management – Alison/Covidien

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Sequel Med Tech, LLC

Pharmacy/Wholesaler License # (if applicable) Pending

Physical Address 50 Commercial Street, Floor 3

City Manchester State NH Zip 03101

Mailing Address (if different from physical address) 50 Commercial Street, Floor 3

City Manchester State NH Zip 03101

Telephone 877-489-4478 Website https://sequelmedtech.com/

Licensing Company Email statelicensing@sequelmedtech.com

Section 2: Personal Information

First Simona Middle _____ Last Jantz

Alias(es, nicknames, name changes, etc.) Simona Markovik

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 50 Commercial Street, Floor 3

City Manchester State NH Zip 03101

Telephone 978-435-5858 Email sjantz@sequelmedtech.com

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	Not Applicable	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Queens University		09/2009 - 06/2013	
Address	**City**	**State**	**Zip**
99 University Ave	Kingston	Ontario	K7L 3N6
Diploma/Degree obtained, if any			
Masters of Science, Neuroscience			

School Name		From - To (MM/YY – MM/YY)	
York University		09/2004 - 06/2008	
Address	**City**	**State**	**Zip**
4700 Keele St	North York	ON	M3J 1P3
Diploma/Degree obtained, if any			
Bachelor of Science, Neuroscience			

School Name		From - To (MM/YY – MM/YY)	
Ljupco Santov		09/1998 - 05/2002	
Address	**City**	**State**	**Zip**
Kocani	North Macedonia		
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2023 - Present	[redacted]	Merrimack	NH	[redacted]
01/21-02/23		Ayer	MA	
02/20-01/21		Westford	MA	
05/18-02/20		611 Old Stone Br.	MA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Sequel Med Tech, LLC			08/2023 - Present
Business Address	**City**	**State**	**Zip**
50 Commercial Street, Floor 3	Manchester	NH	03101
Phone	**Title**		**Number of Employed Hours**
877-489-4478	VP, Quality		3840
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Getinge - Atrium Medical			03/2022 - 08/2023
Business Address	**City**	**State**	**Zip**
40 Continental Blvd	Merrimack	NH	03054
Phone	**Title**		**Number of Employed Hours**
603-880-1433	Head of Quality, Director of Quality, Regulatory and		2880
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Insulet Corporation			06/2020 - 03/2022
Business Address	**City**	**State**	**Zip**
100 Nagog Park	Acton	MA	01720
Phone	**Title**		**Number of Employed Hours**
978-600-7000	Sr. Continuous Improvement Manager		3680
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Insulet Corporation			04/2018 - 06/2020
Business Address	**City**	**State**	**Zip**
100 Nagog Park	Acton	MA	01720
Phone	**Title**		**Number of Employed Hours**
978-600-7000	Sr. QA Plant Manager, USA Operations		3840
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		x
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Simona Jantz, **certify that as the designated representative for**

Sequel Med Tech, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SJ I am at least 21 years of age;
3. SJ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SJ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SJ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SJ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SJ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Simona Jantz

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

30-MAY-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Simona Jantz

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

30-MAY-2025

Date

Please have this section completed in the presence of a Notary Public.

State of New Hampshire, ss. County of Hillsborough

I, Simona Jantz, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

30-MAY-2025

Date

Subscribed and Sworn to before me this 30th day of May.

Notary Public Signature

XIOMAYRI C. PINA
NOTARY PUBLIC
EXP. 12/18/2029
NEW HAMPSHIRE

(Seal)

Last Name	Preferred/First Name
Zhou	Stella
Jantz	Simona
Leblanc	Jennifer
Logan	Erica
Murphy	Christopher
Wells	Jim
Reilly	Jeremiah
Tayebi	Dalia
Ross	Emily
Gong	Hoyt
Bennett	Keith
Sueltenfuss	Patrick
Gilbert	Christopher
Kleiner	Jessica
Reinitz	Steve
Babcock	Robin
Enman	David
Higgins	Jake
Goodrich	Hannah
Balch	RJ
Martin	Nicole
Lewis	Tristan
Whitton	Laura
Lavoie	Evan
Mooney	Chuck
White	Kristi
Sherman	Chip
Sprague	Susan
Roy	Derek
Schrempf	Kerensa
Spencer	Michael
Romeo	Eric
Callahan	Kristen
Munroe	Mike
Bennett	Heather
O'Neill	Don
McKoy	Matt

O'Brien	Mandy
Dickerson	Pearl
Patel	Nitaben
Kheav	Linda
Dacey	Kristi
Demers	Karen
Simmons	Rob
Detcher	Jean-Marie
Lynch	Joanne
Haskell	Justin
Venkatesan	Ashwin
Beaulieu	Jim
Dickens	Genesis
Trimble	Fredrick
LaMothe	Greg
Ridge	Ryan
Bellomo	Noah
Thomas	Jonathan
Smith	Riley
Pina	Xio

411

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Birdi, Inc.

Physical Address: 43811 Plymouth Oaks Blvd. Ste 100

City: Plymouth, State: MI Zip: 48170

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Name of Designated Representative (DR): Peter fleck

Licensing Company Email: _____ DR Email: _____

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others: Distribution

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A



Original Signature (electronic, copies or stamps not accepted)

9/25/2025

Date

Birdi, Inc has not begun wholesale distribution activities as of the date of this application. However, below is listed the supplier we intend to do business with.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Teva Pharmaceuticals USA, Inc.
Address: 1090 Horsham Rd. City: North Whales State: PA Zip: 19454

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): MI Equity Holdings, LLC
Corporation/Organization Name: Birdi, Inc.
Mailing Address: 43811 Plymouth Oaks Blvd. Ste 100
City: Plymouth State: MI Zip: 48170
Telephone: 888-678-7790 Email: Licensing@BirdiWholesale.com
Contact Person Name: Peter Fleck

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. Michigan only provides license Verifications	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/ Birdi, INC is 100% owned by a business, MI Equity Holdings LLC		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Birdi, Inc.

Facility Name

Aaron Roberts

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9/25/2025

Date

Board Use Only	Date Received: 10/8/25	Amount: $ Waived

CORPORATE OFFICE
43811 Plymouth Oaks Blvd Ste. 100
Plymouth, MI 48170

Current Officers and Board of Directors

- **Aaron Roberts,** President
- **James Gollaher,** Treasurer
- **Stephen Howe,** Director
- **Frederick Howe,** Director

CORPORATE OFFICE
43811 Plymouth Oaks Blvd Ste. 100
Plymouth, MI 48170

Corporate Officers & Ownership Information

Name	Role	Title	Address	Ownership %
Aaron Roberts [redacted]	Director & Officer	President & Treasurer	[redacted]	0%
James Gollaher [redacted]	Director & Officer	CFO & Secretary	[redacted]	0%

Birdi, Inc. is wholly (100%) owned by:
MI Equity Holdings, LLC
[redacted]
10181 Scripps Gateway, Cr.
Sandiego, CA 92131

Phone: 858-566-2727

State of Incorporation: Delaware

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BIRDI, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF JULY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

4538652 8300

SR# 20253332376

Authentication: 204169580

Date: 07-11-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

5306008304APP25

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

BIRDI, INC.
43811 PLYMOUTH OAKS BLVD
SUITE 100
PLYMOUTH, MI 48170

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR LICENSE

BIRDI, INC.
43811 PLYMOUTH OAKS BLVD
SUITE 100
PLYMOUTH, MI 48170

LICENSE NO.
5306008304

EXPIRATION DATE
08/12/2027

25224100813

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

GRETCHEN WHITMER
GOVERNOR

MARLON I. BROWN, DPA
DIRECTOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

VERIFICATION OF LICENSURE

MICHIGAN BOARD OF PHARMACY

VERIFICATION OF LICENSURE AS OF 08/12/2025

NAME: **Birdi, Inc.**
ADDRESS: 43811 Plymouth Oaks Blvd
Suite 100
Plymouth, MI 48170

STATUS: Active

LICENSE TYPE: Wholesale Distributor License

LICENSE NUMBER: 530600B304

ORIGINAL DATE: 08/12/2025
EXPIRATION DATE: 08/12/2027
SPECIALTY:
None

EXAM DATE	EXAM TYPE	EXAM RESULTS
	None	

OPEN FORMAL COMPLAINTS

No

DISCIPLINARY ACTION	START DATE	END DATE
None		

Brian DeBano, Division Director
Bureau of Professional Licensing
Licensing Division
(517) 241-0199

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 72BSBJD5076

Application/License No. _____

BIRDI, INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 43811 Plymouth Oaks Blvd., Ste. 100 Plymouth, MI 48170 (Address of Applicant/Principal), as PRINCIPAL, and HARTFORD FIRE INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Hartford Plaza Hartford, CT 06155 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 1, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 19th day of September, 2025.

APPLICANT/PRINCIPAL
BIRDI, INC.

COMPANY

Authorized Representative

SURETY
HARTFORD FIRE INSURANCE COMPANY

Surety Company's Representative

Vanessa Fong, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Meghan Curry

Witness Sam Russell

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT

A Notary Public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los Angeles

On SEP 19 2025 before me, Becky Gomez, Notary Public, personally appeared Vanessa Fong who proved to me on the basis of satisfactory evidence to be the person~~(s)~~ whose name~~(s)~~ is/~~are~~ subscribed to the within instrument and acknowledged to me that ~~he~~/she/~~they~~ executed the same in ~~his~~/her/~~their~~ authorized capacity~~(ies)~~, and that by ~~his~~/her/~~their~~ signature~~(s)~~ on the instrument the person~~(s)~~, or the entity upon behalf of which the person~~(s)~~ acted, executed the instrument.

BECKY GOMEZ
Notary Public - California
Orange County
Commission # 2455974
My Comm. Expires Jul 30, 2027

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature _____
Signature of Notary Public

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: AON RISK INS SERVICES WEST INC
Agency Code: 72-254300

- ☒ **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- ☒ **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- ☒ **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- ☐ **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, ***up to the amount of*** Unlimited :
Rosa E. Rivas of Irvine CA, Tracy Aston, Meghan Curry , Vanessa Fong, Samantha Russell, Mary L. Yohnke of LOS ANGELES, California

their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of September 19, 2025 .

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

Revised: July 31, 2024

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Birdi, Inc.

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 43811 Plymouth Oaks Blvd. Ste 100

City Plymouth, State MI Zip 48170

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 888-678-7790 Website BirdiWholesale.com

Licensing Company Email Licensing@BirdiWholesale.com

Section 2: Personal Information

First Peter Middle Duff Last Fleck

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Royal Oak State MI Zip [redacted]

Telephone [redacted] Email Peter.Fleck@BirdiRx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Michigan State Univerity		09/2022-05/2027	
Address	**City**	**State**	**Zip**
220 Trowbridge Rd	East Lansing	MI	48824
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
University of Michigan College of Pharmacy		09/2007-06/2011	
Address	**City**	**State**	**Zip**
428 Church St	Ann Arbor	MI	48109
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2015-Present	[redacted]	Royal Oak	MI	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Birdi, Inc.			11/2015-current	
Business Address		**City**	**State**	**Zip**
43811 43811 Plymouth Oaks Blvd.		Plymouth	MI	48170
Phone	**Title**		**Number of Employed Hours**	
888-678-7790	Sr. Director of Pharmacy		15,600	
Description of Duties				
Oversee all pharmacy operations, including regulatory compliance, licensing, distribution, and quality assurance. Provide strategic leadership for clinical, retail, and pharmacy services. Develop policies and drive operational efficiency.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N/A	

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Peter Fleck, **certify that as the designated representative for**

Birdi, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PF I am at least 21 years of age;
3. PF I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PF I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PF I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PF I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PF I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Peter Fleck

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10-2-25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Peter Flecle

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10-2-25

Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Wayne

I, Peter Flecle, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10-2-25

Date

Subscribed and Sworn to before me this 2nd day of October.

Notary Public Signature

NATALIE BATES
NOTARY PUBLIC - STATE OF MICHIGAN
COUNTY OF WAYNE
MY COMMISSION EXPIRES DEC 13, 2031
ACTING IN THE COUNTY OF Wayne

(Seal)

CORPORATE OFFICE
43811 Plymouth Oaks Blvd Ste. 100
Plymouth, MI 48170

Full Employee List

- Doug Massey
- Sherry Yanez-Gregor
- Peter Fleck
- Denise Rodriguez
- Daniel Welch
- Janiris Steele
- Ophelia Barkus
- Heather Hollenbeck
- Heather Johnson

4JJ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☒ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Klutch Cargo LLC

Physical Address: 300 N OAKley BLVD

City: Chicago State: IL Zip: 60612

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 708-370-2301 Website: www.klutchcargo.com

Name of Designated Representative (DR): Ronald A. Tucci JR.

Licensing Company Email: rtucci@klutchcargo.com DR Email: _____

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☒ Warehouse
☒ Veterinarians		☒ Retail pharmacy wholesale distributor
☒ Others: API		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

8-1-25
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A New wholesaler Have not sold any · Address: _____ City: _____ State: _____ Zip: _____

Name: _____ Address: _____ City: _____ State: _____ Zip: _____

Name: _____ Address: _____ City: _____ State: _____ Zip: _____

Name: _____ Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: Klutch Cargo LLC.

Mailing Address: 300 N Oakley Blvd

City: Chicago State: IL Zip: 60612

Telephone: 206-370-2301 Email: rtucci@klutchcargo.com.

Contact Person Name: Ron Tucci

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		X
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• List of all Officers and Directors.	✓	✓		
• List the top four corporation shareholders and their percent ownership.	✓			
• List of all corporation shareholders and their percent ownership.		✓		
• List of all partners and their percent ownership.			✓	
• Certificate of Corporate Status or Certificate of Good Standing obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last 12 months.	✓	✓	✓	✓
• Designated Representative form must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• Personal History Record Application must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• Copy of DEA certificate if handling controlled substances	✓	✓	✓	✓
• Copy of current SEC 10K or 8K (First 15 pages only)	✓			
• List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.	✓	✓	✓	✓
• Copy of your license, certification, permit or registration issued to your wholesaler business from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. (REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)	✓	✓	✓	✓
• [a]Medical Devices, Equipment and Gases (MDEG) Administrator form must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957). The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• Submit Fingerprints following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• Copy of a bond in an amount of $100,000 made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the Surety Bond form at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Klutch Cargo LLC
Facility Name

Ronald A. Tucci Jr.
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

8-1-25
Date

Board Use Only	Date Received: _____	Amount: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Klutch Cargo LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) 004.005661 State of IL

Physical Address 300 N Oakley Blvd

City Chicago State IL Zip 60612

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 708-370-2301 Website www.klutchcargo.com

Licensing Company Email rtucci@klutchcargo.com

Section 2: Personal Information

First Ronald Middle Anthony Last Tucci

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Bloomdale State IL Zip [redacted]

Telephone 708-370-2301 Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Klutch Cargo LLC Information

FEIN 92-1861680

Organized in the State of Delaware

Members:

1. Ronald A. Tucci Jr., Chief Pharmacy Officer, [redacted] Bloomingdale, IL [redacted] 33%
2. John Burns, CEO, [redacted] River Forest, IL [redacted] 34%
3. Jonathan Lichterman, Chief Legal Counsel, [redacted] River Forest, IL [redacted] 33%
4. Resident Agent, John Burns, CEO, [redacted] River Forest, IL [redacted]

File Number 1273021-7

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

KLUTCH CARGO, LLC, HAVING ORGANIZED IN THE STATE OF ILLINOIS ON JANUARY 19, 2023, APPEARS TO HAVE COMPLIED WITH ALL PROVISIONS OF THE LIMITED LIABILITY COMPANY ACT OF THIS STATE, AND AS OF THIS DATE IS IN GOOD STANDING AS A DOMESTIC LIMITED LIABILITY COMPANY IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 6TH *day of* AUGUST *A.D.* 2025 .

Authentication #: 2521802480 verifiable until 08/06/2026
Authenticate at: https://www.ilsos.gov

SECRETARY OF STATE

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
004.005661

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
12/31/2026

LICENSED WHOLESALE DRUG DISTRIBUTOR

WHOLESALE DRUG

KLUTCH CARGO LLC
RONALD A TUCCI JR
300 N OAKLEY BLVD STE A
CHICAGO, IL 60612-2216

MARIO TRETO, JR.
SECRETARY

CAMILE LINDSAY
DIRECTOR

The official status of this license can be verified at IDFPR.Illinois.gov

20225309

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 4882430

Form **LLC-5.5**	**Illinois** **Limited Liability Company Act** **Articles of Organization**	**FILE # 12730217**
Secretary of State Alexi Giannoulias Department of Business Services Limited Liability Division www.ilsos.gov	**Filing Fee:** $150 **Approved By:** MAG	**FILED** **JAN 19 2023** **Alexi Giannoulias** **Secretary of State**

1. Limited Liability Company Name: KLUTCH CARGO, LLC

2. Address of Principal Place of Business where records of the company will be kept:
726 FRANKLIN AVENUE

RIVER FOREST, IL 60305

3. The Limited Liability Company has one or more members on the filing date.

4. Registered Agent's Name and Registered Office Address:

THOMAS J DWYER & ASSOCIATES, LLC
400 LATHROP AVE STE 200
RIVER FOREST, IL 60305-1871

5. Purpose for which the Limited Liability Company is organized:
"The transaction of any or all lawful business for which Limited Liability Companies may be organized under this Act."

6. The LLC is to have perpetual existence.

7. Name and business addresses of all the managers and any member having the authority of manager:

LICHTERMAN, JONATHAN D.
726 FRANKLIN AVENUE
RIVER FOREST, IL 60305

BURNS, JOHN W.
817 FRANKLIN AVENUE
RIVER FOREST, IL 60305

8. **Name and Address of Organizer**
I affirm, under penalties of perjury, having authority to sign hereto, that these Articles of Organization are to the best of my knowledge and belief, true, correct and complete.

Dated: JANUARY 19, 2023

THOMAS J DWYER JR
400 LATHROP AVENUE SUITE 200
RIVER FOREST, IL 60305

This document was generated electronically at www.ilsos.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. BX00Z0172

Application/License No. _____

Klutch cargo LLC, doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
300 North Oakley Boulevard, Chicago, IL 60612, as
Address of Applicant/Principal
PRINCIPAL, and Jet Insurance Company, a
Surety Company
corporation organized under the laws of the state of North Carolina
State of Incorporation
and authorized to transact a general surety business in the State of
Nevada, whose address for purposes of service is
6701 Carmel Rd Ste 250 Charlotte, NC 28226 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 07/09/2025.
Effective Date

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 9th day of July, 2025.

APPLICANT/PRINCIPAL

COMPANY

Klutch cargo LLC

Authorized Representative

SURETY

Jet Insurance Company

Surety Company's Representative

JET INSURANCE COMPANY CORPORATE SEAL NORTH CAROLINA

David Gonsalves, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Nick Brady
Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by: David Gonsalves 3349773

Nevada Resident Agent

Bond Number: **BX0070172**

JET INSURANCE COMPANY

POWER OF ATTORNEY

NOW ALL BY THESE PRESENTS: That **JET INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of North Carolina, having its principal office in Charlotte, North Carolina does hereby constitute and appoint

Name	Limit of Liability per Bond
David Gonsalves	**$25,000.00**

its true and lawful Attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds, undertakings, contracts of indemnity, recognizances and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, provided that the liability of such shall not exceed the limit stated above.

The execution of such instrument(s) in pursuance of these presents, shall be as binding upon **JET INSURANCE COMPANY** as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by its regularly elected officers at the principal office.

The Power of Attorney is executed and may be certified so, and may be revoked, pursuant to and by authority of the following resolutions adopted by the Board of Directors of **JET INSURANCE COMPANY** by unanimous written consent dated August 03, 2018, of which the following is a true excerpt:

RESOLVED that the President, or any Vice President, acting with any Secretary or Assistant Secretary, shall have power and authority to appoint Attorney(s)-in-fact, and to authorize them to execute on behalf of the Company, attach the Seal of the Company thereto and deliver, bonds, undertakings, contracts of indemnity, recognizances and other writings obligatory in the nature thereof; to prescribe their respective duties and the respective limits of their authority; and to revoke, at any time, any such Attorney-in-fact and revoke the authority given.

Further, this Power of Attorney is signed and sealed by facsimile pursuant to resolution of the Board of Directors of the Company adopted by unanimous written consent dated August 3, 2018, of which the following is a true excerpt:

RESOLVED that the signature of any authorized officer and the Seal of the Company may be affixed by facsimile to any Power of Attorney or certification thereof authorizing the execution on behalf of the Company and delivery of any bond, undertaking, contract of indemnity, recognizance and other writings obligatory in the nature thereof, and such signature and seal when so used shall have the same force and effect as though manually affixed.

IN WITNESS WHEREOF, **JET INSURANCE COMPANY** has caused this instrument to be signed and its corporate seal to be affixed by its authorized officer, this 17th day of May, 2023.

SEAL

JET INSURANCE COMPANY

Spencer Siino, President

Richard Popp, Secretary

STATE OF NORTH CAROLINA
County of Mecklenburg

On this 17th day of May, 2023 before me came the individuals who executed the preceding instrument, to me personally known, and being by me duly sworn, said that each is the herein described and authorized officer of Jet Insurance Company; that the seal affixed to said instrument is the Corporate Seal of said Company; that the Corporate Seal and each signature were duly affixed by order of the Board of Directors of said Company.

Sara C. Holt
Notary Public, State of North Carolina
County of Mecklenburg
My Commission Expires 09/11/2027

IN WITNESS WHEREOF, I have hereunto set my hand at Jet Insurance Company offices the day and year above written.

SARA C. HOLT
Notary Public, North Carolina
Mecklenburg County
My Commission Expires
September 11, 2027

I, Richard Popp, Secretary of **JET INSURANCE COMPANY**, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney executed by **JET INSURANCE COMPANY**, which is still in full force and effect.

IN WITNESS WHEREOF, I have thereunto set my hand and attached the seal of said Company this **9th** day of **July**, **2025**.

SEAL

Richard Popp, Secretary

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Klutch Cargo LLC
Pharmacy/Wholesaler License # (if applicable) IL license # 004.005661
Physical Address 300 N. Oakley Blvd
City Chicago State IL Zip 60612
Mailing Address (if different from physical address) _____
City _____ State _____ Zip _____
Telephone 708-370-2301 Website www.klutchcargo.com
Licensing Company Email rtucci@klutchcargo.com

Section 2: Personal Information

First Ronald Middle Anthony Last Tucci Jr.
Alias(es, nicknames, name changes, etc.) _____
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X
Mailing Address [redacted]
City Bloomingdale State IL Zip [redacted]
Telephone [redacted] Email RTucci@klutchcargo.com
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Midwestern University College of Pharmacy		1993 – 1996	
Address: 555 31st	City: Downers Grove	State: IL	Zip: 60515
Diploma/Degree obtained, if any: Bachelors of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Triton College		1991 – 1993	
Address	City: River Grove	State: IL	Zip
Diploma/Degree obtained, if any: Pre-Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Holy Cross High School		87 – 91	
Address	City: River Grove	State: IL	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/21 – Date	[redacted]	Bloomingdale	IL	[redacted]
11/14 – 8/2021	[redacted]	Bloomingdale	IL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: CVS Health Mail Order Pharmacy			From - To (MM/YY – MM/YY): 6/2014 – 2/2025
Business Address: 1780 Wall Street	City: Mt Prospect	State: IL	Zip:
Phone:	Title: Director of Mail Pharmacy OPS		Number of Employed Hours: 21,000 hours
Description of Duties: Responsible for 500 employees, two locations, Dispensy 30 Million prescriptions per year			

Business Name: Rescare Inc – Pharmacy Alternatives			From - To (MM/YY – MM/YY): 6/2009 – 6/2014
Business Address:	City: Louisville	State: KY	Zip:
Phone:	Title: VP of Pharmacy OPS		Number of Employed Hours: 13000 hours
Description of Duties: In charge of 8 Longterm Care pharmacies nationwide			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I, Ronald A. Tucci Jr., **certify that as the designated representative for** Klutch CARGO LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ronald Tucci Jr.
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-15-25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ronald A Tucci Jr

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/23/25

Date

Please have this section completed in the presence of a Notary Public.

State of IL, ss. County of Cook.

I, Ronald A Tucci Jr, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/23/25

Date

Subscribed and Sworn to before me this 23 day of June.

Renee P. Saunoras

Notary Public Signature

Official Seal
RENEE F SAUNORAS
Notary Public, State of Illinois
Commission No. 1003029
My Commission Expires January 21, 2029

(Seal)

Ronald A. Tucci Jr. R. Ph. |

[redacted]

LSSGB

Operations Management Executive

Noted for managing multi-million-dollar pharmacies, generating double-digit revenue growth, achieving Six Sigma quality results, and consistently exceeding company and industry employee engagement benchmarks.

Resourceful leader known for optimizing multi-site pharmacy operations, implementing innovative process improvements, and developing high-performing teams across retail and mail-order settings. Experienced in driving high-value cost savings through strategic initiatives, accelerating operational efficiency through workflow modifications, and maintaining exceptional customer service metrics. Distinguished for expanding organizational footprint, directing successful pharmacy openings across multiple states, and managing entire lifecycle of pharmacy operations from staffing to inventory control to regulatory compliance.

Areas of Expertise

- Pharmacy Operations Management
- Long-term Care Pharmacy Services
- Team Leadership & Development
- Mail-order Pharmacy Operations
- Inventory Optimization & Control
- Revenue, Profitability Enhancement
- Employee Engagement & Retention
- Customer Experience Management
- Healthcare Regulatory Compliance
- Continuous Process Improvement
- Business Expansion Planning
- Creative Problem-solving
- Quality Control Systems
- Facility Launch & Setup
- Budget & Cost Control

Signature Accomplishments

- Leveraged strong business acumen and market insights to accomplish $60M revenue growth.
- Positioned Chicagoland mail-order pharmacy center as a top-tier site for employee growth and facility tours.
- Drove network-wide operational and procedural improvements as a model for corporate best practices and excellence.
- Enhanced customer service by reducing medication transit time by two days and achieving over 99% pharmacy turnaround.

Professional Experience

CVS/Caremark PBM **2014 – Present**

Lead Director of Operations

Capitalize on a unique combination of leadership, managerial, and analytical skills to direct daily operations of back-end mail order pharmacy nationwide and supervise a team of 500 employees. Accelerate team productivity and engagement through talent development initiatives such as role clarification, goal setting, recognition programs, and efficiency tools.

- Led filing and shipment of 30M prescriptions annually, improving Six Sigma quality, profitability, and exceeding revenue goals.
- Innovated and executed staffing action plans to enhance top talent diversity and improve prescription output performance.
- Accomplished optimum employee engagement scores, surpassing company and industry averages for 5 consecutive years.
- Launched a Satellite mail order pharmacy in San Antonio, Texas, for GLP-1 cold medications, saving $2.2M annually.
- Steered establishment of the "Big Little Breakthrough" supervisor development and process improvement program.

- Delivered Six Sigma quality outcomes by leading quality team in implementing process improvements and controls.
- Secured best employee engagement survey scores in company, outpacing competitors by 10 points.
- Achieved all service metric and client performance guarantee goals, saving $2.5M.
- Received Leadership Breakthrough Awards for dedicated team development.
- Slashed pharmacist hours by 20% by instituting new process improvement.

Pharmacy Alternatives (PAL), a division of ResCare Incorporated ***(Multiple Promotions) (2009 – 2014)***

Vice President of Pharmacy Operations **2013 – 2014**

Oversaw daily operations of nine long-term care pharmacies, producing $100M in annual revenue. Formulated and implemented strategic plans to enhance operational capacities, improve client satisfaction, and ensure financial sustainability.

- Orchestrated notable revenue escalation from $45M to $100M by devising strategic plans.
- Spearheaded entire organization towards improved customer satisfaction.
- Expanded operations by establishing new sites to drive revenue growth.
- Boosted number of patients catered to from 6,000 to 17,000.
- Guided a team of 200 dedicated employees to success.

Regional Director of Pharmacy Operations **2011 – 2013**

Administered daily activities for seven long-term care pharmacies across the nation, generating $70M annual revenue. Oversaw corporate functions, including integration, audit, purchasing, and medical records departments. Executed major HR functions such as recruiting management staff, including Director of Pharmacy staff, Pharmacy Managers, and Department Managers for Pharmacy Alternatives. Served as Co-Chair for the Natural Disaster Emergency Preparedness team.

- Supervised and guided a team of 190 employees, focusing on ensuring optimal performance levels.
- Spearheaded consistent expansion efforts resulting in opening of an additional pharmacy in 2013-2014, increasing revenue by $4M and extending services to three more states.
- Supervised third-party vendor for pharmacy operating system and assessed efficiency capabilities.
- Teamed up with IT department and software vendor (Softwriters) to conduct software upgrades and drive pharmacy metrics.
- Boosted operating facilities by twofold through establishment of four new long-term care pharmacies in four states.
- Boosted productivity by implementing companywide pharmacy workflow adjustment using Six Sigma principles.

Director of Pharmacy **2009 – 2011**

Directed seamless delivery of optimal pharmacy services to long-term care facilities catering to individuals with developmental disabilities. Coordinated delivery of drugs to facilities and managed as well as ensured optimal levels of pharmacy inventory.

- Led a team of 25 employees, trained nursing facility staff, and ensured strict compliance with legal pharmacy paperwork.
- Attained 10% increase in customer satisfaction levels by enhancing customer service relations and resolution time.
- Headed daily pharmacy operations and provided services to 2,800 beds, generating an annual revenue of $12M.
- Negotiated win-win contracts with drug manufacturers and suppliers to maintain cost-effective supplies.
- Fostered strong business relationships with directors of long-term care facilities.

Additional Experience

Pharmacy Manager | Walgreens Pharmacy

- Achieved promotion to a pharmacy with increased revenue.
- Ensured compliance with all legal requirements of pharmacy law.
- Recruited and provided training to students from Chicago College of Pharmacy.

1552

- Resolved customer complaints and managed drug ordering, returns, and inventory control using SIMS computer system.

Education & Credentials

Bachelor of Science, Pharmacy | Midwestern University – College of Pharmacy
Lean Six Sigma Green Belt | College of DuPage (2018)
Registered Pharmacist in IL, KY, VA, KS, LA and GA | National Association of Boards of Pharmacy
U.S. Customers Broker | U.S. Customs & Border Protection

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Klutch Cargo LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) IL # 001005661

Physical Address 300 N Oakley Blvd

City Chicago State IL Zip 60612

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 708-370-2301 Website www.KlutchCargo-com)

Licensing Company Email rtucci@klutchcargo.com

Section 2: Personal Information

First Ronald Middle Anthony Last Tucci Jr.

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Bloomingdale State IL Zi[redacted]

Telephone 908 370-2301 Email rtucci@KlutchCargo.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		Y
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		Y
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		Y
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Midwestern University			1993 - 1996	
Address		City	State	Zip
555 31st		Downers Grove	IL	60515
Diploma/Degree obtained, if any				
Bachelor of Science Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/21 - Date	[redacted]	Bloomingdale	IL	[redacted]
1/14 - 8/21	[redacted]	Bloomingdale	IL	[redacted]
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Klutch Cargo LLC			2/25 - Date	
Business Address		**City**	**State**	**Zip**
300 N Oakley Blvd		Chicago	IL	60612
Phone	**Title**			
708-310-2301	Chief Pharmacy Officer			
Description of Duties				
Act wholesale ops, compliance				

Business Name			From - To (MM/YY – MM/YY)	
CVS Health			6/14 - 2/25	
Business Address		**City**	**State**	**Zip**
1780 Wall St		Mt Prospect	IL	60085
Phone	**Title**			
	Mail order Direct Pharmacy OPS			
Description of Duties				
In charge of mail order pharmacy Division.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ronald Tucci

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/23/2025

Date

Please have this section completed in the presence of a Notary Public.

State of IL., ss. County of Cook

I, Ronald A Tucci Jr, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/23/2025

Date

Subscribed and Sworn to before me this 23 day of June.

Renee F. Saunoras

Notary Public Signature

Official Seal
RENEE F SAUNORAS
Notary Public, State of Illinois
Commission No. 1003029
My Commission Expires January 21, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application
Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Klutch Cargo LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) 4004.00516061

Physical Address 300 N. Oakley Blvd.

City Chicago State IL Zip 60612

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Jonathan Middle David Last Lichterman

Alias(es, nick[redacted] _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 300 N Oakley Blvd.

City Chicago State IL Zip 60612

Telephone 773-720-5504 Email JLichterman@Klutchcargo.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		N
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		N
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		N

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		N
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Burns

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/6/2025

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Georgetown University			1993 – 1996
Address	City	State	Zip
	Washington	DC	
Diploma/Degree obtained, if any	Juris Doctor		

School Name			From - To (MM/YY – MM/YY)
University of Michigan			1987 - 1991
Address	City	State	Zip
	Ann Arbor	MI	
Diploma/Degree obtained, if any	Bachelor of Arts		

School Name			From - To (MM/YY – MM/YY)
St. Louis Park Senior High School			1983 – 1987
Address	City	State	Zip
	St. Louis Park	MN	55416
Diploma/Degree obtained, if any	Diploma		

School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/19 - Pres	[redacted]	River Forest	IL	[redacted]
12/04 - 10/19	[redacted]	River Forest	IL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Klutch Cargo LLC			From - To (MM/YY – MM/YY): 1/23 – Present
Business Address: 300 N. Oakley Blvd.	City: Chicago	State: IL	Zip: 60612
Phone: 1800-896-7136	Title: Owner/Manager		
Description of Duties:			

Business Name: Citizens Rx 2LC			From - To (MM/YY – MM/YY): 11/10 – 12/21
Business Address: 1144 Lake Street	City: Oak Park	State: IL	Zip: 60301
Phone: —	Title: Chief Legal Officer / EVP		
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Lichterman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/6/25

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Lichterman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10-6-25

Date

Please have this section completed in the presence of a Notary Public.

State of IL, ss. County of Cook

I, Jonathan Lichterman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10-6-25

Date

Subscribed and Sworn to before me this 6 day of October.

Renee F. Saunoras

Notary Public Signature

Official Seal
RENEE F SAUNORAS
Notary Public, State of Illinois
Commission No. 1003029
My Commission Expires January 21, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Klutch Cargo LLC.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (If applicable) 024. 00516612

Physical Address 300 N. Oakley Blvd

City Chicago State IL Zip 60612.

Mailing Address (If different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First John Middle W. Last Burns

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 300 N Oakley Blvd.

City Chicago State IL Zip 60612

Telephone [redacted] Email JWB@Klutchcargo.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
DePaul University			1989 - 1991	
Address		City	State	Zip
1 E. Jackson		Chicago	IL	60604
Diploma/Degree obtained, if any				
MA Technical Writing (Not completed)				
School Name			From - To (MM/YY – MM/YY)	
Northern IL University			1984 - 1988	
Address		City	State	Zip
1425 W. Lincoln Hwy		DeKalb	IL	60115
Diploma/Degree obtained, if any				
BA - English				
School Name			From - To (MM/YY – MM/YY)	
St. Viator High School			1980 - 1984	
Address		City	State	Zip
1213 E. Oakton		Arlington Heights	IL	60004
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/27/06 – Curre	[redacted]	Von Fores	IL	[redacted]
12/10/19 - 2022		ong Beach	IL	
07/16 - 4/24		New Buffalo	MI	
05/24 – Curre		ong Beach	IN	
03/22 - Curre		hicago	IL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Citizens Rx			From - To (MM/YY – MM/YY): 2011 – 2020
Business Address: 1144 Lake St.	City: Oak Park.	State: IL	Zip: 60301
Phone	Title: CEO / Chairman		
Description of Duties			

Business Name: Kluth Cargo			From - To (MM/YY – MM/YY)
Business Address: 300 N Oakley	City: Chicago	State: IL	Zip: 60612
Phone: 800-896-7136	Title: Founder.		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Burns

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10-6-25

Date

Please have this section completed in the presence of a Notary Public.

State of IL, ss. County of Cook

I, John Burns, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10-6-25

Date

Subscribed and Sworn to before me this 6 day of October.

Renee F. Saunoras

Notary Public Signature

Official Seal
RENEE F SAUNORAS
Notary Public, State of Illinois
Commission No. 1003029
My Commission Expires January 21, 2029

(Seal)

Form **LLC-5.5**	**Illinois** **Limited Liability Company Act** **Articles of Organization**	**FILE # 12730217**
Secretary of State Alexi Giannoulias Department of Business Services Limited Liability Division www.ilsos.gov	**Filing Fee:** $150 **Approved By:** MAG	**FILED** **JAN 19 2023** **Alexi Giannoulias** **Secretary of State**

1. Limited Liability Company Name: KLUTCH CARGO, LLC

2. Address of Principal Place of Business where records of the company will be kept:
726 FRANKLIN AVENUE

RIVER FOREST, IL 60305

3. The Limited Liability Company has one or more members on the filing date.

4. Registered Agent's Name and Registered Office Address:

THOMAS J DWYER & ASSOCIATES, LLC
400 LATHROP AVE STE 200
RIVER FOREST, IL 60305-1871

5. Purpose for which the Limited Liability Company is organized:
"The transaction of any or all lawful business for which Limited Liability Companies may be organized under this Act."

6. The LLC is to have perpetual existence.

7. Name and business addresses of all the managers and any member having the authority of manager:

LICHTERMAN, JONATHAN D.
726 FRANKLIN AVENUE
RIVER FOREST, IL 60305

BURNS, JOHN W.
617 FRANKLIN AVENUE
RIVER FOREST, IL 60305

8. **Name and Address of Organizer**
I affirm, under penalties of perjury, having authority to sign hereto, that these Articles of Organization are to the best of my knowledge and belief, true, correct and complete.

Dated: JANUARY 19, 2023

THOMAS J DWYER JR
400 LATHROP AVENUE SUITE 200
RIVER FOREST, IL 60305

This document was generated electronically at www.ilsos.gov

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ronald A. Tucci Jr.

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8-6-25

Date

Please have this section completed in the presence of a Notary Public.

State of Illinois, ss. County of Cook

I, Ronald A. Tucci Jr., being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8-6-25

Date

Subscribed and Sworn to before me this 6 day of Aug, 2025.

Renee F Saunoras

Notary Public Signature

Official Seal
RENEE F SAUNORAS
Notary Public, State of Illinois
Commission No. 1003029
My Commission Expires January 21, 2029

(Seal)

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

8-1-25
Date

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Kinetic Cargo LLC			From - To (MM/YY – MM/YY): 3/25 – Date
Business Address: 300 N Oakley Blvd	City: Chicago	State: IL	Zip: 60612
Phone: 208 320-2301	Title: Chief Pharmacy Operations Officer		
Description of Duties: All pharmacy / wholesale operations.			

Business Name: CVS Caremark			From - To (MM/YY – MM/YY): 6/2014 – 2/2025
Business Address: 1280 Main Street	City: Mt Prospect	State: IL	Zip: 60 056
Phone	Title: Director of Mail Pharmacy Operations		
Description of Duties: In charge of Mail order pharmacy Dispensy. 50 million prescriptions per year.			

Business Name: Pharmacy Alternatives			From - To (MM/YY – MM/YY): 6/2008 – 6/2014
Business Address	City: Louisville	State: Ky	Zip
Phone	Title: VP of Pharmacy Operations		
Description of Duties: In charge of 8 Long term Care pharmacies across several States.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.).

School Name		City	State	Zip	From - To (MM/YY – MM/YY)
Midwestern University		Downers Grove	IL		8/1993 – 6/1996
Address					
Diploma/Degree obtained, if any					

School Name		City	State	Zip	From - To (MM/YY – MM/YY)
Triton College		River Grove	IL		8/1991 – 6/1993
Address					
Diploma/Degree obtained, if any					

School Name		City	State	Zip	From - To (MM/YY – MM/YY)
Holy Cross High School		River Grove	IL		1988 – 1991
Address					
Diploma/Degree obtained, if any					

School Name		City	State	Zip	From - To (MM/YY – MM/YY)
Address					
Diploma/Degree obtained, if any					

School Name		City	State	Zip	From - To (MM/YY – MM/YY
Address					
Diploma/Degree obtained, if any					

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/1/2024 – Date	[redacted]	Bloomdale	IL	[redacted]
1/2014 – 8/202	[redacted]	Bloomdale	IL	[redacted]
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Employee Information
Klutch Cargo, LLC
Printed on 3/6/26

Last	First	Department
Burns	Joseph	Warehouse
Cerone	Nicholas	Operations
Cerone	Vincent	Warehouse
Connelly	John	Warehouse
Cruz	Jose	Warehouse
Donlan	Jack	Warehouse
Gerin	Virgil	Sales
Lichterman	Jonathan	Owner
Santos	Romulo	Operations
Saunoras	Renee	Operations
Tucci	Jack	Warehouse
Tucci	Ronald	Operations

4KK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Renown Pharmacy

Physical Address: 640 Maestro Drive, Suite 100

City: Reno State: NV Zip: 89511

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 775-982-5280 Toll Free # (NAC 639.708, NRS 639.23286): 833-999-0365

Fax: 775-982-5250 Contact Email: israa.mahmood@renown.org

Website: renown.org/pharmacy

Nevada Business License # (if applicable) NV19851012417

Supervising/Managing Pharmacist Name (NRS 639.220): Israa Mahmood

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19322

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Israa Mahmood	NV Pharmacist Registration #: 19322
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Renown Health

Corporation/Organization Name: Renown Regional Medical Center

Mailing Address: 1155 Mill Street

City: Reno State: NV Zip: 89502

Telephone: 775-982-6838 Email: adam.porath@renown.org

Contact Person Name: Adam Porath

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Vice President of Pharmacy S (title) for Renown Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Adam Porath, PharmD

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2/27/26

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Adam Porath, PharmD hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Vice President of Pharmacy Service (title) for Renown Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

MICHELLE A BAY
Notary Public-State of Nevada
Appointment No. 9-54385-2
My Appointment Expires 10-28-2029

SUBSCRIBED AND SWORN TO
Before me, a notary public this 2nd day of March, 20 26

Notary Public

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Israa Mahmood Pharmacist Registration #: 19322

Pharmacy Name: Renown Pharmacy

Initial each statement below to indicate you have read and agree with the following:

IM I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

IM I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

IM I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

IM I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

IM I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

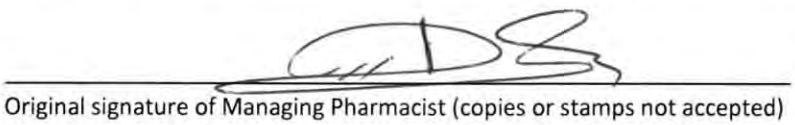
Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.



Original signature of Managing Pharmacist (copies or stamps not accepted)

3/2/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Adam Porath, PharmD

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

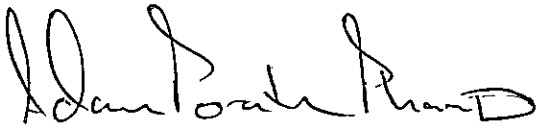
2/26/26

Date

Board Use Only	Date Received: 3/2/26	Amount: $500.00

Explanation of Section 3, Question 3

There is currently a pending Board of Pharmacy action regarding a different pharmacy within the Renown Health organization. Case # 25-139-N is scheduled to be heard by the Board of Pharmacy in April of 2026.



Renown Pharmacies Organization Structure



Renown Health Board Members

Brian Erling, MD	President and CEO
Anna Loomis	Chief Financial Officer
Tammy Dermody	Board Chair
Jeff Eller	Board Member
Adam Kramer	Board Member
Cliff Deveny, MD	Board Member
Bijel Doshi	Board Member
Stephanie Lepori	Board Member
Marc Mora, MD	Board Member
Chris Ott	Board Member
Jeffrey Resnick	Board Member
Brian Sandoval	Board Member

Renown Regional Medical Center Officers

Chris Nicholas	CEO
Amy McCombs	COO
Brett Moore	CFO
Adam Porath	VP of Pharmacy Services

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational or qualification, as applicable, documents on file in this office for

RENOWN REGIONAL MEDICAL CENTER

Organizational Documents on File	Filing Date
Amended and Restated Articles	02/04/2016
Amendment	10/16/2006
Amendment	11/21/1986
Articles of Incorporation	07/29/1985

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence RENOWN REGIONAL MEDICAL CENTER, as a DOMESTIC NONPROFIT CORPORATION (82) duly organized or formed and existing, or duly qualified or registered, as applicable, and by virtue of the laws of the State of Nevada since 07/29/1985, and is in good standing in this state.

SECRETARY OF STATE

STATE OF NEVADA

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 03/02/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202603026523766
You may verify this certificate online at
https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Renown Pharmacy

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 640 Maestro Dr, suite #100

City Reno State NV Zip 89511

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Israa Middle _____ Last Mahmood

Alias(es, nicknames, name changes, etc.) [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Idaho State University		80/2009-05/2015	
Address	**City**	**State**	**Zip**
921 S 8th Ave	pocatello	ID	83209
Diploma/Degree obtained, if any			
PharmD and Bachelor in Biology			
School Name		**From - To (MM/YY – MM/YY)**	
Almustansirya University-College of Pharmacy		09/2004-07/2008	
Address	**City**	**State**	**Zip**
Bab Almuadhem	Baghdad		
Diploma/Degree obtained, if any			
Bachelor in Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Balqees HS		09/2002-05/2004	
Address	**City**	**State**	**Zip**
Alshaab	Baghdad		
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2019-current	[redacted]			
01/2018-07/2019				
01/2017-01/2018				
05/2014-01/2017				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Renown Health			11/2025-current	
Business Address		**City**	**State**	**Zip**
21 Locust St		Reno	NV	89502
Phone	**Title**		**Number of Employed Hours**	
775-982-5291	Pharmacy Director		500	
Description of Duties				
Overseeing all outpatient pharmacy operations with Renown Health.				

Business Name			From - To (MM/YY – MM/YY)	
Renown Health			01/2024-11/2025	
Business Address		**City**	**State**	**Zip**
21 Locust St		Reno	NV	89502
Phone	**Title**		**Number of Employed Hours**	
775-982-5291	Pharmacy Manager		4000	
Description of Duties				
Managing all 3 retail pharmacies with Renown Health				

Business Name			From - To (MM/YY – MM/YY)	
Renown Health			12/2019-01/2024	
Business Address		**City**	**State**	**Zip**
21 Locust		Reno	NV	89502
Phone	**Title**		**Number of Employed Hours**	
775-982-5291	Pharmacy Supervisor		8000	
Description of Duties				
Supervising duties/PIC for the retail pharmacy on 21 Locust				

Business Name			From - To (MM/YY – MM/YY)	
Renown Health			12/2017-11/2019	
Business Address		**City**	**State**	**Zip**
21 Locust		Reno	NV	89502
Phone	**Title**		**Number of Employed Hours**	
775-982-5291	Clinical Pharmacist		4000	
Description of Duties				
staff pharmacist in the retail capacity along with clinical duties at the Health care Center pharmacotherapy/diabetes clinic				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Israa Mahmood, **certify that as the designated representative for**

Renown Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. IM I am at least 21 years of age;
3. IM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. IM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. IM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. IM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. IM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Israa Mahmood

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/9/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Israa Mahmood

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/9/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Washoe

I, Michelle A Bay, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02.09.2026

Date

Subscribed and Sworn to before me this 9th day of Feb.

Notary Public Signature

MICHELLE A BAY
Notary Public-State of Nevada
Appointment No. 9-54385-2
My Appointment Expires 10-28-2029

(Seal)

4LL

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☑ Out-of-Nevada	☑ Ownership Change*	☐ Hospital (# beds _____)	☑ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: [redacted]
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☑ Non-sterile Compounding
			☑ Sterile Compounding
			☑ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH PH04447		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: AccuMix Pharmacy LLC

Physical Address: 655 West Grand Avenue, Suite 240

City: Elmhurst State: IL Zip: 60126

Mailing Address (if different from physical address): 655 West Grand Avenue, Suite 240

City: Elmhurst State: IL Zip: 60126

Telephone: (630) 749-2771 Toll Free # (NAC 639.708, NRS 639.23286): (866) 817-5303

Fax: (866) 817-5305 Contact Email: info@accumixrx.com

Website: www.accumixrx.com

Nevada Business License # (if applicable) N/A-Not Applicable

Supervising/Managing Pharmacist Name (NRS 639.220): Marco V. Onoroto

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22932

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Marco V. Onoroto	NV Pharmacist Registration #: 22932
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A-Not Applicable	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A-Not Applicable

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): NikRx Holdings LLC (50%) and KamCo Holdings LLC (50%)

Corporation/Organization Name: AccuMix Pharmacy LLC

Mailing Address: 820 Locust Road

City: Wilmette State: IL Zip: 60091

Telephone: (832) 758-2616 Email: jabern@accumixrx.com

Contact Person Name: Jaber Niknam, President, Secretary and Treasurer

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A-Not Applicable

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A-Not Applicable

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President, Secretary and Treasurer (title) for AccuMix Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Jaber Niknam

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1/23/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jaber Niknam, President, Secretary and Treasurer

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1/23/26

Date

Board Use Only	Date Received: 2/2/26	Amount: ~~$500~~ $500.00 CC

Owners and Officers

Name and Title	Work Address and Telephone	Home Address and Telephone	Ownership %
NikRx Holdings LLC Parent / Member	820 Locust Road Wilmette, IL 60091 (832) 758-2616 jabern@accumixrx.com	[redacted]	50% (Direct)
KamCo Capital LLC Parent / Member	820 Locust Road Wilmette, IL 60091 (832) 758-2616 jabern@accumixrx.com		50% (Direct)
Jaber Niknam President, Secretary and Treasurer	655 West Grand Avenue, Suite 240 Elmhurst, IL 60126 (832) 758-2616 jabern@accumixrx.com		100% (Indirect)

File Number 1191759-3

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

ACCUMIX PHARMACY, L.L.C., A DELAWARE LIMITED LIABILITY COMPANY HAVING OBTAINED ADMISSION TO TRANSACT BUSINESS IN ILLINOIS ON JULY 07, 2022, APPEARS TO HAVE COMPLIED WITH ALL PROVISIONS OF THE LIMITED LIABILITY COMPANY ACT OF THIS STATE, AND AS OF THIS DATE IS IN GOOD STANDING AS A FOREIGN LIMITED LIABILITY COMPANY ADMITTED TO TRANSACT BUSINESS IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 19TH *day of* DECEMBER *A.D.* 2025 .

Authentication #: 2535303772 verifiable until 12/19/2026
Authenticate at: https://www.ilsos.gov

Alexi Giannoulias
SECRETARY OF STATE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler AccuMix Pharmacy LLC

Pharmacy/Wholesaler License # (if applicable) PH04447

Physical Address 655 West Grand Avenue, Suite 240

City Elmhurst State IL Zip 60126

Mailing Address (if different from physical address) 655 West Grand Avenue, Suite 240

City Elmhurst State IL Zip 60126

Telephone (630) 749-2771 Website www.accumixrx.com

Licensing Company Email info@accumixrx.com

Section 2: Personal Information

First Marco Middle V Last Onoroto

Alias(es, nicknames, name changes, etc.) N/A-Not Applicable

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Midwestern University College of Pharmacy		09/95 - 05/99	
Address	**City**	**State**	**Zip**
555 31st St.	Downers Grove	IL	60515
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
St. Xavier University		09/90-05/94	
Address	**City**	**State**	**Zip**
10300 S Central Park	Chicago	IL	
Diploma/Degree obtained, if any			
Pre-Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Quigley South High School		09/86 - 05/90	
Address	**City**	**State**	**Zip**
7900 S Western Ave	Chicago	IL	60629
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2018 - Present	[redacted]			
03/2015 - 11/2018				
07/2007 - 03/2015				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
Accumix Pharmacy		to Present	
Business Address	**City**	**State**	**Zip**
655 W Grand Suite 240	Elmhurst	IL	60126
Phone	**Title**	**Number of Employed Hours**	
630-749-2771	Pharmacy Manager	1600	
Description of Duties			
Oversight of daily pharmacy operations			

Business Name		From - To (MM/YY – MM/YY)	
La Rabida Children's Hospital		08/19 - 03/21	
Business Address	**City**	**State**	**Zip**
6500 S Promontory Drive	Chicago	IL	60632
Phone	**Title**	**Number of Employed Hours**	
773-217-6000	Director of Pharmacy	2900	
Description of Duties			
Oversight of daily pharmacy operations			

Business Name		From - To (MM/YY – MM/YY)	
Loretto Hospital		09/18-08/19	
Business Address	**City**	**State**	**Zip**
645 S Central Ave	Chicago	IL	60649
Phone	**Title**	**Number of Employed Hours**	
	Director of Pharmacy	1760	
Description of Duties			
Oversight of daily pharmacy operations			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Applicant's Initials _____ 4

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Marco V. Onoroto, **certify that as the designated representative for**

AccuMix Pharmacy LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Marco V. Onoroto
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/23/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Marco V. Onoroto
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/23/26
Date

Please have this section completed in the presence of a Notary Public.

State of Illinois, ss. County of DuPage

I, Marco V. Onoroto, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/23/26
Date

Subscribed and Sworn to before me this 23rd day of January 2026

Notary Public Signature

OFFICIAL SEAL
JAY NATHAN ZELMAN
Notary Public, State of Illinois
Commission No. 1002367
My Commission Expires January 09, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: AccuMix Pharmacy LLC

NV Pharmacy or Outsourcing facility license # (if applicable): PH04447

Physical Address: 655 West Grand Avenue, Suite 240

City: Elmhurst State: IL Zip: 60126

Mailing Address (if different from physical address): 655 West Grand Avenue, Suite 240

City: Elmhurst State: IL Zip: 60126

Telephone: (630) 749-2771 Toll Free # (NAC 639.708, NRS 639.23286): (866) 817-5303

Fax: (866) 817-5305 Contact Email: info@accumixrx.com

Website: www.accumixrx.com

Nevada Business License # (if applicable) N/A-Not Applicable

Supervising/Managing Pharmacist Name (NRS 639.220): Marco V. Onoroto

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22932

Name of Designated Person(s) as defined by revised USP-797 guidelines: Marco V. Onoroto

Email of Designated Person(s): marcoo@accumixrx.com

Telephone of Designated Person(s): (630) 749-2771

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☑ Category 1 ☑ Category 2 ☑ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☑ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☑ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ☑ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? Dec 2025

6. What is the frequency of the recertification for the ISO classified areas? 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ☑ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☑ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? weekly

10. Will you be performing sterile hazardous drug compounding? Yes (No)

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Tirzepatide / Niacinamide
Semaglutide / Cyanocobalamin

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL

Address: 840 Research parkway, Ste. 546

City: Oklahoma city State: ok Zip: 73104

Telephone:

13. What is your procedure for visual inspection of compounded sterile products?

Visual inspection for clarity, turbidity and particulates against a dark and light field

14. How often do you perform glove fingertip and medial fill testing? Every 3 months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Each member receives training and is certified in Sterile compounding

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Daily Cleaning with 3% Hydrogen peroxide of all Horizontal surfaces followed by Sterile IPA. Weekly cleaning of all surfaces with a sporicidal agent (Acetic Acid/3% H_2O_2.)

17. Who performs the sterile compounding process at your facility? Certified pharmacy technicians and pharmacists.

18. Who is responsible and accountable for the sterile compounding process at your facility?

Designated person - PIC

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

package and transit/cold chain testing

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)			
1. What type of primary engineering controls will you be using in your facility? 2 x Baker Edgegard Laminar Flow Hoods			
2. Are you complying with all USP 800 guidelines?		(Yes)	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?		(Yes)	No
4. Is your BSC or CACI vented 100% to the outside?		(Yes)	No
5. Do you have a negative pressure buffer room at your facility?		(Yes)	No
6. Will you be compounding with antineoplastic HDs or HD API?		Yes	(No)
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	N/A	Yes	No
8. Will you be utilizing a closed system transfer device?	N/A	Yes	No
9. If yes, list the name of the device:			

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

N/A

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

N/A

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

Tirzepatide/Niacinamide
Semaglutide/Cyanocobalamin

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

Initially and every 3 months

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? (Yes) No

4. What is the frequency for completing volumetric active air sampling?

Monthly

5. What is the frequency for completing surface sampling? weekly		
6. What is the frequency for using sporicidal agents? weekly		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	(Yes)	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	(Yes)	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Marco V. Onoroto

Name of Person who Completed the Form

Pharmacist-in-Charge

Title

Signature (copies or stamps not accepted)

1/23/26

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	1631980		**Inspection Information**
Legal Business Name:	Accumix Pharmacy LLC	**Conference Call Date:**	N/A
Doing Business As (DBA):	Accumix Pharmacy	**Start Time: 24-hour format (13:00)**	N/A
Address:	655 W Grand Ave, Ste 240	**End Time: 24-hour format (13:00)**	N/A
City:	Elmhurst	**Onsite Inspection Date(s):**	2/5/2024
State:	Illinois	**Start Time(s): 24-hour format (13:00)**	8:15
Zip Code:	60126	**End Time(s): 24-hour format (13:00)**	14:30
Telephone number:	630.749.2771	**Inspector Name:**	Zach Roberts, RPh
Toll free number:	866.817.5303	**Inspection Performed by (NABP, State, etc):**	NABP
Fax number:	866.817.5305	**Observer Name/Affiliation (if applicable):**	N/A
Website:	www.accumixrx.com	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The facility is encouraged to read the inspection report in its entirety and carefully.
Specific Module(s) and/or Question(s) to which the facility may want to consider further response are:
General Pharmacy- 15.00, 29.00, 31.00, 39.01, 39.02, 47.06, 54.00, 71.00, 78.00, 87.00, 89.00, 90.00, 92.00 and 93.00
Nonsterile -1.0-1.2, 1.7-1.10, 1.14, 2.0-2.2, 3.0-3.3, 4.0, 6.3, 10.3, 15.0-15.2, 15.4, 15.7, 17.0, 26.0, 26.2-26.4, 27.0, 29.11-29.13, 32.0-34.0, 36.1-36.3, 40.0, 45.0-45.5, 51.0 and 52.0
Allergenic Extracts - 2.0-2.3, 10.0, 12.0, 12.2, 14.0-14.1, 18.0, 18.1, 18.3, 18.13, 18.14, 19.0 and 19.1

Additional information on NABP's Inspection website.

NABP Disclaimer: NABP can only verify the authenticity of an Inspection Report if it is transmitted directly from NABP to an intended recipient. NABP cannot verify the authenticity of an Inspection Report transmitted from any other party.

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			X
Monday	8:30	17:30	
Tuesday	8:30	17:30	
Wednesday	8:30	17:30	
Thursday	8:30	17:30	
Friday	8:30	17:30	
Saturday			X

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Marco Onoroto	marcoo@accumixrx.com	148399
Nonsterile Compounding Supervisor	Marco Onoroto	marcoo@accumixrx.com	148399
Sterile Compounding Supervisor	Marco Onoroto	marcoo@accumixrx.com	148399
Hazardous Compounding Supervisor	N/A	N/A	N/A

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Marco Onoroto	PIC	Y
2	Mark Agular	Technician	Y
3	Jenny Klevin	Technician	Y
4			
5			
6			
7			
8			
9			
10			

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

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Business Licensure Information for State of Residence and Federal
(board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Illinois Department of Financial and Professional Regulation - State Board of Pharmacy	Accumix Pharmacy LLC	Pharmacy	054.022076 / 3/31/2024
Illinois Department of Financial and Professional Regulation - State Board of Pharmacy	Accumix Pharmacy LLC	Controlled Substance - Pharmacy	320.013612 / 3/31/2024
Drug Enforcement Administration	Accumix Pharmacy LLC	DEA (Facility)	FA1313282 / 6/30/2025

Inspector Notes: List states in which Non-Resident licenses are held
SC, MN, AR, NJ, PA, MO, ND, CT, RI, NM, TX, AK, AZ, CO, DE, FL HI, ID, IA, ME, MI, MO, NV, NH, NY, NC, OH, WI

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01_AE2.2; Doc02_AE2.2; Doc03_AE2.2: Doc04_GP69.00; Doc05_GP15.00; Doc06_NS58.6; Doc07_NS29.00; Doc08_AE7.1	Sterile competencies performed by third party; Sterile compounding training documents; Sterile compounding training documents; Sample labels; Facility license list; COAs for allergenic extracts; Sample of CSP and CNSP compounding records; January 2024 clean room certification reports.
Photo01_GP87.03; Photo02_GP87.01; Photo03_GP87.03; Photo04_NS59.00; Photo05_NS1.6; Photo06_NS1.6	Occurrence and complaint report 1/3; Occurrence and complaint report 2/3;Occurrence and complaint report 3/3; Allergenic extract for further dilution with an expiration date over a year out; CNSP equipment (not in use yet) 1/4; CNSP equipment (not in use yet) 2/4.
Photo07_NS1.6; Photo08_NS1.6; Photo09_GP47.00; Photo10_GP47.00: Photo11_GP47.00; Photo12_GP47.00	CNSP equipment (not in use yet) 3/4; CNSP equipment (not in use yet) 4/4; Allergenic extracts and diluents 1/11; Allergenic extracts and diluents 2/11; Allergenic extracts and diluents 3/11; Allergenic extracts and diluents 4/11.
Photo13_GP47.00; Photo14_GP47.00; Photo15_GP47.00; Photo16_GP47.00; Photo17_GP47.00; Photo18_GP47.00	Allergenic extracts and diluents 5/11; Allergenic extracts and diluents 6/11; Allergenic extracts and diluents 7/11; Allergenic extracts and diluents 8/11; Allergenic extracts and diluents 9/11; Allergenic extracts and diluents 10/11
Photo19_GP47.00; Photo20_AE10.0; Photo21_AE10.0; Photo22_AE10.0; Photo23_AE10.0	Allergenic extracts and diluents 11/11; Opti-Cide bottle in the clean room 1/4; Opti-Cide bottle in the clean room 2/4; Opti-Cide bottle in the clean room 3/4; Opti-Cide bottle in the clean room 4/4

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	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Telepharmacy	
Open to the Public		Central Fill/Processing/Shared Services	
Closed Door	X	Specialty Pharmacy	
Drive-through window		Handles Medical Marijuana	
Mail/Deliver (in state)	X	Nuclear Pharmacy	
Mail/Deliver (out-of-state list below)	X	Manufacturer	
Veterinary Pharmacy		Wholesale Distributor	
Investigational Drugs, Clinical Trials/Research		Provide products for "Office Use"	X
Institutional		Outsourcing Facility	
Long-Term Care		Nonsterile Compounding	X
HMO/PBM only		Nonsterile Hazardous Drug Compounding	
Internet Pharmacy (New Rx)		Sterile Compounding	X
Internet Pharmacy (Refill Rx)		Sterile Hazardous Drug Compounding	

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements	
CNSPs for INDs		CSPs for INDs	
CNSPs which are essential copies of a commercially available drug product on the Drug Shortage List or justified by a documented medical need for an individual patient - If so, list		CSPs which are essential copies of a commercially available drug product on the Drug Shortage List or justified by a documented medical need for an individual patient - If so, list	
CNSPs sold OTC		CSPs sold OTC	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific:		Patient specific:	
CNSPs for animals		CSPs for animals	
CNSPs for human patients	X	CSPs for human patients	X
Distributed (eg non patient-specific):		Distributed (eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous	X	Category 1 CSPs	
Nonaqueous		Category 2 CSPs	X
Specific types:		Category 3 CSPs	
Solid oral preparations		Types of CSPs:	
Liquid oral preparations	X	Allergenic extracts	X
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	
Topical preparations:		Blood-derived or other biological material (eg autologous serum)	
Creams		Injections including infusions	
Gels		Irrigations for internal body cavities (eg bladder or peritoneal cavity)	
Ointments		Ophthalmic dosage forms	
Lotions		Aqueous preparations for pulmonary inhalation	
Nasal and sinus preparations:		Baths and soaks for live organs and tissues	
Nasal sprays		Implants/ Pellets	
Nasal irrigations		Other (please list):	
Other (please list):			

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Facility Size in Square Feet and Number of PECs		Personnel	
Total Pharmacy size:	2,500	Total Pharmacists:	2
Nonsterile Compounding Room size:	1200	Number of Compounding Pharmacists	1
Nonsterile Compounding powder hoods number:	0	Total Graduate Students or Residents:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	0	Total Student Interns:	0
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	0	Total Technicians:	2
Sterile Compounding Ante Room size:	136	Number of Compounding Technicians	2
Sterile Compounding Clean/Buffer Room size:	255	Of technicians, how many are certified?	2
Sterile Compounding Number LAFW hoods/areas:	2	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number BSC hoods:	0	Total Other Licensed Personnel:	0
Sterile Compounding Number CAI/CACI hoods:	0	Total Other Unlicensed Personnel:	0
Negative Pressure Sterile HD Room size:	48	Ratio #Tech:#RPh present at time of inspection:	2:1
Sterile HD Compounding Number of BSC hoods:	1	Total Pharmacist Hours Per Week:	80
Sterile HD Compounding Number of CACI hoods:	0	Total Technician Hours Per Week:	80

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	Windows to see in

	Volume Dispensed		Volume Distributed
Total Prescriptions Dispensed/day:	20	Total Orders Distributed/day:	0
% Veterinary Prescriptions	0%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	0%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	50%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	50%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	0%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)			
Alaska (AK)			
Arizona (AZ)			
Arkansas (AR)	20	0	Month
California (CA)			
Colorado (CO)			
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)			
Georgia (GA)			
Hawaii (HI)			
Idaho (ID)			
Illinois (IL)	320	0	Month
Indiana (IN)			
Iowa (IA)			
Kansas (KS)			
Kentucky (KY)			
Louisiana (LA)			
Maine (ME)			
Maryland (MD)			
Massachusetts (MA)			
Michigan (MI)			
Minnesota (MN)			
Mississippi (MS)			
Missouri (MO)			
Montana (MT)			

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States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):

Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)			
Nevada (NV)			
New Hampshire (NH)			
New Jersey (NJ)			
New Mexico (NM)	20	0	Month
New York (NY)			
North Carolina (NC)			
North Dakota (ND)			
Ohio (OH)			
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)			
Rhode Island (RI)			
South Carolina (SC)			
South Dakota (SD)			
Tennessee (TN)			
Texas (TX)	40	0	Month
Utah (UT)			
Vermont (VT)			
Virginia (VA)			
Washington (WA)			
West Virginia (WV)			
Wisconsin (WI)			
Wyoming (WY)			
Other:			

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Accumix Pharmacy LLC dba Accumix Pharmacy
e-Profile ID: 1631980
Inspection Date: 2/5/2024

		Finding	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	40 Hours
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	Yes	AccuRx sales personnel also work onsite. AccuRx is the support/sales piece of the endeavor and is its own LLC separate from Accumix.
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	No	
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		Mark Aguilar, Technician Jenny Klevin, Technician

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Facility Name: Accumix Pharmacy LLC dba Accumix Pharmacy
e-Profile ID: 1631980
Inspection Date: 2/5/2024

		Finding	Notes
	Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	Yes	80% of the prescriptions are delivered to the provider's office in all the states.
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	All the prescriptions are patient specific.
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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General Pharmacy Inspection

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Facility Name: Accumix Pharmacy LLC dba Accumix Pharmacy

e-Profile ID: 1631980

Inspection Date: 2/5/2024

		Finding	Notes
	General Operations and Licensure **If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc*	No	The facility is a closed door pharmacy and only displays their home state licensure. The facility is licensed in SC, MN, AR, NJ, PA, MO, ND, CT, RI, NM, TX, AK, AZ, CO, DE, FL HI, ID, IA, ME, MI, MO, NV, NH, NY, NC, OH, WI. The license certificates for NM, IA, NJ, NV, MO, and MN were expired. The license certificates for AK, AZ, CO, DE, HI, ID, ME, MI, NV, NY, OH, and WI were missing. See Doc05_GP15.00.
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	The last state board inspection was in 2021 and was included in the facility's application.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected*	No	No deficiencies were noted.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction*	No	The pharmacy has an exemption in NM to have an active license until March 31, 2024 so that the facility can have a VPP inspection completed as part of the licensure renewal.
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance*	No	
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item*	No	

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		Finding	Notes
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	Yes	The DEA visited the facility in November 2021, due to the initial registration of the facility. No deficiencies noted.
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	No	
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	Records are kept onsite for 5 years.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	E-scripts are printed and placed in the profile folder for each patient.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Dispensing records are kept electronically. The facility uses Summit to process prescriptions and BestRx for the POS system.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Records cannot be deleted from the system.

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		Finding	Notes
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	No records are stored offsite.
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	No	
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Personnel licenses are on display.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Unknown	The PIC stated that a primary source verification on personnel licenses is performed annually and documented but when this documentation was requested by the inspector, it could not be produced.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	N/A	
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	The facility has an ADT system for fire and burglar monitoring that consists of two systems, one for the pharmacy and one for the rest of the facility. The pharmacy system has door and motion sensors. The facility system has motion, door, and window break sensors. Only pharmacy personnel can disable the alarm system in the pharmacy.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	N/A	There are no CIIs onsite.
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	The pharmacy would be closed for business and products would be secured in the onsite safe.

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		Finding	Notes
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site*	N/A	No products are destroyed onsite.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used*	Yes	AMS Store and Shred, LLC
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used*	N/A	There are no HDs onsite.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe*	N/A	This facility is a closed-door pharmacy.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection*	Yes	The current temperature is 70.7°F.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	No	The CRT area is not continuously monitored.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	No	

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		Finding	Notes
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	The refrigerators are continuously monitored by a LaCrosse Alerts Mobile system. Fridge 1 alerts at 32° and 46°F Fridge 2 alerts at 30° and 46°F Fridge 3 alerts at 32° and 46°F Temperature alerts go to technician Mark Aguilar, Mark monitors the temperatures for issues, but since the allergenic extracts are allowed large excursions temperatures are usually not an issue. Allergenic extracts can be placed in another refrigerator if there is an issue.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	Fridge 1 = 42.4°F Fridge 2 = 42.8°F Fridge 3 = 44.2°F
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	There are no frozen products onsite.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	There are no frozen products onsite.
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	Products would be moved to another refrigerator or to a cooler with ice packs.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	No compounding would occur until the issue was fixed.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	No	
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	

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		Finding	Notes
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	The facility only orders allergenic extracts and sterile water/saline. Allergenic Extracts are produced by Greer, ALK, and Hollister. This facility sources extracts from Greer and ALK, with ALK being the primary supplier. Greer and ALK also supply the sterile water/saline solution for dilution. See Photo09_GP47.00, Photo10_GP47.00, Photo11_GP47.00, Photo12_GP47.00, Photo13_GP47.00, Photo14_GP47.00, Photo15_GP47.00, Photo16_GP47.00, Photo17_GP47.00, Photo18_GP47.00, and Photo19_GP47.00.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	Yes	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	No	All products are purchased from Greer and ALK.
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	N/A	
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	No	
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	No	Greer and ALK have BLA resaler licenses.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	N/A	The facility only purchases allergenic extracts and sterile water/saline.

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		Finding	Notes
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	N/A	The facility only purchases allergenic extracts and sterile water/saline.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	N/A	The facility only purchases allergenic extracts and sterile water/saline.
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	N/A	The facility only purchases allergenic extracts and sterile water/saline.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	N/A	The facility only purchases allergenic extracts and sterile water/saline.
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	N/A	There are no controlled substances onsite or ordered by the facility.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	N/A	There are no controlled substances onsite or ordered by the facility.
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	There are no controlled substances onsite or ordered by the facility.
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	N/A	There are no controlled substances onsite or ordered by the facility.
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	

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		Finding	Notes
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity)*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc)*	No	
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made*	N/A	
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	N/A	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place*	N/A	There are no controlled substances onsite.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years)*	No	No controlled substance inventory is documented.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	No	No controlled substance inventory is documented.
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types*	No	

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		Finding	Notes
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	The Summit system tracks lot numbers and expiration dates of products. Products are pulled one month out.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?		The Summit system instructs when to pull products. Products are inspected prior to compounding.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	N/A	All prescriptions are mailed to the patient or provider.
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	All prescriptions are mailed to the patient or provider.

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		Finding	Notes
	Prescription Processing **If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Pharmacists and technicians enter profile data and the profile is updated whenever a new order is received.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	N/A	
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	The facility only can only fills allergenic extract prescriptions from Internal Medicine physicians that are enrolled with AccuRx. The Summit tracks clinics and providers and if a prescription comes from provider not in the system the pharmacist would investigate and get the prescriber enrolled in AccuRx or deny the prescription. Allergenic extract prescriptions must be faxed. Summit cannot receive E-Rxs. The BestRx system can receive E-Rxs, but these are always prescriptions mistakenly sent to the facility and are never filled.
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process*	Yes	The facility will notify providers if they cannot fill a prescription.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	The facility only can only fills allergenic extract prescriptions from Internal Medicine physicians that are enrolled with AccuRx.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both*	Yes	Both noncontrols and controls.
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	N/A	No electronic prescriptions are accepted. The BestRx system has electronic prescription capabilities so that it can report PMP data (which are all zero reports) to the states.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

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Inspection Date: 2/5/2024

		Finding	Notes
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom*	Yes	Pharmacists must verify all prescriptions.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	N/A	No DURs are performed since the facility only fills allergenic extracts.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR*	N/A	No DURs are performed since the facility only fills allergenic extracts.
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe*	N/A	No DURs are performed since the facility only fills allergenic extracts.
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	USP Compounding Compendium, Facts and Comparisons, Trissel's Handbook on Injectable Drugs, Extended Stability for Parenteral Drugs, Trissel's Stability of Compounded Formulations, The Art, Science, and Technology of Pharmaceutical Compounding, Pharmaceutical Calculations, The CDC Handbook
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe*	Yes	BestRx sends PMP data (zero reports) daily.
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	No	
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability*	N/A	No DURs are performed since the facility only fills allergenic extracts.

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		Finding	Notes
67.07	Is the DUR process performed electronically by the computer system? *Identify integrated drug database used.*	N/A	No DURs are performed since the facility only fills allergenic extracts.
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	N/A	No DURs are performed since the facility only fills allergenic extracts.
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	N/A	The facility does not dispense any veterinary prescriptions.
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	Pharmacists verify prescriptions prior to dispensing and document the check on the compounding record.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	See Doc04_GP69.00.
70.00	**Confidentiality**: Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	BestRx and Summit are password protected and limit functions based on user profiles.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Unknown	The facility ships prescriptions via ground or second day delivery. Interviewed staff claim they perform winter and summer testing on their packouts but could not provide any of the data. The facility does not have standard packouts that are followed when shipping prescriptions and pack boxes with arbitrary amounts of cold packs.
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	

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		Finding	Notes
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	Prescriptions are never picked up at the pharmacy.
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer."*	N/A	Prescriptions are never picked up at the pharmacy.
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	Prescriptions are never picked up at the pharmacy.

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		Finding	Notes
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer"*	N/A	Prescriptions are never picked up at the pharmacy.
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	N/A	Prescriptions are never picked up at the pharmacy.
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer"*	N/A	Prescriptions are never picked up at the pharmacy.
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how*	No	There is an 866 number on the label for patients to call, but no written offer to counsel is provided with the prescription. Counseling on the prescription is usually provided by the prescribers.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how*	N/A	
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how*	N/A	The facility only fills allergenic extracts.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how*	N/A	The facility only fills allergenic extracts.

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		Finding	Notes
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin or Tikosyn)*	N/A	The facility only fills allergenic extracts.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how*	Yes	Any patient counseling would be documented in the notes section of the patient profile, but this facility has never had to counsel a patient.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation)*	Yes	After hours calls are forwarded to the PIC's cellular phone.
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	No	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list*	N/A	

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Facility Name: Accumix Pharmacy LLC dba Accumix Pharmacy
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		Finding	Notes
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program*	No	
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both*	N/A	Facility P&Ps are available in hard copy and electronic form.
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	Events are documented in an occurrence report. See Photo01, Photo02, and Photo03.
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	N/A	There is no formal CQI program.
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic*	Yes	Hard copy

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		Finding	Notes
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc)*	No	Issues are analyzed and fixed after they occur.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	No	
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	N/A	

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		Finding	Notes
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	N/A	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	The facility would complete MedWatch forms for any issues with the allergenic extracts. The appropriate state BoP would be notified if a patient was harmed.
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	No	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	No	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	Complaints are documented in an occurrence report.

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Accumix Pharmacy LLC dba Accumix Pharmacy

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Inspection Date: 2/5/2024

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)			
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? ***If no, go to compliance statements.***	No		11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. ***Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.***			4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. ***Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."***			2, 11
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. ***Inspector note: Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."***			3.3, 11

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		Observation	Inspector Notes	USP Reference(s)
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. ***Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."***			6.2, 11
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. ***Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."***			4.2, 11
1.6	**Equipment**: The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). ***Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."***		The pharmacy purchased equipment in preparation of performing more nonsterile compounding, but it has not been used yet. See Photo05_NS1.6, Photo06_NS1.6, Photo07_NS1.6, and Photo08_NS1.6.	6.1, 11
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. ***Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."***			6.2.5, 11

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		Observation	Inspector Notes	USP Reference(s)
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. ***Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."***			7.1, 11
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. ***Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."***			9, 11
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel; adherence to procedures; and prevention and detection of errors and quality issues. ***Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."***			11, 12 USP <1163>
1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. ***Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."***			1.1.3, 11, 12.1, 12.2, 12.3

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		Observation	Inspector Notes	USP Reference(s)
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. *Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."*			11, 13.1
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. *Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."* *If the pharmacy does not transport CNSPs, inspecto r should answer statement as N/A.*			11, 13.2
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. *Inspector note: Per USP, "The facility must have procedures in place to:* *- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)* *- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy* *- Investigate if other lots are affected and recall if necessary* *An SOP for recall of dispensed CNSPs must contain:* *- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall* *- Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution* *- Procedures to identify patients who have received the CNSP* *- Procedures for disposal and documentation of the recalled CNSP (and)* *- Procedures to investigate and document the reason for recall."*			12.1

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		Observation	Inspector Notes	USP Reference(s)
	Designated Person(s) and Personnel Training Program			
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If no, go to compliance statements.***	No		1.1.4
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	No		1.1.4, 12
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***	Unknown	PIC says reviewed annually, but not documented.	1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes		1.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes		1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	Yes		1.1.4

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Accumix Pharmacy LLC dba Accumix Pharmacy

e-Profile ID: 1631980

Inspection Date: 2/5/2024

		Observation	Inspector Notes	USP Reference(s)
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Yes		1.1.4, 11
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.	Yes		1.1.4
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If no, go to compliance statements.***	No		2, 14
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	No		2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	No		2, 14

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		Observation	Inspector Notes	USP Reference(s)
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** ***If questions 2.0-2.12 in the records review tab for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered no. For details, see the Records Review module.***	No		2, 14
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*** ***Inspector should complete the <795> Records Review module question 3.0.***	No		2, 14
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***	Yes		

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		Observation	Inspector Notes	USP Reference(s)
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.	Yes		3
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***	Yes		3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.	Yes		3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.	Yes		3.2 Box 1
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***	Yes		3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.	No		3.3
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.	Yes		3.3
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).	Yes		3.3
6.7	Gowns that are reused do not leave the compounding area.	Yes		3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).	Yes		3.3
6.9	Soiled garb is disposed of or sent for laundering.	Yes		3.3
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.	Yes	Staff wear face mask, gown, gloves.	3.3
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?	N/A	No goggles/non-disposable garb in use.	3.3
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? *If no, go to compliance statements.*	Yes		4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.	Yes		4.1
8.2	The compounding area is well lit.	Yes		4.1
8.3	The compounding area is clean and sanitary.	Yes		4.1
8.4	The compounding area is orderly (eg, clutter free, no tripping hazards).	Yes		4.1

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		Observation	Inspector Notes	USP Reference(s)
8.5	The compounding area is in a good state of repair.	Yes		4.1
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished CNSPs.	Yes		4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes		4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.	Yes		4.1
9.0	Is the compounding area free of carpet?	Yes		4.1
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes		4.2
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."***	Yes		4.2

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		Observation	Inspector Notes	USP Reference(s)
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.*** ***Monitoring devices are typically calibrated or replaced.***	No	Not calibrated regularly	4.2
10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."***	Yes		4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.	Yes		4.2
11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***	[redacted]	70.7F	4.2

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		Observation	Inspector Notes	USP Reference(s)
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.	Yes		4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.	Yes		4.3
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***	N/A	No equipment to clean.	4.3 USP <1231>

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		Observation	Inspector Notes	USP Reference(s)
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***	[redacted]	Sterile alcohol	5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If no, go to compliance statements.***	No		5 Table 1
15.1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.	No	Compounding occurred on the island in the middle of the pharmacy and was cleaned with sterile alcohol prior to cleaning.	5 Table 1
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.	No	Compounding occurred on the island in the middle of the pharmacy and was cleaned with sterile alcohol prior to cleaning.	5 Table 1
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components**.	Yes	The areas was cleaned with sterile alcohol prior to compounding.	5 Table 1
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.	No		5 Table 1
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***	Yes		5 Table 1

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		Observation	Inspector Notes	USP Reference(s)
15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.	Yes		5 Table 1
15.7	Storage shelving is cleaned and sanitized at least every three months.	No		5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***	Yes		5
	Equipment and Components			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***	No		6.1
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If no, go to compliance statements.***	Yes		6.1

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		Observation	Inspector Notes	USP Reference(s)
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***	Yes	The only equipment needed is a syringe and needle to draw up and measure allergenic extract and move it from bottle to bottle.	6.1
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."*** ***If no, inspector should describe observations.***	Yes		6.1
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:*** ***- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;*** ***- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;*** ***- Under the work surface of a BSC is cleaned and sanitized at least monthly; and*** ***- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.*** ***If no, inspector should describe observations.***	Yes		6.1 Table 2

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		Observation	Inspector Notes	USP Reference(s)
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***	Yes		6.1
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***	N/A	The CVE is verified but not in use yet.	6.1
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***	N/A		6.1
19.0	Does the pharmacy compounding CNSPs use APIs?	No		6.2
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*** ***If no, go to compliance statements.***	N/A		6.2.1

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		Observation	Inspector Notes	USP Reference(s)
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***	N/A		6.2.1
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***	N/A		6.2.1
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.***	N/A		6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	Yes		6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***		Sterile water and saline are used.	6.2.1
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.2

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23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***	Yes		6.2.2
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	Yes		6.2.2, 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations 797 , 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***	N/A	All have expiration date.	6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		6.2.2

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		Observation	Inspector Notes	USP Reference(s)
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.	Yes		6.2.2
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? *If no, go to compliance statements.*	Yes		6.2.3, 6.2.4
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).	Yes		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	Yes		6.2.3
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.	Yes		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.	Yes		6.2.4

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Accumix Pharmacy LLC dba Accumix Pharmacy

e-Profile ID: 1631980

Inspection Date: 2/5/2024

		Observation	Inspector Notes	USP Reference(s)
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***	Yes		6.2.4
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If no, go to compliance statements.***	No		6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).	Yes		6.2.5
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	No		6.2.5, 14
26.3	The pharmacy has a readily accessible spill kit in the compounding area.	No		6.2.5
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.	No		6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.5

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		Observation	Inspector Notes	USP Reference(s)
	Master Formulation Records (MFR) and Compounding Records (CR) **Inspector should review a minimum of five (5) MFRs and five (5) CRs.**			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If no, go to compliance statements.***	No	The pharmacy only has CR since their nonsterile compounding consists of diluting allergenic extracts.	7.1
27.1	An MFR is created for each unique formulation.	N/A		7.1 Box2
27.2	Any changes or alterations to the MFR are approved and documented.	N/A		7.1
27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***	N/A		7.1, 10.2 Table 4

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		Observation	Inspector Notes	USP Reference(s)
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***	N/A		7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	N/A		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	N/A		7.1
28.3	MFR includes the type of container–closure system(s).	N/A		7.1
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***	N/A		7.1
28.5	MFR has a physical description of the final CNSP.	N/A		7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	N/A		7.1

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		Observation	Inspector Notes	USP Reference(s)
28.7	MFR contains the reference source to support the assigned BUD.	N/A		7.1
28.8	Labeling requirements (eg, shake well) are described on the MFR.	N/A		7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	N/A		7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.	N/A		7.1
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***	Yes	See Doc07_NS29.00.	7.2, 14
29.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.2, 14
29.3	The CR includes the date (or date and time) the CNSP was prepared.	Yes		7.2, 14
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).	Yes		7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14

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		Observation	Inspector Notes	USP Reference(s)
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes		7.2, 14
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.	Yes		7.2, 14
29.8	The CR includes the weight or measurement of each component.	Yes		7.2, 14
29.9	The CR identifies the total quantity compounded.	Yes		7.2, 14
29.10	The CR lists the assigned BUD and storage requirements.	Yes		7.2, 14
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.	No		7.2, 14
29.12	The CR has a physical description of the final CNSP.	No		7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	No		7.2, 14
29.14	The CR contains a MFR reference for the CNSP.	N/A	There are no MFRs at the pharmacy.	7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.	Yes		7.2, 8
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.	Yes		7.2, 12.1, 14

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		Observation	Inspector Notes	USP Reference(s)
30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation.*** ***Inspector should describe their observations in the Inspector Notes.***	Yes	The pharmacist checks that the appropriate allergenic extracts were diluted accordingly.	2, 7.2, 8
	Labeling			
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		9
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."***	Yes		9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).	Yes		9
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		9

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		Observation	Inspector Notes	USP Reference(s)
31.6	The label on the immediate container includes the BUD. ***If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***	Yes		9
31.7	The label on the immediate container includes the dosage form.	Yes		9
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.	Yes		9
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***	No		9
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? ***Inspector note: Per USP, this is a recommendation.***	No		9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***	No		9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CNSP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.*** ***If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A .***	Yes	Initials on label may not match who compounded the prescription, but the compounding record would be initialed after compounding. During the inspection the inspector noticed that a vial of compounded allergenic extract had a BUD of 2/14/2025, which is over a year away. The PIC stated that this label was mistakenly printed with the incorrect BUD.	9

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		Observation	Inspector Notes	USP Reference(s)
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date." If no, go to compliance statements.***	Yes	Allergenic extracts receive a one year expiration date.	10 USP <7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.	No	The label has an expiration date instead of a BUD.	10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.	No	The label has an expiration date instead of a BUD.	10.1
36.3	BUDs are assigned from the date (and time) of preparation.	No	Assigned from the date but not the time.	10.1
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***	Yes		10.3
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4

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		Observation	Inspector Notes	USP Reference(s)
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		10.4
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If no, who establishes the maximum BUD for a MFR?***	Yes		7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?	No		10.5
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If no, go to compliance statements.***	No		10.5
40.1	Pharmacy staff have access to the USP monograph for reference.	N/A		10.5
40.2	CNSPs are prepared in accordance with the USP monographs. ***If no, inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
40.3	Components used by the compounder match those listed in the monograph. *If no, describe the source of the component in monograph and the source that the pharmacy used.*	N/A		10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. *If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.*	N/A		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	Yes		10.4
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? *Inspector note: This question is for the CNSPs compounded that are not following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.* *If no, go to compliance statements.* *If all CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.*	N/A	The pharmacy adheres to BUD limits for allergenic extracts.	10.4

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		Observation	Inspector Notes	USP Reference(s)
42.1	**Non-preserved, Aqueous Dosage Forms**: The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>

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		Observation	Inspector Notes	USP Reference(s)
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.*** ***If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>

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		Observation	Inspector Notes	USP Reference(s)
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?	N/A		10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? *If no, go to compliance statements.*	N/A		10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. *If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.*	N/A		10.5
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days. *If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.*	N/A		10.5
44.3	Pharmacy is following the results of their own stability study. *If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.* *If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study.* *If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.*	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***	N/A		10.5

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Accumix Pharmacy LLC dba Accumix Pharmacy

e-Profile ID: 1631980

Inspection Date: 2/5/2024

		Observation	Inspector Notes	USP Reference(s)
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.***	N/A		10.5
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***	No		1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***	No		12
45.2	The QA/QC programs address adherence to procedures.	No		12
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.	No		12

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e-Profile ID: 1631980

Inspection Date: 2/5/2024

		Observation	Inspector Notes	USP Reference(s)
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***	No		12
45.5	The QA/QC programs address appropriate investigations and corrective actions.	No		12
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?	No		12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.2
47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."***	Yes		12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes		12.2
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.	Yes		12.2
47.4	Complaints are fully investigated.	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.	Yes		12.2
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***	Yes		12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 12.2
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.*** ***Review most recent recall and describe in the Inspector Notes.*** ***If the pharmacy has not had any recalls within the past two years, inspector should answer the question as No.***	No		12.1, 14
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.1, 12.2, 12.3
49.1	The pharmacy has procedures to determine when recalls must be initiated.	Yes		12.1
49.2	The pharmacy documented the implementation of the recall.	Yes		12.1
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).	Yes		1.1.3, 12.1

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		Observation	Inspector Notes	USP Reference(s)
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	Yes		12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***	Yes		12.1
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If no, go to compliance statements.***	No		13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).	Yes		13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).	No	The facility ships prescriptions via ground or second day delivery. Interviewed staff claim they perform winter and summer testing on their packouts but could not provide any of the data. The facility does not have standard packouts that are followed when shipping prescriptions and pack boxes with arbitrary amounts of cold packs.	13.1

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		Observation	Inspector Notes	USP Reference(s)
	Compounding Personnel Observations - *Inspector must observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with two creams or other drugs) as long as all observations can be viewed.*			
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).	Yes		3.1
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	Yes		3.1
54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.2, Box 1

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		Observation	Inspector Notes	USP Reference(s)
54.1	All personnel who enter the compounding area to compound performed hand hygiene.	Yes		3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3 Box 1
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3 Box 1
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***	Yes		3.2, 3.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration.	[redacted]	U-SLIT ME	
58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? *If no, go to compliance statements.*	Yes		2 Box 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.	Yes		3.1, 4.1
58.2	The compounding personnel started with a clean compounding area for CNSPs.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.	N/A		7, 7.1 Box 2
58.4	The compounding personnel performed hand hygiene. *Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.*	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***	Yes	See Doc06_NS58.6.	6.2 (6.2.1 - 6.2.5)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***	Yes		6.1 Table 2
58.8	The compounding personnel have knowledge of and access to any SDS.	Yes		6.2
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes		1.1.3
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***	Yes		7.1, 7.2 Box 2

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		Observation	Inspector Notes	USP Reference(s)
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***	N/A		7.2, 14 Box 3
58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***	Yes		14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If no, describe observations in Inspector Notes.***	Yes		7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.	Yes		8.1 Box 2
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***	Yes		9
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***	Yes		7.2, 8, 14 Box 3
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
59.0	**Final CNSP check observation**: Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If no, go to compliance statements.***	Yes	Initials on label may not match who compounded the prescription, but the compounding record would be initialed after compounding. During the inspection the inspector noticed that a vial of compounded allergenic extract had a BUD of 2/14/2025, which is over a year away. The PIC stated that this label was mistakenly printed with the incorrect BUD. See Photo04.	8, 8.1, 9
59.1	CNSP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).	Yes		8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
59.3	CNSP label was verified against the prescription or medication order.	Yes		8, 8.1, 9
59.4	CNSP label was verified against the MFR.	N/A	There is no MFR, just a CR.	8, 8.1, 9
59.5	CNSP label was verified against the CR.	Yes		8, 8.1, 9
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	Yes		8, 8.1
59.7	All checks and inspection that are performed are properly documented.	Yes		8.1, 14

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		Observation	Inspector Notes	USP Reference(s)
59.8	CNSP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal	Yes		8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes	Diluted allergenic extracts.	12
61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If no, go to compliance statements.***	Yes	The compounding area is cleaned prior to compounding. There is no equipment to clean.	5
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	Yes		5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***	Yes		5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).	Yes		6.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	Yes		5 Table 1

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Nonsterile <795> Employee File Records Review

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. *Do not record the employee name, list only their title or position.
From the drop-down List:
*Mark as "Yes" if the document is present in the records and the competency evaluation was conducted in compliance with USP <795> requirements.
*Mark as "No" if the document is present in the records but is not in compliance with USP <795> requirements.
*Mark as "Missing" if any part of the record is missing and explain in Notes column.
*Mark as "N/A" if the training does not apply (e.g., long-term employee may not have initial training available). Document further in the Notes column.

		Employee Records #1	Employee Records #2	Employee Records #3	Employee Records #4	Employee Records #5	
	Employee Title	PIC	Pharmacist	Technician	Technician		Notes
1.0	The training program provides initial training, evaluation, and documentation on the core competencies listed below:						
1.1	Compounding personnel are trained on facility SOPs.	Missing	Yes	Yes	Missing		
1.2	Compounding personnel are trained on USP <795> standards.	Missing	Yes	Yes	Missing		
1.3	The training record for hand hygiene is complete.	Missing	Yes	Yes	Missing		
1.4	The training record for garbing is complete.	Missing	Yes	Yes	Missing		
1.5	The training record for cleaning and sanitizing is complete.	Missing	Yes	Yes	Missing		
1.6	The training record for handling and transporting components and CNSPs is complete.	Missing	Yes	Yes	Missing		
1.7	The training record for measuring and mixing is complete.	Missing	Yes	Yes	Missing		

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	Employee Title	PIC	Pharmacist	Technician	Technician		Notes
1.8	The training record for proper use of equipment is complete.	Missing	Yes	Yes	Missing		
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Missing	Yes	Yes	Missing		
1.10	The training record for interpreting a Certification of Analysis (COA) is complete.	Missing	Yes	Yes	Missing		
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete.	Missing	Yes	Yes	Missing		
1.12	The training record for spill management is complete.	Missing	Yes	Yes	Missing		
2.0	The annual competency assessment was evaluated and documented on the following topics:						
2.1	Compounding personnel are re-trained on facility SOPs.	Missing	Missing	Missing	Missing		
2.2	Compounding personnel are re-trained on USP <795> standards.	Missing	Missing	Missing	Missing		
2.3	The annual competency assessment for hand hygiene is complete.	Missing	Missing	Missing	Missing		
2.4	The annual competency assessment for garbing is complete.	Missing	Missing	Missing	Missing		
2.5	The annual competency assessment for cleaning and sanitizing is complete.	Missing	Missing	Missing	Missing		
2.6	The annual competency assessment for handling and transporting components and CNSPs is complete.	Missing	Missing	Missing	Missing		
2.7	The annual competency assessment for measuring and mixing is complete.	Missing	Missing	Missing	Missing		

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	Employee Title	PIC	Pharmacist	Technician	Technician		Notes
2.8	The annual competency assessment for proper use of equipment is complete.	Missing	Missing	Missing	Missing		
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Missing	Missing	Missing	Missing		
2.10	The annual competency assessment for interpreting a COA is complete.	Missing	Missing	Missing	Missing		
2.11	The annual competency assessment for how to read/interpret a SDS is complete.	Missing	Missing	Missing	Missing		
2.12	The annual competency assessment for spill management is complete.	Missing	Missing	Missing	Missing		
3.0	The designated person(s) has documented a (periodic) evaluation of their direct observations for compounding activities and documented any deficiencies in the record. *Inspector note: if there are not observations documented, the inspector should answer this question as N/A. Per USP, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*	Missing	Missing	Missing	Missing		

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Glossary & References	USP <795>
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as a bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added Substance	An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient.
Administration	The preparation of a nonsterile pharmacologic or other therapeutic agent for ingesting, inserting, applying, or otherwise providing a nonsterile medication in its final form to a single patient. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.
Alcohol-based hand rub	An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Assigned trainer	One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CNSPs.
Beyond-use date (BUD)	The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.
Biological Safety Cabinet (BSC)	A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
Bulk drug substance	See the entry for Active Pharmaceutical Ingredient.
Certificate of analysis (COA)	A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
Cleaning	The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleaning agent	An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Closed-system processing device	A device designed to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples include CVEs, BSCs, or single-use containment glove bags.

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Glossary & References	USP <795>
Component	Any ingredient used in the compounding of a preparation, including any API, added substance, or conventionally manufactured product.
Compounded nonsterile preparation (CNSP)	A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.
Compounding	The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.
Compounding area	An area that is specifically designated for nonsterile compounding.
Compounding personnel	Personnel trained to compound or oversee compounding of preparations.
Compounding record (CR)	Documents the compounding of each CNSP.
Container closure system	Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.
Containment glove bag	A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE)	A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
Conventionally manufactured product	A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Designated person(s)	One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs.
FDA	US Food and Drug Administration
Formulation	The specific qualitative and quantitative composition of the final CNSP.
Hazardous Drug (HD)	Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low dose in humans or animals; genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See <800>.
Label	The part of the labeling on the immediate container.
Labeling	All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container.

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Glossary & References	USP <795>
Master formulation record (MFR)	A detailed record of procedures that describes how the CNSP is to be prepared.
Monograph	A quality documentary standard within USP–NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Oversight	The review, monitoring, and supervision of actions taken by personnel; bearing responsibility for those actions; and being available if and when needed for consultation, even if not physically present.
Preservative	A substance added to inhibit microbial growth.
Purified water	The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). This source water may be purified using unit operations that include deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See <1231>, 3.1.1 Purified Water.)
Quality Assurance (QA)	A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
Quality Control (QC)	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CNSP.
Reconstitution	The process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.
Release inspection and testing	Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Sanitizing agent	An agent for reducing, on inanimate surfaces, the number of microorganisms (eg, 70% isopropyl alcohol).
SDS	Safety data sheet.
SOP	Standard operating procedure.
Specification	The tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.
Stability	The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Verify	To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Water activity (a_w)	A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Note that a_w is not water content.

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Sterile Compounding Inspection for USP <797> Allergenic Extracts

Compounding Allergenic Extracts is for the preparation of patient prescription sets only, and any compounding (e.g., dilution) outside of patient sets must meet the requirements of <797>.

Facility Name: Accumix Pharmacy LLC dba Accumix Pharmacy
e-Profile ID: 1631980
Inspection Date: 2/5/2024

		Observation	Notes	USP Reference(s)
	Personnel Qualifications			
1.0	Does the facility have (a) designated person(s) who meet(s) the requirements in compliance with USP <797> standards for compounding allergenic extracts prescription sets? ***Inspector note: The allergenic extracts prescription sets designated person(s) can be separate from the usual designated person(s).*** ***If no, go to compliance statements.***	Yes		1.1.3, 2, 21.1. 21.2
1.1	The designated person(s) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		18, 21.1
1.2	The designated person(s) is trained and qualified with expertise in allergen immunotherapy.	Yes		21.1
1.3	The designated person(s) is responsible for ensuring that the personnel who will be preparing allergenic extract prescription sets are trained, evaluated, and supervised.	Yes		21.1
2.0	Does the facility ensure that all compounding personnel meet the qualification requirements for compounding allergenic extract prescription sets?	No		21.1

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		Observation	Notes	USP Reference(s)
2.1	Before beginning to independently prepare allergenic extracts, all compounding personnel complete a documented formal sterile compounding training program. ***Inspector note: Per USP, before beginning to independently prepare allergenic extracts, all compounding personnel must complete training and be able to demonstrate knowledge of principles and skills for sterile compounding.***	No		21.1
2.2	Compounding personnel complete documented training and competency **annually.**	No	Annual training and competencies are missing. See Doc01_AE2.2, Doc02_AE2.2, and Doc03AE2.2.	21.1
2.3	Personnel who have not compounded an allergenic extract prescription set in more than **6 months** are evaluated in all core competencies before resuming compounding duties.	No		21.1
3.0	**Hand Hygiene and Garbing Evaluation:** Are the facility's documented hand hygiene and garbing competency evaluations compliant with USP <797> standards for compounding allergenic extract prescription sets? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.***	Yes		21.1, 21.2

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		Observation	Notes	USP Reference(s)
3.1	Before beginning to compound independently, personnel have successfully completed an initial garbing and hand hygiene competency evaluation. ***Inspector note: Per USP, all compounders must successfully complete gloved fingertip and thumb sampling on both hands no fewer than 3 separate times. Each fingertip and thumb evaluation must occur after performing separate and complete hand hygiene and garbing procedures.*** ***It is a RECOMMENDATION the three (3) successful completions be in succession.*** ***If no, inspector should describe what is missing in notes column.***	Yes		21.1, 21.2
3.2	The facility conducts gloved fingertip and thumb sampling procedures as described in **USP <797> Box 1.**	Yes		21.1, 21.2
3.3	Results for all plates are recorded for each sample and do not exceed **USP <797> Table 1** action levels. ***After garbing: >0 cfu/total from both hands***	Yes		21.1, 21.2
3.4	Compounding personnel completes documented hand hygiene and garbing competency evaluations at least every 12 months.	Yes		21.1, 21.2

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		Observation	Notes	USP Reference(s)
3.5	Personnel who fail competency evaluations must successfully pass reevaluations in the deficient area(s) before they can resume compounding of allergenic extract prescription sets. ***Inspector note: Per USP, the designated person(s) must identify the cause of failure and determine appropriate retraining requirements.***	Yes		21.1, 21.2
4.0	**Sterile Technique Evaluation (Media Fill):** Is the pharmacy's documented sterile technique competency evaluation and media fill test compliant with USP <797> standards for compounding allergenic extract sets? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.***	Yes		21.1
4.1	The sterile technique competency evaluation consists of media-fill testing followed by a surface sampling of the direct compounding area. ***Inspector note: If compounding outside of a PEC, the post-media-fill surface sample is not required.***	Yes		21.1
4.2	The facility conducts gloved fingertip and thumb sampling procedures as described in **USP <797> Box 1**	Yes		21.1

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		Observation	Notes	USP Reference(s)
4.3	Results for all plates are recorded for each sample and do not exceed **USP <797> Table 1** action levels. ***After media fill testing: >3 cfu/total from both hands***	Yes		21.1
4.4	Personnel who fail competency evaluations must successfully pass reevaluations in the deficient area(s) before they can resume compounding of allergenic extract prescription sets. ***Inspector note: Per USP, the designated person(s) must identify the cause of failure and determine appropriate retraining requirements.***	Yes		21.1
	Facility Design and Engineering Controls			
5.0	**Primary Engineering Control (PEC):** Does the facility use a **PEC** to compound allergenic extracts? ***Inspector note: Per USP, PECs used to compound allergenic extracts must meet all certification requirements outlined in USP <797>.*** ***If a dedicated Allergenic Extract Compounding Area (AECA) is used for compounding, inspector should mark as N/A.***	Yes		21.3

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		Observation	Notes	USP Reference(s)
6.0	Are **PECs** used to prepare allergenic extracts located in the appropriate space in compliance with USP <797> standards for compounding allergenic extract prescription sets? ***Inspector to review certification reports and observe compounding area(s) to evaluate.*** ***If no, go to compliance statements.*** ***If a dedicated AECA is used for compounding, inspector should mark as N/A.***	Yes		21.3
6.1	The PEC used to compound allergenic extract prescription sets is located away from unsealed windows, doors that connect to the outdoors, and traffic flow.	Yes		21.3
6.2	The PEC is located away from areas that could negatively affect air quality (e.g., restrooms, warehouses, or food preparation areas).	Yes		21.3
6.3	The PEC is located at least 1 meter away from a sink.	Yes		21.3

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		Observation	Notes	USP Reference(s)
7.0	Does the facility ensure that **PECs** used for compounding allergenic extracts are maintained and certified in compliance with USP <797> standards for compounding allergenic extract prescription sets? ***If no, go to compliance statements.*** ***Inspector is to review current certification reports to verify.*** ***If a dedicated AECA is used, inspector should mark as N/A.***	Yes		21.3, 21.8, 5, 5.1
7.1	The most recent PEC certification report(s) are available for review. ***Inspector note: Per USP, PECs used to compound allergenic extracts must be certified at least every 6 months.***	Yes	See Doc08_AE7.1.	4.2, 5, 20, 21.3, 21.8
7.2	Certification reports are reviewed by the designated person(s). ***Inspector note: If the designated person review is not documented, describe how it is ensured that the review occurred.***	Yes		4.2, 5

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		Observation	Notes	USP Reference(s)
7.3	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. ***Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.*** ***If no, describe what occurred and the facility's response to total airborne particle sampling results, data evaluation, and action level (eg, facility took PEC out of service, facility ordered new HEPA filter, PEC was repaired and re-certified).***	Yes		4.1.1, 5.1, Table 4
7.4	Dynamic airflow smoke pattern testing in the PECs were conducted at all critical sites and demonstrates unidirectional airflow and sweeping action over and away from the CSPs. ***Describe if smoke pattern testing of PEC was documented thoroughly in the report or through the use of a video.***	Yes		4.2.2, 4.2.3, 4.5, 5, 9.1

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		Observation	Notes	USP Reference(s)
7.5	**Total (nonviable) particle count** testing was performed under dynamic operating conditions using calibrated electronic equipment. ***Per USP, "Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures...Measurements of total airborne particles in other classified areas, including the buffer room(s) and anteroom(s), should be taken at representative locations that reflect the quality of air in the room(s)."***	Yes		5, 5.1
7.6	All PEC HEPA filters were leak tested (to confirm **HEPA filter integrity**). ***Inspector note: The certification report for each PEC should show velocities within the PEC. In general, the velocities (numbers) should be consistent to identify any HEPA filter leaks that need repair.***	Yes		5
7.7	All PEC HEPA filters with leaks identified were repaired. ***If leaks were not repaired, describe what actions facility took (example: PEC taken out of service until HEPA filter could be replaced).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A		5

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		Observation	Notes	USP Reference(s)
8.0	**Allergenic Extract Compounding Area (AECA):** Does the facility use an **AECA** to compound allergenic extracts? ***If a PEC is used for compounding, inspector should mark as N/A.***	N/A		21.3
9.0	**Allergenic Extract Compounding Area (AECA):** Does the facility meet the facility requirements when using a dedicated **AECA** to compound allergenic extracts in compliance with USP <797> standards for compounding allergenic extracts prescription sets? ***If no, go to compliance statements.*** ***If a PEC is used to compound, inspector should mark as N/A.***	N/A		21.3
9.1	The AECA used to compound allergenic extract prescription sets is located away from unsealed windows, doors that connect to the outdoors, and traffic flow.	N/A		21.3
9.2	The AECA is located away from areas that could negatively affect air quality (eg, restrooms, warehouses, or food preparation areas).	N/A		21.3
9.3	The work surfaces in the AECA are located at least 1 meter away from a sink.	N/A		21.3

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		Observation	Notes	USP Reference(s)
9.4	The AECA is designed to provide a well-lit working environment.	N/A		21.3
9.5	The AECA is designed with temperature and humidity controls. ***Inspector note: Per USP, temperature and humidity controls are for the comfort of compounding personnel wearing the required garb.***	N/A		21.3
9.6	A visible perimeter defines the AECA and access to the AECA during compounding is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning.***	N/A		21.3
9.7	During compounding activities, no other activity is permitted in the AECA.	N/A		21.3
9.8	The surfaces of walls, floors, fixtures, shelving, counters, and cabinets in the AECA are cleanable. ***Inspector note: Per USP, surface should be resistant to damage by cleaning and disinfecting agents. Additionally, carpet is not allowed in the AECA.***	N/A		21.3

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		Observation	Notes	USP Reference(s)
9.9	The surfaces in the AECA upon which the allergenic extract prescription sets are prepared are smooth, impervious, free from cracks and crevices, and non-shedding to allow for cleaning and disinfecting.	N/A		21.3
9.10	If overhangs or ledges are present, they are easily cleanable. ***Inspector note: Dust-collecting overhangs such as utility pipes, ledges, and windowsills should be minimized.***	N/A		21.3
	Cleaning and Disinfection			
10.0	Does the facility clean and disinfect all interior surfaces in the PEC in compliance with USP <797> standards for compounding allergenic extract prescription sets? ***If no, go to compliance statements.*** ***If an AECA is used to compound, inspector should mark as N/A.***	Unknown	Cavicide and Preempt are the daily cleaners, Peridox RTU is the monthly sporicidal. During the inspection there was a bottle of Opti-Cide that did not have a preparation or expiration date. See Photo20_AE10.0, Photo 21_AE10.0, Photo22_AE10.0, and Photo23_AE10.0.	21.4
10.1	The interior and work surfaces of the PEC are cleaned and disinfected each day of use before compounding begins.	Yes		21.4
10.2	The interior and work surfaces of the PEC are cleaned and disinfected when surface contamination is known or suspected.	Yes		21.4

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797> Allergenic Extracts

Compounding Allergenic Extracts is for the preparation of patient prescription sets only, and any compounding (e.g., dilution) outside of patient sets must meet the requirements of <797>.

Facility Name: Accumix Pharmacy LLC dba Accumix Pharmacy
e-Profile ID: 1631980
Inspection Date: 2/5/2024

		Observation	Notes	USP Reference(s)
10.3	Sterile 70% IPA is applied to the horizontal work surface between each prescription set.	Yes		21.4
11.0	Does the facility meet the cleaning and disinfecting requirements for compounding allergenic extracts in an AECA? ***If no, go to compliance statements.*** ***If a PEC is used to compound, inspector should mark as N/A .***	N/A		21.4
11.1	The work surfaces of the AECA, where direct compounding occurs, are cleaned and disinfected each day of use before compounding begins.	N/A		21.4
11.2	The work surfaces of the AECA, where direct compounding occurs, are cleaned and disinfected when surface contamination is known or suspected.	N/A		21.4
11.3	Sterile 70% IPA is applied to the horizontal work surface between each prescription set.	N/A		21.4
11.4	If present, walls, doors, and door frames within the perimeter of the AECA are cleaned and disinfected monthly and when surface contamination is known or suspected.	N/A		21.4
11.5	Ceilings within the perimeter of the AECA are cleaned and disinfected when visibly soiled and when surface contamination is known or suspected.	N/A		21.4

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e-Profile ID: 1631980
Inspection Date: 2/5/2024

		Observation	Notes	USP Reference(s)
	Compounding Personnel Observation - Inspector must observe personnel performing compounding and related activities. If the inspector is unable to view activities from a window or other observation area, it is expected they will gown/garb into compounding area. It is acceptable for facility staff to perform mock compounding activities (with sterile saline or other drug) as long as all observations can be viewed.			
12.0	**Hand Hygiene Observation:** Were compounding personnel entering the compounding area observed performing the appropriate hand washing procedures in compliance with USP <797> standards for compounding allergenic extract prescription sets? ***If no, go to compliance statements.***	No		3.2, Box 3, 21.2
12.1	All personnel entering the compounding area performed hand hygiene.	Yes		3.2, Box 3, 21.2
12.2	Fingernails are cleaned under warm running water using a disposable nail cleaner (eg, nail pick). ***Inspector note: During observations, inspect whether nail picks are available for use when performing hand hygiene.***	No	A nail pick was not used.	3.2, Box 3, 21.2
12.3	Hands and forearms are washed up to the elbows with soap and warm water for at least 30 seconds. ***Inspector note: Compounding personnel describe method for ensuring they have washed for 30 seconds (example: clock or timer is available near the sink).***	Yes		3.2, Box 3, 21.2

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		Observation	Notes	USP Reference(s)
12.4	Hands and forearms are completely dried up to the elbows with low-lint disposable towels or wipers.	Yes		3.2, Box 3, 21.2
12.5	Hand dryers are not used for hand hygiene.	Yes		3.2, Box 3, 21.2
13.0	**Garbing Observation:** Were compounding personnel observed wearing the appropriate garb in compliance with USP <797> standards for compounding allergenic extract prescription sets? ***Inspector note: Garbing procedures must be performed per facility SOPs. The type of garb must be available and utilized per USP <797>.*** ***If no, go to compliance statements.***	Yes		21.2
13.1	The compounder is observed wearing a gown and/or coveralls that are low lint with sleeves that fit snugly around the wrists and an enclosed neck.	Yes		21.2
13.2	The compounder is observed wearing a disposable, low-lint head cover that covers the hair and ears.	Yes		21.2

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		Observation	Notes	USP Reference(s)
13.3	The facility stocks facial hair covers (not masks) that are disposable and low lint. ***If the facility does not have personnel with beards, inspector should answer this statement as N/A.***	Yes		21.2
13.4	The compounder is observed wearing a face mask.	Yes		21.2
13.5	The compounder is observed wearing sterile, powder-free gloves.	Yes	Gloves were donned in anteroom, hands were sprayed with sterile alcohol prior to donning gloves.	21.2
14.0	**Compounding Observation:** Are compounding personnel observed using the appropriate aseptic technique that ensures the quality of the preparation and the environment is maintained, in compliance with USP <797> standards for compounding allergenic extract prescription sets? ***If no, go to compliance statements.***	No	Items not wiped with sterile alcohol before introducing them to the sterile field.	1, 1.1.2, 2.1, 2.3

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		Observation	Notes	USP Reference(s)
14.1	Throughout the compounding process, compounding personnel were observed applying sterile 70% IPA onto all surfaces of the gloves and allowing them to dry thoroughly.	No	Gloves were not sprayed with alcohol each time they were reintroduced into the hood. Gloves are not thoroughly dry before compounding was started/restarted.	21.2
14.2	Compounding personnel ascertain before use that components are of the correct identity, appropriate quality, within the expiration date, and have been stored under the proper conditions.	Yes		9.3.3
14.3	Aseptic processes and manipulations are performed in a manner intended to minimize the risk of contamination. ***Inspector note: Observe the compounder's technique to ensure proper aseptic technique is utilized, such as: preparation occurs in the direct compounding area (DCA); the compounder does not interrupt first air during the compounding process; proper set up of equipment, supplies, and components that ensure first air is not interrupted; the compounder handles the syringe in a manner that does not introduce contaminants (touch contamination on the plunger rod); proper entry and exit of materials in ISO Class 5 PEC; and frequent sanitization of gloves.***	Yes		2.3

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		Observation	Notes	USP Reference(s)
14.4	All critical sites (eg, vial stoppers, ampule necks, and IV bag septums) are wiped with sterile 70% IPA in the PEC and allowed to dry before puncturing.	Yes		7, 8.3, 21.4
14.5	Gloves are regularly inspected for holes, punctures, or tears and are replaced immediately if such defects are detected.	Yes		3.3
	Establishing BUDs			
15.0	Does the facility assign **beyond use dates (BUDs)** in compliance with USP <797> standards for compounding allergenic extract prescription sets? ***If no, go to compliance statements.***	Yes		21.5
15.1	The assigned BUD for the prescription set is no later than the earliest expiration date of any allergenic extract or any diluent that is part of the prescription set.	Yes		21.5
15.2	The assigned BUD does not exceed 1 year from the date the prescription set was mixed or diluted.	Yes		21.5

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		Observation	Notes	USP Reference(s)
	Documentation			
16.0	Does the facility maintain the required documentation in compliance with USP <797> standards for compounding allergenic extract prescription sets? ***Inspector note: Per USP, documents may be maintained in written and/or electronic format.*** ***If no, go to compliance statements.***	Yes		21.8
16.1	The facility maintains written or electronic personnel training records, competency assessments, and qualification records, including corrective actions for any failures .	Yes		21.8
16.2	The facility maintains written or electronic temperature logs for refrigerator(s).	Yes		21.8
16.0	The facility maintains written or electronic compounding records (CR) for individual allergenic extract prescription sets.	Yes		21.8
16.3	The facility maintains written or electronic documents for all complaints and adverse events, including corrective actions taken.	Yes		21.8

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		Observation	Notes	USP Reference(s)
17.0	Are the facility's **labels** for allergenic extract prescription sets in compliance with USP <797> standards for compounding allergenic extract prescription sets and display all required information? ***If no, go to compliance statements.***	Yes		21.6
17.1	The label of each vial of an allergenic extract prescription set displays the patient's name.	Yes		21.6
17.2	The label of each vial of an allergenic extract prescription set displays the type and fractional dilution of each vial, with a corresponding vial number.	Yes		21.6
17.3	The label of each vial of an allergenic extract prescription set displays the BUD.	Yes		21.6
17.4	The label of each vial of an allergenic extract prescription set displays the preparation storage conditions.	Yes		21.6

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		Observation	Notes	USP Reference(s)
18.0	Are **Compounding Records (CR)** for allergenic extracts created and maintained in compliance with USP <797> standards for compounding allergenic extract prescription sets? ***Inspector note: Per USP, a prescription, medication order, or label may serve as the CR. Also, a copy of the MFR can be made that contains spaces for recording the information needed to complete the CR (eg, both the MFR and CR are on the same document/form). A CR may be kept electronically, if readily retrievable, as long as it contains all required information.*** ***If no, go to compliance statements.***	No		21.8, Box 10
18.1	The facility creates and maintains CRs for all individual allergenic extract prescription sets.	No		21.8, Box 10
18.2	The CR includes the name, strength or activity, and dosage form of the allergenic extract.	Yes		21.8, Box 10
18.3	The CR includes the date and time of preparation.	No	Time is missing	21.8, Box 10
18.4	The CR includes an assigned internal identification number (eg, prescription, order, or lot number).	Yes		21.8, Box 10

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		Observation	Notes	USP Reference(s)
18.5	The CR includes the identity of the individual(s) involved in the compounding process.	Yes		21.8, Box 10
18.6	The CR includes the identity of the individual(s) verifying the final preparation.	Yes		21.8, Box 10
18.7	The CR includes the name of each component.	Yes		21.8, Box 10
18.8	The CR includes the vendor/manufacturer, lot number, and expiration date for each component.	Yes		21.8, Box 10
18.9	The CR includes the weight or volume of each component.	Yes		21.8, Box 10
18.10	The CR includes the strength or activity of each component.	Yes		21.8, Box 10
18.11	The CR includes the total quantity compounded.	Yes		21.8, Box 10
18.12	The CR includes the final yield (eg, quantity, containers, number of units).	Yes		21.8, Box 10
18.13	The CR includes the assigned BUD and storage requirements.	No	Expiration date instead of BUD, no storage requirements	21.8, Box 10

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		Observation	Notes	USP Reference(s)
18.14	The CR includes results of quality control procedures (eg, visual inspection, filter integrity testing, pH testing).	No	No description (color etc)	21.8, Box 10
18.15	Calculations have been made to determine and verify quantities and/or concentrations of components and dilutions.	Yes		21.8, Box 10
	Shipping and Transporting			
19.0	Is the facility's shipping and transporting process in compliance with USP <797> standards for compounding allergenic extract prescription sets? ***If no, go to compliance statements.*** ***If the facility does not ship or transport compounded allergenic extract prescription sets, inspector should answer this statement as N/A.***	Unknown	The facility ships prescriptions via ground or second day delivery. Interviewed staff claim they perform winter and summer testing on their packouts but could not provide any of the data. The facility does not have standard packouts that are followed when shipping prescriptions and pack boxes with arbitrary amounts of cold packs.	21.7

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		Observation	Notes	USP Reference(s)
19.1	The facility selects the appropriate mode of transport to deliver properly packed prescription sets in an undamaged, sterile, and stable condition.	Unknown	The facility ships prescriptions via ground or second day delivery. Interviewed staff claim they perform winter and summer testing on their packouts but could not provide any of the data. The facility does not have standard packouts that are followed when shipping prescriptions and pack boxes with arbitrary amounts of cold packs.	21.7
19.2	When shipping or transporting allergenic extract prescription sets that require special handling, specific handling instructions are included on the exterior of the container.	N/A		21.7

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Sterile Compounding Personnel Records Review

Select personnel with compounding responsibilities for your records review; preferably select staff performing compounding duties at time of inspection or staff identified during CR review.
- Recommend also pulling supervising personnel file.
- Inspector can consider pulling non-compounder employee file ("Other") who cleans and stocks compounding area but who does not compound (Note: frequency of competency assessment will be defined by pharmacy SOPs).
Review five (5) personnel files and document your observations. (For applicants seeking a Class E-S Non-Resident Sterile Compounding Inspection (Texas Sampling), review a total of 10 personnel records.)
- *Note: long-term employees may not have initial training available, if this is the case, you may select an alternative file. If an alternate file is not available, document length of service of long-term employee.
Inspector Note: soybean casein digest medium and trypticase soy broth are the same media.

Inspector Instructions

1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position.
2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.
3. Select the appropriate response for each item reviewed.
-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.
-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.
-Select "Missing" if the document is not present in the file.
-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.
4. Use the notes column to document any pertinent information.

Demonstrating Knowledge and Competency of Core Skills (Section 2.1)

USP requirements:
1. Personnel who perform or oversee compounding *or support activities* must be trained in the SOPs and trained on maintaining the quality of the environment (See Table 2).
2. Compounding personnel and supervising personnel must complete training needed to demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions (See Table 2 and Table 3). This must be completed initially and every 12 months in at least the following areas:
-Hand hygiene
-Garbing
-Cleaning and disinfection
-Calculations, measuring, and mixing
-Aseptic technique
-Achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components)
-Use of equipment
-Documentation of the compounding process (eg, master formulation and compounding records)
-Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area
-Proper use of PECs
-Principles of movement of materials and personnel within the compounding area
3. Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control (PEC) must complete ongoing training as required by the facility's SOPs (See Table 3).
4. Personnel compounding only immediate-use CSPs must complete training as required by the facility's SOPs (See Table 3).
5. All training and evaluations must be documented.

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Compounding SOPs	*Initial Training and Competency in Maintaining the Quality of the Environment	*Initial Training and Competency in Sterile Compounding Principles and Practices	Ongoing Training and Competency in Sterile Compounding Principles and Practices	Notes
				Compounders and Supervising Personnel: Initially and at least every 12 months Other Personnel (examples: persons who do not compound but clean/disinfect and restock or who perform in-process checks; persons who only compound immediate use): Initially and as defined by pharmacy SOPs				
#1	Pharmacist	Supervising/Direct Oversight	Category 2 only	Missing	Missing	Missing	Missing	

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#2	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Missing	Found intitial training and competency for Mark and Hanieh Ekhtera, not Jenny or Marco
#3	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Missing	
#4	Pharmacy Technician	Compounder	Category 2 only	Missing	Missing	Missing	Missing	GFS and MF performed, but not annual training/testing (last done 2022)
#5								
#6								
#7								
#8								
#9								
#10								

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Inspector Instructions	Hand Hygiene and Garbing Competency Evaluation (Section 2.2)
1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position. 2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency. 3. Select the appropriate response for each item reviewed. -Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards. -Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column. -Select "Missing" if the document is not present in the file. -Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column. 4. Use the notes column to document any pertinent information.	USP requirements: 1. The garbing and hand hygiene competency evaluation consists of a visual observation and gloved fingertip and thumb sampling (GFT) of both hands. 2. The initial competency evaluation consists of three (3) separate and complete hand hygiene observation, followed by a full garbing procedure and a GFT after garbing. The initial three (3) successful completions must be in succession—failure of any of the three (3) initial garbing competency evaluations requires repeat testing until personnel successfully complete three (3) evaluations in a row. 3. The pharmacy uses a microbiological growth media device (eg, plates, paddles, or slides) containing general microbial growth agar (eg, trypticase soy agar [TSA]) supplemented with neutralizing additives (eg, lecithin and polysorbate 80) that supports both bacterial and fungal growth. 4. The media device is incubated at 30°C-35°C for no less than 48h and then at 20°C-25°C for no less than an additional five days. 5. Failure is indicated by visual observation of improper hand hygiene and garbing procedures and/or GFT results that exceed the defined action levels. Action level after garbing: >0 cfu/total from both hands. 6. Documentation includes, at minimum: -Name of the person evaluated -Evaluation date and time -Media and components used including manufacturer, expiration date, and lot number -Starting temperature for each interval of incubation -Dates of incubation -Results (the number of cfu per hand must be recorded; microbial identification of the cfu is not required by the chapter for GFT) -Results of the evaluation and any corrective actions -Name of the observer and personnel reading and documenting the results

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Hand Hygiene and Garbing Visual Observation	*Initial GFT x 3 (Post hand washing and garbing)	Subsequent GFT (Post handwashing and garbing)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
				Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially at least every 3 months Supervising Personnel: Initially and at least every 12 months				
#1	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	N/A	
#2	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	N/A	

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#3	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	N/A	
#4	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	N/A	
#5								
#6								
#7								
#8								
#9								
#10								

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Inspector Instructions	Aseptic Manipulation Competency (Section 2.3)
1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position. **2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.** **3. Select the appropriate response for each item reviewed.** **-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.** **-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.** **-Select "Missing" if the document is not present in the file.** **-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.** **4. Use the notes column to document any pertinent information.** **5. Document in notes if initial aseptic manipulation competencies are present in files (*unless long-term employee).**	**USP requirements:** **1. Media-fill testing procedures simulate the most difficult compounding procedures encountered by personnel.** **2. The pharmacy conducts media-fill testing as described in Box 2.** **3. The final containers are incubated at 20°C-25°C and 30°C-35°C for a minimum of seven days at each temperature band.** **4. Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container closure unit(s) on or before 14 days.** **5. Immediately following the media-fill test, GFT is performed on both hands and inside of an ISO Class 5 PEC. Failure is indicated by visual observation of GFT results that exceed defined action levels. Action level after media-fill testing: >3 cfu/total from both hands.** **6. Immediately following the GFT, a surface sample of the direct compounding area inside the PEC is performed in accordance with USP standards for surface sample monitoring and action levels. Action level ISO Class 5: >3 cfu/media device.** **7. Failure in the media fill, GFT, or surface sampling constitutes an overall failure of the aseptic manipulation competency.** **8. Documentation includes, at minimum:** **-Name of the person evaluated** **-Evaluation date and time** **-Media and components used including manufacturer, expiration date, and lot number** **-Starting temperature for each interval of incubation** **-Dates of incubation** **-Results (for GFT, the number of cfu per hand must be recorded and for surface samples, the number of cfu per sample must be recorded. Note: microbial identification of the cfu is not required for media-fill testing)** **-Results of the evaluation and any corrective actions** **-Name of the observer and personnel reading and documenting the results**

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Aseptic Manipulation Visual Observation	Media-fill	GFT (post media-fill)	Surface Sampling (post media-fill)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
				Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially and at least every 3 months Supervising Personnel: Initially and at least every 12 months					
#1	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	N/A	
#2	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	N/A	

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#3	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	N/A	
#4	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	N/A	
#5									
#6									
#7									
#8									
#9									
#10									

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GLOSSARY USP <797>
ACD: Automated compounding device.
ACPH: Air changes per hour.
Active pharmaceutical ingredient (API): Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as *Bulk drug substance*. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added substance: An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms *inactive ingredient, excipient, and pharmaceutical ingredient.*
Administration: The direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise providing a sterile product or preparation in its final form.
Airlock: A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas (generally with different air cleanliness standards). The intent of an airlock is to prevent ingress of particulate matter and microbial contamination from a lesser-controlled area.
Alcohol-based hand rub: An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Allergenic extract compounding area (AECA): A designated space, area, or room that is not required to be classified, with a visible perimeter that is suitable for preparation of allergenic extract prescription sets.
Allergenic extract prescription set: Combinations of licensed allergenic extracts that would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved BLAs for the licensed biological products.
Allergenic extract: A biological substance used for the diagnosis and/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy.
Anteroom: An ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The anteroom is the transition room between the unclassified area of the facility and the buffer room.
Aseptic processing: A method by which separate, sterile components (eg, drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (eg, by membrane filtration or by autoclave).

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GLOSSARY USP <797>
Aseptic technique: A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.
Assigned trainer: One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CSPs.
Batch: More than one CSP prepared as described in the MFR in a single, discrete process, and expected to have uniform character and quality, within specified limits.
Beyond-use date (BUD): The date, or the hour and date, after which a CSP must not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
Biological safety cabinet (BSC), Class II: A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare a CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.
Biological safety cabinet (BSC): A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
BLA: Biological license application.
Blood components: Any therapeutic constituent of blood separated by physical or mechanical means (eg, white cells, red cells, platelets, plasma, serum). It is not intended to include plasma-derived products (eg, albumin, coagulation factors, immunoglobulins) manufactured under an approved BLA or equivalent.
BMBL: Biosafety in Microbiological and Biomedical Laboratories.
Buffer room: An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.
Bulk drug substance: See the entry for *Active pharmaceutical ingredient.*
Category 1 CSP: A CSP that is assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in this chapter.
Category 2 CSP: A CSP that may be assigned a BUD of greater than 12 hours at controlled room temperature or greater than 24 hours refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in this chapter.

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GLOSSARY USP <797>
Category 3 CSP: A CSP that may be assigned a BUD exceeding the limits in *Table 13* for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter.
CDC: Centers for Disease Control and Prevention.
Certificate of analysis (COA): A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
CFU: Colony-forming units.
Classified area: An area that maintains an air quality classification based on the ISO standards required in this chapter (see also the definition for *ISO class).*
Cleaning agent: An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Cleaning: The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleanroom suite: A classified area that consists of both an anteroom and buffer room.
Component: Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.
Compounded sterile preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.
Compounded stock solution: A sterile mixture of components that is used to compound additional CSPs.
Compounding area: The area where compounding is occurring (ie, a cleanroom suite, inside the perimeter of the SCA, or AECA).
Compounding aseptic containment isolator (CACI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for the compounding of sterile HDs.
Compounding aseptic isolator (CAI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile non-HDs.

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Compounding record (CR): Documents the compounding of each CSP.
Compounding: The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation.
Container closure system: Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection.
Containment glove bag: A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE): A non-ISO classified full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.
Conventionally manufactured product: A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Critical site: A location that includes any component or fluid pathway surfaces (eg, vial septa, injection ports, and beakers) or openings (eg, opened ampules and needle hubs) that are exposed and at risk of direct contact with air (eg, ambient room or HEPA filtered), moisture (eg, oral and mucosal secretions), or touch contamination.
Designated person(s): One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CSPs.
Direct compounding area (DCA): A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
Disinfectant: A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that also are effective against bacterial and fungal spores.
Dynamic airflow smoke pattern test: A PEC test in which a visible source of smoke, which is neutrally buoyant, is used to observe air patterns within the unidirectional space (i.e., the DCA) under dynamic operating conditions (see the entry for *Dynamic operating conditions).* This test is not appropriate for ISO Class 7 or ISO Class 8 cleanrooms that do not have unidirectional airflow (see the entry for *Visual smoke study).*
Dynamic operating conditions: Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).

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GLOSSARY USP <797>
ECV: Endotoxin challenge vial.
EPA: US Environmental Protection Agency.
Excipient: See the entry for *Added substance*.
FDA: US Food and Drug Administration.
Filter integrity test: A test (eg, bubble point test) of the integrity of a sterilizing-grade filter performed after the filtration process to detect whether the integrity of the filter has been compromised.
Final yield: The total number of containers prepared at the end of the compounding process prior to release testing.
First air: The air exiting the HEPA filter in a unidirectional air stream.
Formulation: The specific qualitative and quantitative composition of the final CSP.
Garb: Items such as gloves, garments (eg, gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle shedding from personnel and minimize the risk of contamination of CSP(s).
GFT: Gloved fingertip and thumb testing.
Hazardous drug (HD): Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.
High-efficiency particulate air (HEPA) filtration: Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.
HVAC: Heating, ventilation, and air conditioning.
Integrated vertical laminar flow zone (IVLFZ): A designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room. In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the worktables and by effective placement of air returns.
IPA: Isopropyl alcohol.

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GLOSSARY USP <797>
ISO class: An air-quality classification from the International Organization for Standardization.
ISO: International Organization for Standardization.
Label: The part of the labeling on the immediate container.
Labeling: All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except any outer shipping container.
Laminar airflow system (LAFS): A device or zone within a buffer room that provides an ISO Class 5 or better air quality environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow.
Laminar airflow workbench (LAFW): A device that is a type of LAFS that provides an ISO Class 5 or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.
Line of demarcation: A visible line on the floor that separates the clean and dirty sides of the anteroom.
Low-lint wiper: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from or easily removed from the wiper material in a dry condition.
Master formulation record (MFR): A detailed record of procedures that describes how the CSP is to be prepared.
MEA: Malt extract agar.
Media-fill test: A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.
Monograph: A quality documentary standard within *USP–NF* that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Multiple-dose container: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed to contain more than one dose of the sterile product. A multiple-dose container is usually required to meet the antimicrobial effectiveness testing criteria. See <659>Injection Packaging Systems, Multiple-dose container.

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GLOSSARY USP <797>
One-step disinfectant cleaner: A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.
Oversight: The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available for consultation if and when needed, even if not physically present.
Pass-through chamber: An enclosure with sealed doors on both sides that should be interlocked. The pass-through chamber is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.
Perimeter: A visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA.
Pharmaceutical isolator: An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. [Note—A CAI or CACI is not a pharmaceutical isolator.]
Pharmacy bulk package: A conventionally manufactured sterile product for parenteral use that contains many single doses intended for use in a pharmacy admixture program. A pharmacy bulk package may either be used to prepare admixtures for infusion or, through a sterile transfer device, for filling sterile containers. See <659>*Injection Packaging Systems, Pharmacy bulk package*.
Positive-pressure room: A room that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the room.
PPE: Personal protective equipment.
Preservative: A substance added to inhibit microbial growth.
Primary engineering control (PEC): A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
Probability of a nonsterile unit (PNSU): The probability of an item being nonsterile after it has been exposed to a verified sterilization process. A PNSU value can only be applied to terminal sterilization. [Note—This is also called the sterility assurance level (SAL).]
Pyrogen: A substance that induces a febrile reaction in a patient.
Quality assurance (QA): A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

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GLOSSARY USP <797>
Quality control (QC): The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.
Reconstitution: The process of adding a diluent to a conventionally manufactured product to prepare a sterile solution or suspension.
Release inspection and testing: Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Repackaging: The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation.
Restricted-access barrier system (RABS): An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.
SDA: Sabouraud dextrose agar.
Secondary engineering control (SEC): The area where the PEC is placed (eg, a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
Segregated compounding area (SCA): A designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only.
Single-dose containers: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed for use with a single patient as a single injection/infusion. A single-dose container usually does not contain a preservative. See <659> Injection Packaging Systems, Single-dose container.
SOP: Standard operating procedure.
Specification: The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.
Sporicidal disinfectant: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
054.022076
051.286496

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
03/31/2026

LICENSED PHARMACY

COMMUNITY, STERILE COMPOUNDING

ACCUMIX PHARMACY LLC
MARCO ONORATO
655 W GRAND AVE STE 240
ELMHURST, IL 60126-1063

MARIO TRETO, JR.
SECRETARY

CAMILE LINDSAY
ACTING DIRECTOR

The official status of this license can be verified at IDFPR.illinois.gov

18502728

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For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 4478285

Illinois Department of Financial and Professional Regulation

Lookup Detail View

Contact

Contact Information

Name	City/State/Zip	DBA / AKA
ACCUMIX PHARMACY LLC	Elmhurst, IL 60126	•

License

License Information

License Number	Description	Status	First Effective Date	Effective Date	Expiration Date	Ever Disciplined
054022076	LICENSED PHARMACY	ACTIVE	11/29/2021	01/11/2024	03/31/2026	N

Other Licenses

Other Licenses

License Number	Description	Status	First Effective Date	Effective Date	Expiration Date	Ever Disciplined
32*****12	LICENSED CONTROLLED PHARMACY SUBSTANCE (Schedules II III IV V)	ACTIVE	11/29/2021	01/11/2024	03/31/2026	N

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☒ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☒ Non-sterile Compounding
			☒ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH 04343		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Apteek Rx, LLC d/b/a Beaker Pharmacy

Physical Address: 7810 Eldorado Pkwy Ste 200

City: McKinney State: TX Zip: 75070

Mailing Address (if different from physical address): same as physical

City: _____ State: _____ Zip: _____

Telephone: (972) 972-4700 Toll Free # (NAC 639.708, NRS 639.23286): (866) 306-3046

Fax: (469) 907-1197 Contact Email: beakerpharmacylicensing@openloophealth.com

Website: https://beakerpharmacy.com/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): David Damaske

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23277

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: David Damaske	NV Pharmacist Registration #: 23277
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): Beaker Pharmacy Buyer, LLC

Corporation/Organization Name: _____

Mailing Address: 317 6TH Ave Ste 400

City: Des Moines State: IA Zip: 50309

Telephone: (303) 532-9007 Email: john.baer@openloophealth.com

Contact Person Name: John Baer

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Apteek Rx, LLC d/b/a Beaker Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Jonathan Lensing

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

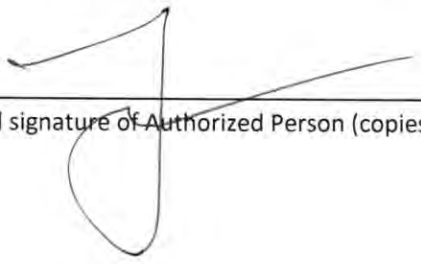
1/15/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Lensing

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

1/15/2026

Date

Board Use Only	Date Received: 1/20/26	Amount: $500 CK 1667572

Apteek Rx, LLC d/b/a Beaker Pharmacy

Owner and Officer List

100% Owner:

Beaker Pharmacy Buyer, LLC
317 6th Ave, Ste 400 Des Moines, IA 50309
FEIN: 39-3019995

Sole Officer:

Jonathan Lensing, President
[redacted]

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for Apteek RX, LLC (file number 802939846), a Domestic Limited Liability Company (LLC), was filed in this office on February 19, 2018.

It is further certified that the entity status in Texas is in existence.

It is further certified that our records indicate DAVID DAMASKE as the designated registered agent for the above named entity and the designated registered office for said entity is as follows:

7810 ELDORADO PKWY, STE 200

MCKINNEY, TX - 75070 USA

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on October 13, 2025.

Jane Nelson
Secretary of State

DISCIPLINARY HISTORY NARRATIVE

TRIAD RX, INC.

Status Summary

- **All disciplinary proceedings have been concluded, and all known investigations closed.**
- **Documentation, including disciplinary complaints, corrective action plans and responses, dispositive pharmacy board orders, and related correspondence are enclosed without exhibits.**
- **All Triad's licenses and permits have remained in good standing at all times.**

Texas Disciplinary Proceeding
(Original – Concluded 2018)

Triad Rx, Inc. ("Triad") holds Texas Pharmacy License #28003 issued by the Texas State Board of Pharmacy (the "TSBP") in 2012. In late 2015, the TSBP adopted rule amendments, effective September 1, 2016, requiring nonresident pharmacies such as Triad to employ a pharmacist-in-charge (a "PIC") who holds a pharmacist license from the TSBP.

On December 15, 2015, the TSBP issued a letter notifying nonresident PICs of this rule change. On June 15, 2016, the TSBP issued a second letter reminding nonresident pharmacy owners of the new PIC-licensing requirement. Both TSBP letters contained the following language "all pharmacy renewal applications submitted on or after September 1, 2016 must include the name and Texas pharmacist license number of the [PIC]...."

Triad's PIC (mis)interpreted this language to mean that TSBP would exercise enforcement discretion with regard to this new requirement so long as a TSBP-licensed PIC was listed on the renewal application next-following the new rule's September 1, 2016 effective date. Accordingly, on February 23, 2017, Robert R. Roberts, III, Triad's PIC, was issued Texas Pharmacist License No. 60196—well in advance of the expiration (and therefore prospective renewal) of Triad's then-current TSBP license.

In March 8, 2018, the TSBP issued a preliminary notice of intent to take disciplinary action (the "Texas Proceeding"), alleging that Triad had operated without a TSBP-licensed PIC from September 1, 2016 through February 22, 2017, in violation of the new rule codified in 22 Tex. Admin. Code § 291.103 (2017).

On April 4, 2018, Triad executed an Agreed Board Order #K-17-005, thereby agreeing to pay an administrative penalty in the amount of $1,000 but without admitting or denying the truth of TSBP's allegations. On May 23, 2018, Triad received notice that the TSBP had taken final agency action in accepting and adopting the Agreed Board Order. Triad self-reported the outcome in writing to the pharmacy regulatory authorities for all other states where Triad holds a pharmacy license within 30 days thereafter.

Triad paid the penalty and retains its Texas license. Triad's PIC did not face any sanction from the TSBP under his Texas pharmacist license.

First Alabama Disciplinary Proceeding
(Derivative – Concluded 2018)

This was derivative of the Texas Proceeding.

Triad is located in Alabama, so Triad's self-reporting of the Texas Proceeding outcome obviously extended to the Alabama Board of Pharmacy (the "ALBP").

In July 2018, the ALBP disclosed its intent to institute disciplinary proceedings against Triad's community pharmacy license. This was a "sister state" action: there were no new facts or substantive allegations in the statement of charges—alleged culpability was to be derived solely from the by-then-concluded matter in Texas described above. In other words, Alabama sought to take disciplinary action and assess a fine against Triad as an Alabama licensee based solely on the fact that another state had previously taken disciplinary action against Triad.

Further, none of the substantive alleged violations—the most recent having occurred over 2 years before the ALBP initiated proceedings, and Triad having passed onsite inspection from ALBP at least twice in that interval—had any direct factual or legal nexus with the State of Alabama, other than the fact that Triad happens to be situated in Alabama.

Triad ultimately signed a consent order to pay a $3,000 fine (triple the amount assessed by the affected State of Texas) because—despite the duplicative nature of the proceedings—the ALBP (technically) had the power to take the disciplinary action in question. This matter was concluded in September 2018.

Maine Disciplinary Proceeding
(Derivative – Concluded 2019)

This was derivative of the Texas Proceeding.

As discussed, Triad self-reported the Texas Proceeding outcome in writing to the pharmacy regulatory authorities for all other states where Triad holds a pharmacy license, including the State of Maine. Maine law, specifically 10 M.R.S. s. 8003-G(2)(C), requires such self-reporting within ten (10) days of final agency action.

Unfortunately for Triad, the Agreed Board Order in the Texas Proceeding was signed on May 1, 2018, but not mailed until May 15; and Triad did not receive it until May 23—well beyond Maine's 10-day deadline.

Accordingly, on July 10, 2019, the State of Maine Board of Pharmacy accepted a Consent Agreement resolving the allegation that Triad had violated 10 M.R.S. s. 8003-G(2)(C) under the following terms: (i) Triad agreed to accept a reprimand and to pay a civil penalty in the amount of $250.00, and (ii) the Maine Board agreed to renew Triad's Maine license.

FDA Warning Letter
(CMS Case #569659)
(Original – Concluded 2023)

Timeline & Summary

- July 2017 – FDA inspected Triad's facility and made observations—all pertaining to sterile compounding.
- July-August 2017 – Triad took immediate and comprehensive corrective action, and requested a reinspection.
- February 2019 – FDA issued a public warning letter 18 months later without any further discussion or acknowledgment.
- October 2019 – FDA replied to Triad's response, claiming that Triad had addressed some, but not all, of the issues, leaving the Warning Letter open until Triad's next inspection.
- July 2021 – Triad ceased all sterile compounding operations.
- December 2022 – FDA conducted a followup inspection.
- May 2023 – FDA notified Triad that the Warning Letter had been closed out, acknowledging that the concerns raised in the Warning Letter had been addressed

Factual Background

1. FDA Inspection, 483, & Triad's Response

On July 17-21, 2017, FDA conducted an onsite inspection of Triad's pharmacy located at 26258 Pollard Road, Daphne, Alabama and licensed by the Board (the "pharmacy"). At the conclusion of that inspection, FDA issued a Form 483 (the "483" – enclosed) describing the inspector's observations. On August 3, 2017, Triad submitted a response to the 483 (the ("483 Response" – enclosed without exhibits) detailing Triad's completed and anticipated corrective actions—and requesting reinspection and/or dialogue.

2. FDA Warning Letter & Triad's Response

FDA did not request a meeting, send a letter or email, make a phone call, or otherwise express dissatisfaction with Triad's 483 Response; and in fact, Triad received no communication from FDA at all for approximately eighteen (18) months—when FDA issued the (public) Warning Letter dated February 5, 2019 (the "Warning Letter").[1]

This course of conduct, although certainly within FDA's discretion, is completely at odds with FDA's stated purpose in issuing 483s in the first instance: "To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration." See 483 at p.4.

Aside from the frustration at FDA having elected to issue the Warning Letter after ignoring Triad's 483 response for a year-and-a-half, Triad was also surprised that FDA placed majority emphasis in the Warning Letter on "ineligible products,"[2] an issue that does not appear **anywhere** in the 483.

In fact, FDA's inspector verbally advised at inspection closeout that he had been instructed through chain of command **not** to include "ineligible products" in 483s issued to 503A pharmacies like Triad, as long as those pharmacies understood the need to "voluntarily" express their willingness to comply with then-interim FDA policy guidance for 503A pharmacies compounding

[1] https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm631101.htm
[2] See Warning Letter, Section B. ("Failure to Meet the Conditions of Section 503A"); Section C. ("Unapproved New Drug Products" and "Misbranded Drug Products"); Section D. ("Corrective Actions").

from bulk drug substances—so as to avoid a warning letter or other regulatory escalation.

Triad naively so "volunteered" in its 483 Response, opening itself to FDA's unprincipled issuance of the Warning Letter, and the resulting deluge of regulatory fallout.

Triad responded to the Warning Letter even more comprehensively than to the 483, painstakingly documenting and detailing each step, each aspect of each particular corrective action. Triad's substantive response to the Warning Letter ("Warning Letter Response" – enclosed without exhibits) is therefore incorporated by reference.

3. FDA Reply & (Eventual) Closeout

On October 18, 2019 FDA replied to Triad's response with the enclosed untitled letter, claiming that Triad had addressed some, but not all, of the issues raised in the Warning Letter.

After nearly **five-and-a-half years**, on December 5-8, 2022, FDA conducted a followup inspection.

By the enclosed letter dated May 3, 2023, FDA notified Triad that, based on the findings of the December 2022 inspection, the Warning Letter had been closed out, acknowledging that the concerns raised in the Warning Letter had been addressed.

Second Alabama Disciplinary Proceeding
(Derivative – Concluded 2022)

Timeline

- July 2021 – Triad ceased **all** sterile compounding operations—for purely business reasons: decreased demand (COVID pandemic), diminishing margins, and rising operational costs (product and environmental testing, inspection/certifications, and regulatory burden).
- May 2022 – ALBOP filed its enclosed complaint in based **solely** on the contents of FDA's 2019 Warning Letter.
- July 2022 – Triad settled with ALBOP effective July 19, 2022 and agreed to pay a fine.

Summary

This was derivative of the Warning Letter, and contained no new allegations. The Consent Order from ALBOP is enclosed.

Wisconsin Disciplinary Proceeding
(Derivative – Concluded 2024)

This was derivative of the (second) Alabama Proceeding, which, in turn, was predicated solely on the issuance of the Warning Letter in 2019.

In September 2023, the Wisconsin Pharmacy Examining Board (the "WPEB") notified Triad of an investigation based on the (second) Alabama proceeding from 2021-22, and eventually initiated disciplinary proceedings (the "Wisconsin Proceeding").

This was another "sister state" action: no new facts or substantive allegations in the

statement of charges—alleged culpability was to be derived solely from Triad's dispensing of sterile compounded preparations to Wisconsin patients—in 2016-17.

Triad ultimately signed a stipulation to pay a $5,000 fine. This matter was concluded in March 2024.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Apteek Rx, LLC dba Beaker Pharmacy

Pharmacy/Wholesaler License # (If applicable): PH04343

Physical Address: 7810 Eldorado Pkwy Ste 200

City: McKinney State: TX Zip: 75070

Mailing Address (if different from physical address): Same

City: State: Zip:

Telephone: (972) 972-4700 Website: https://beakerpharmacy.com/

Licensing Company Email: beakerpharmacylicensing@openloophealth.com

Section 2: Personal Information

First: David Middle: Last: Damaske

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	Address	City	State	Zip	From - To (MM/YY – MM/YY)	Diploma/Degree obtained, if any
Apollo High School		Glendale	AZ		92-96	Gen. Studies
Grand Canyon University		Phoenix	AZ		96-98	N/A
Midwestern University - Glendale		Glendale	AZ		98-01	Pharm. D
Univ. Of Memphis		Memphis	TN		2014-17	MBA

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/24 - present	[redacted]			
2/07 - 5/24				

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Beaker Pharmacy			11/18 – present
Business Address	**City**	**State**	**Zip**
7810 Eldorado Pkwy #200	McKinney	TX	75070
Phone	**Title**	**Number of Employed Hours**	
972-972-4702	PIC	16000 hrs	
Description of Duties			
Founder & PIC; all day to day operations			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, David Damaske, **certify that as the designated representative for**

Apteek Rx, LLC dba Beaker Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

David Damaske

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/16/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Damashe

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/16/26

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Collin

I, David Damashe, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/16/26

Date

Subscribed and Sworn to before me this 6th day of Jan 26.

Notary Public Signature

Harendra Patel
NOTARY PUBLIC - STATE OF TEXAS
ID# 134216212
COMM. EXP. 02-23-2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Apteek Rx, LLC d/b/a Beaker Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): PH04343

Physical Address: 7810 Eldorado Pkwy Ste 200

City: McKinney State: TX Zip: 75070

Mailing Address (if different from physical address): Same

City: State: Zip:

Telephone: (972) 972-4700 Toll Free # (NAC 639.708, NRS 639.23286): (866) 306-3046

Fax: (469) 907-1197 Contact Email: beakerpharmacylicensing@openloophealth.com

Website: https://beakerpharmacy.com/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): David Damaske

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23277

Name of Designated Person(s) as defined by revised USP-797 guidelines: David Damaske

Email of Designated Person(s): david@beakerpharmacy.com

Telephone of Designated Person(s): 972-972-4700

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ☐ Category 2 ☑ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☐ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ☑ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? Iso 7

6. What is the frequency of the recertification for the ISO classified areas? Q6 mo

7. Were there any follow-up items required from the most recent certification report? ☑ Yes ☐ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☑ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? _____

10. Will you be performing sterile hazardous drug compounding? (Yes) (No)

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Semaglutide + B6 + L-carnitine
Tirzepatide + B6 + L-carnitine
NAD+
Glutathione
Testosterone

12. What laboratory performs your sterility or endotoxin testing?

Name: PCCA / Eagle
Address: 11111 S. Wilcrest Dr 51000
City: Houston State: TX Zip: 77099
Telephone: 800-745-8916

13. What is your procedure for visual inspection of compounded sterile products?

Check each vial against black/white board
Make sure crimped & sealed properly
clear of particulates

14. How often do you perform glove fingertip and medial fill testing?

Q3mo

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Initial GFT - 3x remem gloves & plate
ongoing - observe gowning Q3mo, plate each hand once; incubate 30-35° x 2d then 5d in 20-25°

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

cleaning ⇒ hood: daily before/after each batch; between batches
Daily hoods, high touch areas, floors

TBI 3300
Peridox

monthly clean - walls, ceiling, hoods, surfaces in all rooms

17. Who performs the sterile compounding process at your facility?

sterile techs

18. Who is responsible and accountable for the sterile compounding process at your facility?

Sheila Cline

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

styrofoam container, foam ice blocks

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Laminar Flow Hoods BSC		
2. Are you complying with all USP 800 guidelines?	(Yes)	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	(Yes)	No
4. Is your BSC or CACI vented 100% to the outside?	(Yes)	No
5. Do you have a negative pressure buffer room at your facility?	(Yes)	No
6. Will you be compounding with antineoplastic HDs or HD API?	(Yes)	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	(Yes)	No
8. Will you be utilizing a closed system transfer device?	Yes	(No)
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

In patient printout there is informatic based on the particular med/API involved.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

See attached checklist

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

Semaglutide + B6 + L-carnitine
Tirzepatide + B12 + L-carnitine
NAD+
Glutathione
Testosteron
Sermorelin
methylcobalamin

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

93 mo

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? (Yes) No

4. What is the frequency for completing volumetric active air sampling?

monthly

5. What is the frequency for completing surface sampling? weekly & after each batch	
6. What is the frequency for using sporicidal agents? weekly in non-HD & w/ monthly clean HD → start & end of cmpd process, between batches & if saturated area	
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	(Yes) No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	(Yes) No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Damoske

Name of Person who Completed the Form

PIC

Title

Signature (copies or stamps not accepted)

1/6/26

Date

Board Use Only	Date Received: 1/7/26 Date Approved: _____ Approved By: _____

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

See attached checklist

Duplicate

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

Semaglutide + B6 + L-carnitine
Tirzepatide + B6 + L-carnitine
NAD+
Glutathione
Testosterone
Sermorelin
methylcobalamin

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

93mo

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? (Yes) No

4. What is the frequency for completing volumetric active air sampling?

monthly

Beaker Pharmacy
7810 Eldorado Pkwy #200
McKinney, TX 75070

STERILE TRAINING CHECKLIST

Employee Name: _____

Sterile Training and Competency Assessment:

Technique & Competency: Sterile Personnel Only	Demonstrated By: Initial/Date	Trainee's Acknowledgement: Initial/Date	Comments
Hand Hygiene and Garbing (PPE)			
Decontamination/Cleaning/Disinfection -Agents and Process			
Aseptic Technique *Vertical Laminar hood *Biological Safety Cabinet			
3X Gloved Fingertip Testing			
Customized High Risk Media Fill Test			
Post-Media fill Surface and Gloved Fingertip sampling			

Sterile Dosage form Competency Assessment:

Sterile Dosage Form	Demonstrated By: Initial/Date	Trainee's Acknowledgement: Initial/Date	Comments
Injection Solution			
Injection Suspension			
Ophthalmic Solution/Suspension			
Inhalation Formulation			
Misc.			

Beaker Pharmacy
7810 Eldorado Pkwy #200
McKinney, TX 75070

Misc.			

Sterile Supplies & Equipment Knowledge Check:

Supplies & Equipment	Demonstrated By: Initial/Date	Trainee's Acknowledgement: Initial/Date	Comments
Filters (Follow Filter Guide) _____ *PTFE (disc & capsule) _____ *PES (disc & capsule) _____ *0.2 micron _____ *1.2 micron _____			
Sterile Vials, seals, stoppers *13mm _____ *20mm _____			
Crimper *13mm _____ *20mm _____			
Sterile Needles & Syringes			
Ophthalmic Droptainers Sizes and assembly			
Filter Integrity Tester			
Depyrogenation Oven (cycle types)			
Autoclave (cycle types)			
Incubator: -Media vials storage _____ -Plates for surface/hand hygiene sampling _____			
BSC-Biological Safety Cabinet			
Vertical Laminar Hood			
Dry Heat Block Incubator			
Powder Containment Hood			

Beaker Pharmacy
7810 Eldorado Pkwy #200
McKinney, TX 75070

Decontaminating Agent: -Peridox-RTU -Avert-RTU -Sodium Hypochlorite 6K sol. (in house)			
Cleaning Agent: -Peridox RTU -Decon-RTU -Sterile Water for Injection			
Disinfection Agent: -Sterile Isopropyl Alcohol 70%			
Sterile Mops/mop covers/wips			
Dishwashing Cleaner: -Luminox -Alconox -Misc.			

Training Documentation Checklist:

Training Documentation	**Trained by: Initial/Date**	**Trainee: Initial/Date**	**Comments**
Facility and Staff Orientation			
SOP Initial and Periodic Review			
Job Description			
OSHA and HIPPA training			
Sterile Log Worksheet Quality check acknowledgement			
Sterile Products quarantine procedure for Third Party batches			
Sterile Supplies-Daily, Weekly, and as needed restocking duties			
Sterile Supply Ordering & Inventory check/management			

Autoclave Block Incubator-STEAM use			
Repeater Pump			
Sterile IV-Tubing			
Labeled-Totes for Supply storage			
Autoclave supplies: -Pouches -Cleaner -Biological Indicator -Chemical Indicator			
Oven supplies: -Nylon bags -Chemical Indicator -Biological Indicator -Foil			
Misc.			

In-House and Third Party Sterile Logs:

Procedure	Demonstrated By: Initial/Date	Trainee's Acknowledgement: Initial/Date	Comments
Sterile Formulation Preparation Procedure			
In-House Sterility Testing Procedure			
Third Party Sterility/Endotoxin Procedure			

Sterile Cleaning Supplies Knowledge:

Cleaning Agent/Supply	Trained by: Initial/Date	Trainee: Initial/Date	Comment/Reference

Beaker Pharmacy
7810 Eldorado Pkwy #200
McKinney, TX 75070

Sterile Environmental monitoring for temperature, pressure, humidity, balance calibration, cleaning, and disinfection of ISO areas: Daily _____ Monthly _____			
Expired chemical identification/removal process			

TEXAS STATE BOARD OF PHARMACY

Pharmacist in Charge Attestation:

I hereby attest the following statements are true and accurate (initial each statement below):

DH I am the Pharmacist-in-Charge (PIC) of *BEAKER PHARMACY*, pharmacy license number *32264*, and I ☐ was/ ☑ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *08/22/2025*.

DH I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

DH I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF.

DH If applicable, the Warning Notice issued contains *1* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

DH I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please email this completed form to the TSBP Compliance Inspector for your area or to inspections@pharmacy.texas.gov within 7 days of the date of the inspection.

Signed: DH

Date: 8/22/25

Printed Name: *DAMASKE, DAVID LAWRENCE*

License No.(If applicable): *41186*

TEXAS STATE BOARD OF PHARMACY

Pharmacist (or other Responsible Party) on Duty Attestation:

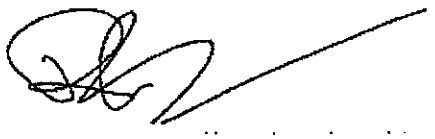
I hereby attest the following statements are true and accurate (initial each statement below):

RB I am the Pharmacist (or other responsible party) on duty at *BEAKER PHARMACY*, pharmacy license number *32264* during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *08/22/2025*.

RB At the conclusion of the inspection, the Officer/Inspector left the following documents in my possession (check each applicable)

- ☑ Notice of Inspection
- ☑ Inspection Report
- ☑ Warning Notice outlining *1* deficiencies
- ☑ Pharmacist-in-Charge Attestation Form with the handout titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF.

RB I will provide all of the records listed above, including this attestation, regarding the inspection to the Pharmacist-in-Charge(PIC), within 3 business days and ensure the PIC understands that he/she must file the completed PIC attestation within 7 days of the date of receipt (unless otherwise noted).

Signed:  Date: *08/22/2025*

Printed Name: *Robert Blanford* License No.(if applicable): *33295*

Texas State Board of Pharmacy

"Red Flags" Checklist for Pharmacies

YOU MIGHT BE A PILL MILL IF...

Check all that apply:

	(1) Your pharmacy fills a discernable pattern of prescriptions for prescribers who write essentially the same prescriptions for numerous persons, indicating a lack of individual drug therapy
	(2) Your pharmacy operates with limited hours of operation or closes after a certain threshold of controlled substance prescriptions are dispensed, and has overall low prescription dispensing volume.
	(3) Prescriptions presented to the pharmacy are for controlled substances with popularity as street drugs, such as opiates, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups, or any combination of these drugs.
	(4) The prescriptions for controlled substances contain nonspecific or no diagnoses.
	(5) The prescriptions are commonly for the highest strength of the drug and/or for large quantities.
	(6) Dangerous drugs or OTC products (such as multi-vitamins or laxatives) are added to the controlled substance prescriptions, maintaining relatively consistent 1:1 ratio of controlled substances to dangerous drugs and/or OTC products dispensed as prescriptions.
	(7) Prescriptions are authorized by the same prescriber with what appears to be different handwriting on the hardcopy prescription drug order forms.
	(8) Upon contact with the prescriber's office, you are unable to engage in comprehensive discussion with the actual prescriber, or he/she is unconcerned about your apprehensions regarding his/her prescribing practices or unwilling to provide additional information, such as treatment goals and/or prognosis with prescribed drug therapy.
	(9) You rely solely on the prescriber's representation, or on the representation of the individual answering the phone at the number on the prescription, that prescriptions are legitimate.
	(10) The prescriber's clinic is not registered as a pain management clinic by the Texas Medical Board, despite routinely receiving prescriptions from the prescriber foropiates, benzodiazepines, and/or muscle relaxants.
	(11) Drugs prescribed are inconsistent with the prescriber's area of practice.
	(12) The prescriber of the drugs is located a significant distance from your pharmacy.
	(13) The prescriber has been subject to disciplinary action by the licensing board, had his/her DEA registration removed, or been subject to criminal action.
	(14) The Texas PMP system indicates that persons are obtaining prescriptions for the same drugs from multiple prescribers or that persons are filling prescriptions for the same drugs at multiple pharmacies.
	(15) The person's address is a significant distance from your pharmacy and/or from the prescriber's office.
	(16) Multiple persons with the same address present prescriptions from the same prescriber.
	(17) Persons pay with cash or credit card more often than through insurance.
	(18) Persons presenting controlled substance prescriptions are doing so in such a manner that varies from seeking routine pharmacy services (e.g., willing to wait in long lines to receive drugs, persons arrive in the same vehicle with prescriptions from same prescriber, one person presents to pick up prescriptions for multiple others, persons refer to drugs by "street names" and/or comment on drug's color, persons seek early refills, persons travel from outside reasonable trade area of pharmacy).
	(19) Your pharmacy charges and persons are willing to pay more for controlled substances than they would at nearby pharmacies.
	(20) Your pharmacy routinely orders controlled substances from more than one drug supplier, or your pharmacy has been discontinued by a drug supplier related to controlled substance orders.
	(21) Sporadic and non-consistent dispensing volume (including zero dispensing) varies from day to day and week to week, and your pharmacy does not maintain operational hours each week on Monday through Friday.
	(22) Your pharmacy employs or contracts security personnel during operational hours to prevent problems.
	(23) Your pharmacy has been previously warned or disciplined by the Texas State Board of Pharmacy for inappropriate dispensing of controlled substances (i.e., corresponding responsibility).

If you checked any of the above items, you should review the laws and rules regarding corresponding responsibility and non-therapeutic dispensing, especially Board rule §291.29, in the law book or on our website: www.pharmacy.texas.gov (click on Texas Pharmacy Rules and Laws). Additional educational material is available at: http://www.pharmacy.texas.gov/Nontherapeutic.asp. Failure of pharmacies and pharmacists to detect patterns of inappropriate dispensing of prescription drugs is unprofessional practice and constitutes grounds for disciplinary action.

Updated 2/2018

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Notice of Inspection

Facility Information

Name: *BEAKER PHARMACY*
License Number: *32264*
Address: *7810 ELDORADO PKWY STE 200, MCKINNEY, TX 75070*
Phone: *(972) 972-4700*
Email:
Class of License: *AS*
License Expiration: *09/30/2026*
DEA #:
DEA Expiration:

Inspection Information

Type: *Compliance*
Purpose: *Other*
Purpose Other: *Emend 08202025*
Date: *08/22/2025*
Arrival Time: *1:15 PM*

Acknowledgment

This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.



Robert Blanford *Staff* *33295*

Witness



Cedric Johnson

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *BEAKER PHARMACY* License Number: *32264*

Class of License: *AS*

Inspection Information

Type: *Compliance* Purpose: *Other* Purpose Other: *Emend 08202025*

Date: *08/22/2025* Arrival Time: *1:15 PM* Departure Time: *2:15 PM*

Action Taken: *Partial Inspection*

General Comments: *Corrected the quoted law in warning notice, regarding out of state practitioners.*

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary	*Not Inspected*
01. Required licenses posted	*Not Inspected*
09. Active licenses/certifications	*Not Inspected*
62. No aiding and abetting	*Not Inspected*
65. Proper registration procedures	*Not Inspected*
79. Identification badges	*Not Inspected*

Inventory Records

15. Change of PIC inventory	*Not Inspected*
17. Meets inventory requirements	*Not Inspected*
59. Proper drug destruction	*Not Inspected*
68. Change of ownership controlled substance inventory	*Not Inspected*
69. Annual controlled substance inventory	*Not Inspected*

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?)	*Not Inspected*
34. Notifications	*Not Inspected*
76. PIC (Does the pharmacy have a pharmacist-in-charge?)	*Not Inspected*

Environment/Equipment/Security

03. Orderly/Clean	*Not Inspected*
04. Balance inspection	*Not Inspected*
05. Equipment Inspection	*Not Inspected*
07. Security	*Not Inspected*
08. Environment	*Not Inspected*
48. Drugs (procurement, temperature, security, out-of-date, samples)	*Not Inspected*
90. TSBP complaint notification	*Not Inspected*

Controlled Substances

10. Prescriptions separated	*Not Inspected*
24. Theft/Loss	*Not Inspected*
26. Controlled substance prescription compliance	***Unsatisfactory***

291.34(b)(2)(B)(ii).
Prescriptions. Written prescription drug orders. Prescription drug orders written by practitioners in another state. A pharmacist may dispense prescription drug orders for controlled substances in Schedule III, IV, or V issued by a physician, dentist, veterinarian, or podiatrist in another state provided:

- the prescription drug order is issued by a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal DEA registration number, and who may legally prescribe Schedule III, IV, or V controlled substances in such other state;
- the prescription drug order is not dispensed or refilled more than six months from the initial date of issuance and may not be refilled more than five times; and
- if there are no refill instructions on the original prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original prescription drug order have been dispensed, a new prescription drug order is obtained from the prescribing practitioner prior to dispensing any additional quantities of controlled substances

Warning Notice **Due Date for Completed Correction:** *09/21/2025*

Failure to comply regarding dispensing prescriptions from foreign practitioners and out-of-state APNs and PAs. Cease this practice and correct/resolve deficiency by date noted.

30. Controlled substance invoices dated/initialed by pharmacist	*Not Inspected*
35. Controlled substance invoices separated	*Not Inspected*
46. Drug distribution	*Not Inspected*
53. Possession of controlled substances	*Not Inspected*
Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?)	*Not Inspected*

Labeling/Prepackaging

32. Prescription label (Is prescription label complete?)	*Not Inspected*
45. Proper dispensing/labeling	*Not Inspected*
54. Proper prepackaging procedures	*Not Inspected*

Library

06. Required Library	*Not Inspected*

Training

60. Documentation of required training	*Not Inspected*
61. Supervision of supportive personnel	*Not Inspected*

Patient/Computer/Dispensing Records

18. Records available	*Not Inspected*
22. Data processing system compliance	*Not Inspected*
25. Prescriptions (complete, retrievable, auto-refills, accelerated refills)	*Not Inspected*
37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?)	*Not Inspected*
56. Prescription transfers	*Not Inspected*
67. Written drug information provided	*Not Inspected*
80. Patient counseling	*Not Inspected*
82. Patient Medication Records	*Not Inspected*
84. Drug regimen review	*Not Inspected*
86. Absence of pharmacist records	*Not Inspected*

Policies & Procedures/SOPs

70. Required policies & procedures/SOPs	*Not Inspected*
92. Automated dispensing policy & procedures/SOPs	*Not Inspected*

Non-Sterile Compounding

03. Orderly/Clean/Hand Hygiene	*Not Inspected*
04. Balance inspection (for non-sterile compounding)	*Not Inspected*
05. Equipment Inspection	*Not Inspected*
06. Non-sterile Library	*Not Inspected*

32. Non-sterile compound label (Is label complete?)	*Not Inspected*
38. Area/Environment for non-sterile compounding	*Not Inspected*
43. Records for non-sterile compounding	*Not Inspected*
60. Documentation of non-sterile required training	*Not Inspected*
70. Required policies & procedures/SOPs	*Not Inspected*
87. Quality Control/Assurance	*Not Inspected*

Compounded Dosage Forms

Allergen extracts	*Not Inspected*
Parenteral solutions	*Not Inspected*
Parenteral suspensions	*Not Inspected*
Preservative-free parenterals	*Not Inspected*
Ophthalmic preparations	*Not Inspected*
Oral or nasal inhalation preparations (not topical spray)	*Not Inspected*
Bath or soaks for live organs/tissues	*Not Inspected*
Irrigations for wounds or body cavities	*Not Inspected*
Any other sterile preparations (implants, pellets, etc) [list]	*Not Inspected*
Investigational drugs	*Not Inspected*
Blood products or other biological materials (wound care, autologous, eye drops, etc)	*Not Inspected*
Any compounds using federally controlled substances Schedule I-V (list and percentage)	*Not Inspected*
Does the pharmacy use lyophilizer?	*Not Inspected*

Environment (Sterile)

S109. Is the cleanroom clean and free of objects that shed particles?	*Not Inspected*
S110. Is the cleanroom used only for sterile preparations?	*Not Inspected*
S119. Does the cleanroom contain only appropriate supplies?	*Not Inspected*
S101. Does the ante-area provide at least ISO Class 8 air quality under dynamic conditions?	*Not Inspected*
S115. Does the ante-area contain a hands-free sink with hot and cold running water?	*Not Inspected*
S102. Does the buffer area provide at least ISO Class 7 air quality under dynamic conditions?	*Not Inspected*
S106. Is the buffer area free from sources of water (e.g., sink, floor drains)?	*Not Inspected*
S108. Is there hands-free access to the buffer area?	*Not Inspected*

S113. Are floors, walls, ceilings & fixtures smooth, impervious and free from cracks & crevices? *Not Inspected*

S112. Does the floor covering enable regular disinfection? *Not Inspected*

S118. Are supplies stored above the floor to permit adequate floor cleaning? *Not Inspected*

S127. Does the clean room have a pressure gauge or velocity meter to monitor pressure differential between buffer area and ante-area and between the ante-area and the general environment? Is the pressure differential at least 0.02" wc? *Not Inspected*

S116. Are temperature and humidity monitored, documented and within the required range? *Not Inspected*

S167. Is there a thermometer available for the cleanroom and refrigerator(s)? *Not Inspected*

Primary Engineering Control (PECs) Device

S126. Is the laminar air flow hood located in a buffer area that has a minimum differential positive pressure of 0.02" wc? *Not Inspected*

S121. Is the PEC able to maintain at least ISO Class 5 conditions while compounding sterile preparations? *Not Inspected*

S246. Are hazardous drugs prepared in a Class II/III vertical flow BSC or CACI located in an ISO Class 7 area physically separated from other areas? *Not Inspected*

S247. Does the area where the BSC or CACI is located have not less than 0.01" wc negative pressure adjacent to the positive pressure ISO Class 7 area? *Not Inspected*

S105. Does the CAI or CACI provide unidirectional airflow? *Not Inspected*

S104. If the CAI or CACI is used for high-risk sterile compounding, is it placed in an ISO Class 8 area? *Not Inspected*

S122. If the CAI is not required to be placed in an ISO Class 7 area, does the pharmacy maintain documentation from the manufacturer? *Not Inspected*

S124. Is the PEC certified by an independent contractor every 6 months and when relocated? *Not Inspected*

S125. Are prefilters inspected periodically and replaced as needed? *Not Inspected*

S128. Are differential pressures monitored and documented at least every work shift (at a minimum daily) or by a continuous recording device? *Not Inspected*

Equipment and Supplies

S174. Does the pharmacy have disposable needles, syringes, and other required or applicable supplies? *Not Inspected*

S177. Does the pharmacy have lint-free towels or wipes? *Not Inspected*

S180. Does the pharmacy have masks, caps, gowns with tight cuffs, shoes covers, and beard covers (if applicable)? *Not Inspected*

S176. Does the pharmacy have handwashing agents with bactericidal action? *Not Inspected*

S175. Does the pharmacy have disinfectant cleaning solutions and dedicated cleaning supplies? *Not Inspected*

S179. Does the pharmacy have hazardous spill kits, if applicable? *Not Inspected*

S171. Does the pharmacy have appropriate containers for needles and syringes? *Not Inspected*

S170. Does the pharmacy have sterile isopropyl alcohol, sterile gloves, and waterless alcohol-based surgical hand scrub? *Not Inspected*

S178. Does the pharmacy have appropriate filters and filtration equipment? *Not Inspected*

S181. If an automated compounding device is used, does the pharmacy calibrate & verify the device for accuracy, and document at least daily? *Not Inspected*

S172. Does the pharmacy have packaging or delivery containers to maintain proper storage conditions for sterile preparations? *Not Inspected*

High Risk CSPs

S103. If high-risk CSPs are compounded, does the buffer area provide physical separation from other compounding areas? *Not Inspected*

S231. Is sterility testing performed if CSPs are prepared in groups > 25, or *Not Inspected*

S232. If MDVs are prepared for multiple patients or when exposed > 12 hours at 2-8 degrees C before sterilized, or *Not Inspected*

S233. If exposed > 6 hours at warmer than 8 degrees C before sterilized? *Not Inspected*

S237. Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with pyrogen-free or depyrogenated sterile water, and then thoroughly drained or dried immediately before use for high-risk sterile compounding? *Not Inspected*

S238. Are all high-risk sterile solutions subjected to terminal sterilization prefiltered using no larger than a 1.2-micron filter to remove particulate matter? Is sterilization by filtration performed with a sterile 0.2 – 0.22 micrometer pore size filter within an ISO Class 5 environment or better? *Not Inspected*

S165. Are filter integrity tests being performed and documented (e.g., bubble point test)? *Not Inspected*

S239. Are pre-sterilization procedures (weighing and mixing) completed in an ISO Class 8 environment or better? *Satisfactory*

Sterile Library

S154. Does the pharmacy have a reference on injectable drugs? *Not Inspected*

S155. Does the pharmacy have a specialty reference? *Not Inspected*

S156. Does the pharmacy have all of the required (USP chapters 71, 85, 795, 797, 1163) and applicable USP chapters? *Not Inspected*

Hazardous CSPs

S242. Do personnel wear protective apparel at all times when hazardous drugs are handled? *Not Inspected*

S243. Do personnel use appropriate safety and containment techniques when preparing hazardous CSPs? *Not Inspected*

S244. Do personnel dispose of hazardous waste in compliance with local, state, and federal regulations?	*Not Inspected*
S245. Do personnel affix a proper label, including proper precautions inside and outside of the packaging?	*Not Inspected*
S248. Does the pharmacy have a pressure indicator that can be readily monitored for correct room pressurization?	*Not Inspected*
S249. Does the pharmacy meet the requirements for low volume preparation of hazardous drugs by using a device that provides two-tiers of containment (e.g., closed-system vial transfer device within a BSC)?	*Not Inspected*
S250. Are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure?	*Not Inspected*
Does the pharmacy have a plan to comply with USP <800> by the implementation date?	*Not Inspected*
Are hazardous drugs stored separately in compliance with USP <800> (negative pressure at least -0.01" wc to adjacent areas and with at least 12 ACPH)?	*Not Inspected*
Is hazardous drug waste quarantined in a designated area?	*Not Inspected*
Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)?	*Not Inspected*

Personnel Cleansing, Garbing, Hand Hygiene

S202. Does hand sanitizing and gowning occur in the ante-area (outside of the buffer area)?	*Not Inspected*
S180. Do compounding personnel don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclose at the neck? Is the order of garbing appropriate (dirtiest to cleanest)?	*Not Inspected*
S194. Before entering the buffer area, do compounding personnel remove cosmetics?	*Not Inspected*
S195. Before entering the buffer area, do compounding personnel remove all hand, wrist, and other body jewelry/piercings?	*Not Inspected*
S196. Are natural nails kept neat and trim and no wearing of artificial nails or extenders?	*Not Inspected*
S200. Do compounding personnel remove debris from underneath fingernails using a nail cleaner under running warm water?	*Not Inspected*
S192. Are personnel with an apparent illness or open lesions compounding sterile preparations?	*Not Inspected*
S241. When compounding personnel temporarily exit the ISO Class 7 environment, are re-donning procedures properly followed?	*Not Inspected*
S201. Do compounding personnel engage in proper hand hygiene?	*Not Inspected*
S203. Do compounding personnel completely dry hands and forearms using lint-free disposable towels or hand dryer?	*Not Inspected*
S204. Is antiseptic hand cleansing performed using waterless alcohol-based surgical scrub once inside the buffer area and prior to donning sterile gloves?	*Not Inspected*

S206. Is sterile isopropyl alcohol applied to gloves throughout the day and when non-sterile surfaces are touched? *Not Inspected*

Cleaning/Disinfection Procedures

S182. Does the pharmacy have written procedures on the cleaning and disinfecting of the direct and contiguous compounding areas (e.g., beginning of shift, every 30 minutes, before each batch, spills)? *Not Inspected*

S230. Is cleaning performed by trained personnel using approved agents (described in written SOPs)? *Not Inspected*

S228. Are supplies & equipment that are removed from shipping cartons wiped with a disinfecting agent (e.g., sterile IPA)? *Not Inspected*

S226. Are work surfaces and floors in the ante-area and buffer area cleaned and disinfected daily with dedicated supplies? *Not Inspected*

S227. Are walls, ceilings and shelving in the ante-area and buffer area cleaned and disinfected at least monthly? *Not Inspected*

S229. Does the pharmacy maintain documentation of cleaning procedures (i.e., date/time of cleaning, type of cleaning, name of individual who performed the cleaning)? *Not Inspected*

Environmental Sampling

S270. Is surface sampling conducted in all ISO classified areas on a periodic basis? *Not Inspected*

S272. Is viable air sampling performed? *Not Inspected*

S273. Is viable air sampling documented by properly trained individuals for all risk levels every 6 months? *Not Inspected*

S271. Are environmental sampling results evaluated and addressed (i.e., action levels followed)? *Not Inspected*

Records of CSPs

S252. Does the pharmacy maintain records relating to CSPs for a minimum of 2 years? *Not Inspected*

S253. Do compounding records include the date and time of preparation of a CSP? *Not Inspected*

S254. Do compounding records include the complete formula of a CSP? *Not Inspected*

S257. Do compounding records include the quantities of materials used in a CSP? *Not Inspected*

S255. Do compounding records include the signature or initials of who prepared a CSP? *Not Inspected*

S256. Do compounding records include the signature or initials of who conducted the final check of a CSP? *Not Inspected*

S258. Do compounding records include the container used and the number of units prepared for a CSP? *Not Inspected*

S259. Do compounding records include the criteria used to determine the beyond-use date of a CSP? *Not Inspected*

S260. Do compounding records include the documentation of performance of quality control procedures? *Not Inspected*

S261. Are master worksheets and preparation worksheets for batch compounding complete? *Not Inspected*

S262. Are master worksheets developed and approved by a pharmacist? *Not Inspected*

General Operational Requirements

S166. Is a pharmacist available at all times (24/7)? *Not Inspected*

S187. Are written SOPs developed and implemented for all significant procedures in the compounding area to include at a minimum: the facility, equipment, personnel, preparation evaluation, quality assurance, preparation recall, packaging, and storage of CSPs? *Not Inspected*

S188. Does the pharmacy have all required written policies (e.g., pharmaceutical care services, sampling plan, recalls)? *Not Inspected*

S158. If the pharmacy compounds commercially available products, does the pharmacy document the need by verifying and monitoring a drug shortage list (including if the preparation is quarantined/not available once removed from the shortage list)? Or, *Not Inspected*

S158. Does the pharmacy document the need for compounding commercially available products by individual patient needs determined by the prescribing practitioner (i.e, hypersensitivity to inactive ingredients or alternate dosage form)? *Not Inspected*

S275. If the pharmacy dispenses prescriptions to patients in other states, does the pharmacy have proper licensure in those states? *Not Inspected*

Office Use Compounding & Distribution of CSPs

S163. Does the pharmacy have a written agreement with the prescriber that meets all requirements to distribute compounded sterile preparations to practitioners for office use? *Not Inspected*

S162. If the pharmacy is distributing CSPs to another pharmacy, does the pharmacy meet the requirements for such distribution? *Not Inspected*

Is the pharmacy registered with the FDA as an Outsourcing Facility (503B)? *Not Applicable*

Quality Control & Verification of Compounding Accuracy

S207. Does a pharmacist review all compounding records for accuracy and perform the final check of a CSP? *Not Inspected*

S185. Are periodic in-process checks for CSPs defined in written procedures and conducted as defined? *Not Inspected*

S191. Are all drug components USP/NF grade substances manufactured in an FDA-registered facility? If USP/NF grade substances are not available, are the drug components of chemical grade in CP, AR, ACS, or Food Chemical Codex categories? *Not Inspected*

S191. Is a Certificate of Analysis available for all components of the preparation if materials are not purchased through an FDA-registered facility? *Not Inspected*

S191. Are any CSPs prepared by the pharmacy listed on the federal FDA list of drug products that are withdrawn or removed from the market for safety reasons? *Not Inspected*

Veterinary Compounding

Are APIs or other components labeled for veterinary use segregated or marked to prevent use for human compounding?	*Not Inspected*
Does the pharmacy meet the same standards for animal compounding as human compounding?	*Not Inspected*
Is the pharmacist knowledgeable or does the pharmacy have up-to-date references regarding species limits that can result in toxicity when compounding with particular drugs/excipients?	*Not Inspected*
Does the pharmacy document if the animal is a pet or used for food?	*Not Inspected*
Is the pharmacist familiar with, or does the pharmacy have the most up-to date references regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals?	*Not Inspected*
Does the pharmacy have a list of drugs and components that have been designated by state or federal authorities as prohibited ingredients in CSPs for food-producing animals?	*Not Inspected*
Is the pharmacist familiar with, or does the pharmacy have the most up-to-date reference regarding regulations for drug use in performance animals?	*Not Inspected*

Label

S209. Is the CSP properly labeled to include the generic name(s), and	*Not Inspected*
S210. For outpatient prescriptions, does the label include a statement that the CSP has been compounded by the pharmacy?	*Not Inspected*
S211. Does the label include a beyond-use date?	*Not Inspected*
S213. If the CSP is compounded as a batch, does the label contain a unique lot number assigned to the batch, and	*Not Inspected*
S214. Quantity, and	*Not Inspected*
S215. Appropriate ancillary instructions, such as storage or cautionary statements, and	*Not Inspected*
S216. Any device-specific instructions, if appropriate?	*Not Inspected*
S220. Are CSPs assigned a beyond-use date based on the specified labeling for the drug, appropriate literature sources, or direct testing?	*Not Inspected*

Training & Competency Testing

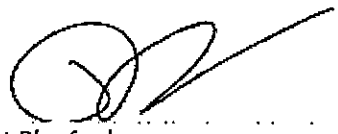
S129. Has each pharmacist completed the required education and training prior to engaging in sterile compounding?	*Not Inspected*
S130. Has each pharmacy technician completed the required education and training prior to engaging in sterile compounding?	*Not Inspected*
S142. Does the pharmacy maintain documentation to demonstrate that all compounding personnel have successfully passed initial competency evaluation/testing (e.g., media-fill testing, gloved fingertip/thumb testing)? Does the pharmacy have an on-the-job training program?	*Not Inspected*

S144. Does the pharmacy maintain documentation of on-going training and testing for all compounding personnel (e.g., observation of aseptic technique, media-fill testing, gloved fingertip/thumb testing, continuing education)? *Not Inspected*

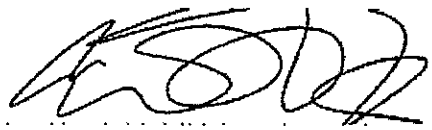
Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



Robert Blanford



Cedric Johnson

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Warning Notice of Violation(s) Requiring Correction

Facility Information

Name: *BEAKER PHARMACY* License Number: *32264*

Class of License: *AS*

Signatures

Notice is hereby given that you are not in compliance with the following laws and rules governing the practice of pharmacy. Unless the conditions noted below are corrected, disciplinary action may be instituted against the pharmacy license and the license of the pharmacist-in-charge.

I hereby acknowledge that the laws and/or rules cited in the Warning Notice below have been explained to me by the Board of Pharmacy Officer/Inspector.

Robert Blanford *Date*

Warning Notice

1. Rule/Law/Code: 291.34(b)(2)(B)(ii).

   Explanation of Violation and Correction Needed:
   Failure to comply regarding dispensing prescriptions from foreign practitioners and out-of-state APNs and PAs. Cease this practice and correct/resolve deficiency by date noted.
   Due Date for Completed Correction: *09/21/2025*

TEXAS STATE BOARD OF PHARMACY

Pharmacist in Charge Attestation:

I hereby attest the following statements are true and accurate (initial each statement below):

I am the Pharmacist-in-Charge (PIC) of *BEAKER PHARMACY*, pharmacy license number *32264*, and I ☐ was/ ☑ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *08/20/2025*.

I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF.

If applicable, the Warning Notice issued contains *1* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please email this completed form to the TSBP Compliance Inspector for your area or to inspections@pharmacy.texas.gov within 7 days of the date of the inspection.

Signed: Date:

Printed Name: *DAMASKE, DAVID LAWRENCE* License No.(if applicable): *41186*

TEXAS STATE BOARD OF PHARMACY

Pharmacist (or other Responsible Party) on Duty Attestation:

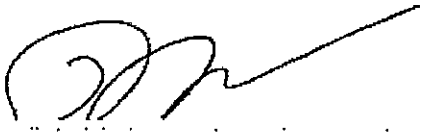
I hereby attest the following statements are true and accurate (initial each statement below):

RB I am the Pharmacist (or other responsible party) on duty at *BEAKER PHARMACY*, pharmacy license number *32264* during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *08/20/2025*.

RB At the conclusion of the inspection, the Officer/Inspector left the following documents in my possession (check each applicable)

- ☑ Notice of Inspection
- ☑ Inspection Report
- ☐ Warning Notice outlining *1* deficiencies
- ☑ Pharmacist-in-Charge Attestation Form with the handout titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF.

RB I will provide all of the records listed above, including this attestation, regarding the inspection to the Pharmacist-in-Charge(PIC), within 3 business days and ensure the PIC understands that he/she must file the completed PIC attestation within 7 days of the date of receipt (unless otherwise noted).

Signed: 

Date: *08/20/2025*

Printed Name: *Robert Blanford*

License No.(if applicable): *33295*

Texas State Board of Pharmacy
"Red Flags" Checklist for Pharmacies
YOU MIGHT BE A PILL MILL IF...

Check all that apply:

	(1) Your pharmacy fills a discernable pattern of prescriptions for prescribers who write essentially the same prescriptions for numerous persons, indicating a lack of individual drug therapy
	(2) Your pharmacy operates with limited hours of operation or closes after a certain threshold of controlled substance prescriptions are dispensed, and has overall low prescription dispensing volume.
	(3) Prescriptions presented to the pharmacy are for controlled substances with popularity as street drugs, such as opiates, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups, or any combination of these drugs.
	(4) The prescriptions for controlled substances contain nonspecific or no diagnoses.
	(5) The prescriptions are commonly for the highest strength of the drug and/or for large quantities.
	(6) Dangerous drugs or OTC products (such as multi-vitamins or laxatives) are added to the controlled substance prescriptions, maintaining relatively consistent 1:1 ratio of controlled substances to dangerous drugs and/or OTC products dispensed as prescriptions.
	(7) Prescriptions are authorized by the same prescriber with what appears to be different handwriting on the hardcopy prescription drug order forms.
	(8) Upon contact with the prescriber's office, you are unable to engage in comprehensive discussion with the actual prescriber, or he/she is unconcerned about your apprehensions regarding his/her prescribing practices or unwilling to provide additional information, such as treatment goals and/or prognosis with prescribed drug therapy.
	(9) You rely solely on the prescriber's representation, or on the representation of the individual answering the phone at the number on the prescription, that prescriptions are legitimate.
	(10) The prescriber's clinic is not registered as a pain management clinic by the Texas Medical Board, despite routinely receiving prescriptions from the prescriber foropiates, benzodiazepines, and/or muscle relaxants.
	(11) Drugs prescribed are inconsistent with the prescriber's area of practice.
	(12) The prescriber of the drugs is located a significant distance from your pharmacy.
	(13) The prescriber has been subject to disciplinary action by the licensing board, had his/her DEA registration removed, or been subject to criminal action.
	(14) The Texas PMP system indicates that persons are obtaining prescriptions for the same drugs from multiple prescribers or that persons are filling prescriptions for the same drugs at multiple pharmacies.
	(15) The person's address is a significant distance from your pharmacy and/or from the prescriber's office.
	(16) Multiple persons with the same address present prescriptions from the same prescriber.
	(17) Persons pay with cash or credit card more often than through insurance.
	(18) Persons presenting controlled substance prescriptions are doing so in such a manner that varies from seeking routine pharmacy services (e.g., willing to wait in long lines to receive drugs, persons arrive in the same vehicle with prescriptions from same prescriber, one person presents to pick up prescriptions for multiple others, persons refer to drugs by "street names" and/or comment on drug's color, persons seek early refills, persons travel from outside reasonable trade area of pharmacy).
	(19) Your pharmacy charges and persons are willing to pay more for controlled substances than they would at nearby pharmacies.
	(20) Your pharmacy routinely orders controlled substances from more than one drug supplier, or your pharmacy has been discontinued by a drug supplier related to controlled substance orders.
	(21) Sporadic and non-consistent dispensing volume (including zero dispensing) varies from day to day and week to week, and your pharmacy does not maintain operational hours each week on Monday through Friday.
	(22) Your pharmacy employs or contracts security personnel during operational hours to prevent problems.
	(23) Your pharmacy has been previously warned or disciplined by the Texas State Board of Pharmacy for inappropriate dispensing of controlled substances (i.e., corresponding responsibility).

If you checked any of the above items, you should review the laws and rules regarding corresponding responsibility and non-therapeutic dispensing, especially Board rule §291.29, in the law book or on our website: www.pharmacy.texas.gov (click on Texas Pharmacy Rules and Laws). Additional educational material is available at: http://www.pharmacy.texas.gov/Nontherapeutic.asp. Failure of pharmacies and pharmacists to detect patterns of inappropriate dispensing of prescription drugs is unprofessional practice and constitutes grounds for disciplinary action.

Updated 2/2018

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Notice of Inspection

Facility Information

Name: *BEAKER PHARMACY*

License Number: *32264*

Address: *7810 ELDORADO PKWY STE 200, MCKINNEY, TX 75070*

Phone: *(972) 972-4700*

Email:

Class of License: *AS*

License Expiration: *09/30/2026*

DEA #: [redacted]

DEA Expiration: *07/31/2027*

Inspection Information

Type: *Compliance*

Purpose: *Follow-up to Warning Notice*

Date: *08/20/2025*

Arrival Time: *11:30 AM*

Acknowledgment

This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.



Robert Blanford *Pharmacy Director* *33295*

Witness



Cedric Johnson

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *BEAKER PHARMACY* License Number: *32264*

Class of License: *AS*

Inspection Information

Type: *Compliance* Purpose: *Follow-up to Warning Notice*

Date: *08/20/2025* Arrival Time: *11:30 AM* Departure Time: *1:15 PM*

Action Taken: *Inspection*

General Comments:

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary	*Not Inspected*
01. Required licenses posted	*Not Inspected*
09. Active licenses/certifications	*Not Inspected*
62. No aiding and abetting	*Not Inspected*
65. Proper registration procedures	*Not Inspected*
79. Identification badges	*Not Inspected*

Inventory Records

15. Change of PIC inventory	*Not Inspected*
17. Meets inventory requirements	*Not Inspected*
59. Proper drug destruction	*Not Inspected*
68. Change of ownership controlled substance inventory	*Not Inspected*
69. Annual controlled substance inventory	*Not Inspected*

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?)	*Not Inspected*
34. Notifications	*Not Inspected*
76. PIC (Does the pharmacy have a pharmacist-in-charge?)	*Not Inspected*

Environment/Equipment/Security

03. Orderly/Clean	*Not Inspected*
04. Balance inspection	*Not Inspected*
05. Equipment Inspection	*Not Inspected*
07. Security	*Not Inspected*
08. Environment	*Not Inspected*
48. Drugs (procurement, temperature, security, out-of-date, samples)	*Not Inspected*
90. TSBP complaint notification	*Not Inspected*

Controlled Substances

10. Prescriptions separated	*Not Inspected*
24. Theft/Loss	*Not Inspected*
26. Controlled substance prescription compliance	***Unsatisfactory***

291.34(b)(2)(C)(ii).

Prescriptions. Written prescription drug orders. Prescription drug orders written by practitioners in the United Mexican States or the Dominion of Canada. Dangerous drug prescription drug orders. A pharmacist may dispense a dangerous drug prescription issued by a person licensed in the Dominion of Canada or the United Mexican States as a physician, dentist, veterinarian, or podiatrist provided:

- the prescription drug order is an original written prescription; and
- if there are no refill instructions on the original written prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original written prescription drug order have been dispensed, a new written prescription drug order shall be obtained from the prescribing practitioner prior to dispensing any additional quantities of dangerous drugs.

Warning Notice

Due Date for Completed Correction: *09/19/2025*

Failure to comply regarding dispensing prescriptions from foreign practitioners and out-of-state APNs and PAs. Cease this practice and correct/resolve deficiency by date noted.

30. Controlled substance invoices dated/initialed by pharmacist	*Not Inspected*
35. Controlled substance invoices separated	*Not Inspected*
46. Drug distribution	*Not Inspected*
53. Possession of controlled substances	*Not Inspected*
Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?)	*Not Inspected*

Labeling/Prepackaging

32. Prescription label (Is prescription label complete?)	*Not Inspected*
45. Proper dispensing/labeling	*Not Inspected*

54. Proper prepackaging procedures — *Not Inspected*

Library

06. Required Library — *Not Inspected*

Training

60. Documentation of required training — *Not Inspected*

61. Supervision of supportive personnel — *Not Inspected*

Patient/Computer/Dispensing Records

18. Records available — *Not Inspected*

22. Data processing system compliance — *Not Inspected*

25. Prescriptions (complete, retrievable, auto-refills, accelerated refills) — *Not Inspected*

37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?) — *Not Inspected*

56. Prescription transfers — *Not Inspected*

67. Written drug information provided — *Not Inspected*

80. Patient counseling — *Not Inspected*

82. Patient Medication Records — *Not Inspected*

84. Drug regimen review — *Not Inspected*

86. Absence of pharmacist records — *Not Inspected*

Policies & Procedures/SOPs

70. Required policies & procedures/SOPs — *Not Inspected*

92. Automated dispensing policy & procedures/SOPs — *Not Inspected*

Non-Sterile Compounding

03. Orderly/Clean/Hand Hygiene — *Not Inspected*

04. Balance inspection (for non-sterile compounding) — *Not Inspected*

05. Equipment Inspection — *Not Inspected*

06. Non-sterile Library — *Not Inspected*

32. Non-sterile compound label (Is label complete?) — *Not Inspected*

38. Area/Environment for non-sterile compounding — *Not Inspected*

43. Records for non-sterile compounding — *Not Inspected*

60. Documentation of non-sterile required training — *Not Inspected*

70. Required policies & procedures/SOPs	*Not Inspected*
87. Quality Control/Assurance	*Not Inspected*

Compounded Dosage Forms

Allergen extracts	*Not Inspected*
Parenteral solutions	*Not Inspected*
Parenteral suspensions	*Not Inspected*
Preservative-free parenterals	*Not Inspected*
Ophthalmic preparations	*Not Inspected*
Oral or nasal inhalation preparations (not topical spray)	*Not Inspected*
Bath or soaks for live organs/tissues	*Not Inspected*
Irrigations for wounds or body cavities	*Not Inspected*
Any other sterile preparations (implants, pellets, etc) [list]	*Not Inspected*
Investigational drugs	*Not Inspected*
Blood products or other biological materials (wound care, autologous, eye drops, etc)	*Not Inspected*
Any compounds using federally controlled substances Schedule I-V (list and percentage)	*Not Inspected*
Does the pharmacy use lyophilizer?	*Not Inspected*

Environment (Sterile)

S109. Is the cleanroom clean and free of objects that shed particles?	*Not Inspected*
S110. Is the cleanroom used only for sterile preparations?	*Not Inspected*
S119. Does the cleanroom contain only appropriate supplies?	*Not Inspected*
S101. Does the ante-area provide at least ISO Class 8 air quality under dynamic conditions?	*Not Inspected*
S115. Does the ante-area contain a hands-free sink with hot and cold running water?	*Not Inspected*
S102. Does the buffer area provide at least ISO Class 7 air quality under dynamic conditions?	*Not Inspected*
S106. Is the buffer area free from sources of water (e.g., sink, floor drains)?	*Not Inspected*
S108. Is there hands-free access to the buffer area?	*Not Inspected*
S113. Are floors, walls, ceilings & fixtures smooth, impervious and free from cracks & crevices?	*Not Inspected*
S112. Does the floor covering enable regular disinfection?	*Not Inspected*
S118. Are supplies stored above the floor to permit adequate floor cleaning?	*Not Inspected*

S127. Does the clean room have a pressure gauge or velocity meter to monitor pressure differential between buffer area and ante-area and between the ante-area and the general environment? Is the pressure differential at least 0.02" wc? *Not Inspected*

S116. Are temperature and humidity monitored, documented and within the required range? *Not Inspected*

S167. Is there a thermometer available for the cleanroom and refrigerator(s)? *Not Inspected*

Primary Engineering Control (PECs) Device

S126. Is the laminar air flow hood located in a buffer area that has a minimum differential positive pressure of 0.02" wc? *Not Inspected*

S121. Is the PEC able to maintain at least ISO Class 5 conditions while compounding sterile preparations? *Not Inspected*

S246. Are hazardous drugs prepared in a Class II/III vertical flow BSC or CACI located in an ISO Class 7 area physically separated from other areas? *Not Inspected*

S247. Does the area where the BSC or CACI is located have not less than 0.01" wc negative pressure adjacent to the positive pressure ISO Class 7 area? *Not Inspected*

S105. Does the CAI or CACI provide unidirectional airflow? *Not Inspected*

S104. If the CAI or CACI is used for high-risk sterile compounding, is it placed in an ISO Class 8 area? *Not Inspected*

S122. If the CAI is not required to be placed in an ISO Class 7 area, does the pharmacy maintain documentation from the manufacturer? *Not Inspected*

S124. Is the PEC certified by an independent contractor every 6 months and when relocated? *Not Inspected*

S125. Are prefilters inspected periodically and replaced as needed? *Not Inspected*

S128. Are differential pressures monitored and documented at least every work shift (at a minimum daily) or by a continuous recording device? *Not Inspected*

Equipment and Supplies

S174. Does the pharmacy have disposable needles, syringes, and other required or applicable supplies? *Not Inspected*

S177. Does the pharmacy have lint-free towels or wipes? *Not Inspected*

S180. Does the pharmacy have masks, caps, gowns with tight cuffs, shoes covers, and beard covers (if applicable)? *Not Inspected*

S176. Does the pharmacy have handwashing agents with bactericidal action? *Not Inspected*

S175. Does the pharmacy have disinfectant cleaning solutions and dedicated cleaning supplies? *Not Inspected*

S179. Does the pharmacy have hazardous spill kits, if applicable? *Not Inspected*

S171. Does the pharmacy have appropriate containers for needles and syringes? *Not Inspected*

S170. Does the pharmacy have sterile isopropyl alcohol, sterile gloves, and waterless alcohol-based surgical hand scrub? *Not Inspected*

S178. Does the pharmacy have appropriate filters and filtration equipment? *Not Inspected*

S181. If an automated compounding device is used, does the pharmacy calibrate & verify the device for accuracy, and document at least daily? *Not Inspected*

S172. Does the pharmacy have packaging or delivery containers to maintain proper storage conditions for sterile preparations? *Not Inspected*

High Risk CSPs

S103. If high-risk CSPs are compounded, does the buffer area provide physical separation from other compounding areas? *Not Inspected*

S231. Is sterility testing performed if CSPs are prepared in groups > 25, or *Not Inspected*

S232. If MDVs are prepared for multiple patients or when exposed > 12 hours at 2-8 degrees C before sterilized, or *Not Inspected*

S233. If exposed > 6 hours at warmer than 8 degrees C before sterilized? *Not Inspected*

S237. Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with pyrogen-free or depyrogenated sterile water, and then thoroughly drained or dried immediately before use for high-risk sterile compounding? *Not Inspected*

S238. Are all high-risk sterile solutions subjected to terminal sterilization prefiltered using no larger than a 1.2-micron filter to remove particulate matter? Is sterilization by filtration performed with a sterile 0.2 – 0.22 micrometer pore size filter within an ISO Class 5 environment or better? *Not Inspected*

S165. Are filter integrity tests being performed and documented (e.g., bubble point test)? *Not Inspected*

S239. Are pre-sterilization procedures (weighing and mixing) completed in an ISO Class 8 environment or better? *Satisfactory*

Sterile Library

S154. Does the pharmacy have a reference on injectable drugs? *Not Inspected*

S155. Does the pharmacy have a specialty reference? *Not Inspected*

S156. Does the pharmacy have all of the required (USP chapters 71, 85, 795, 797, 1163) and applicable USP chapters? *Not Inspected*

Hazardous CSPs

S242. Do personnel wear protective apparel at all times when hazardous drugs are handled? *Not Inspected*

S243. Do personnel use appropriate safety and containment techniques when preparing hazardous CSPs? *Not Inspected*

S244. Do personnel dispose of hazardous waste in compliance with local, state, and federal regulations? *Not Inspected*

S245. Do personnel affix a proper label, including proper precautions inside and outside of the packaging? *Not Inspected*

S248. Does the pharmacy have a pressure indicator that can be readily monitored for correct room pressurization?	*Not Inspected*
S249. Does the pharmacy meet the requirements for low volume preparation of hazardous drugs by using a device that provides two-tiers of containment (e.g., closed-system vial transfer device within a BSC)?	*Not Inspected*
S250. Are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure?	*Not Inspected*
Does the pharmacy have a plan to comply with USP <800> by the implementation date?	*Not Inspected*
Are hazardous drugs stored separately in compliance with USP <800> (negative pressure at least -0.01" wc to adjacent areas and with at least 12 ACPH)?	*Not Inspected*
Is hazardous drug waste quarantined in a designated area?	*Not Inspected*
Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)?	*Not Inspected*

Personnel Cleansing, Garbing, Hand Hygiene

S202. Does hand sanitizing and gowning occur in the ante-area (outside of the buffer area)?	*Not Inspected*
S180. Do compounding personnel don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclose at the neck? Is the order of garbing appropriate (dirtiest to cleanest)?	*Not Inspected*
S194. Before entering the buffer area, do compounding personnel remove cosmetics?	*Not Inspected*
S195. Before entering the buffer area, do compounding personnel remove all hand, wrist, and other body jewelry/piercings?	*Not Inspected*
S196. Are natural nails kept neat and trim and no wearing of artificial nails or extenders?	*Not Inspected*
S200. Do compounding personnel remove debris from underneath fingernails using a nail cleaner under running warm water?	*Not Inspected*
S192. Are personnel with an apparent illness or open lesions compounding sterile preparations?	*Not Inspected*
S241. When compounding personnel temporarily exit the ISO Class 7 environment, are re-donning procedures properly followed?	*Not Inspected*
S201. Do compounding personnel engage in proper hand hygiene?	*Not Inspected*
S203. Do compounding personnel completely dry hands and forearms using lint-free disposable towels or hand dryer?	*Not Inspected*
S204. Is antiseptic hand cleansing performed using waterless alcohol-based surgical scrub once inside the buffer area and prior to donning sterile gloves?	*Not Inspected*
S206. Is sterile isopropyl alcohol applied to gloves throughout the day and when non-sterile surfaces are touched?	*Not Inspected*

Cleaning/Disinfection Procedures

S182. Does the pharmacy have written procedures on the cleaning and disinfecting of the direct and contiguous compounding areas (e.g., beginning of shift, every 30 minutes, before each batch, spills)?	*Not Inspected*
S230. Is cleaning performed by trained personnel using approved agents (described in written SOPs)?	*Not Inspected*
S228. Are supplies & equipment that are removed from shipping cartons wiped with a disinfecting agent (e.g., sterile IPA)?	*Not Inspected*
S226. Are work surfaces and floors in the ante-area and buffer area cleaned and disinfected daily with dedicated supplies?	*Not Inspected*
S227. Are walls, ceilings and shelving in the ante-area and buffer area cleaned and disinfected at least monthly?	*Not Inspected*
S229. Does the pharmacy maintain documentation of cleaning procedures (i.e., date/time of cleaning, type of cleaning, name of individual who performed the cleaning)?	*Not Inspected*

Environmental Sampling

S270. Is surface sampling conducted in all ISO classified areas on a periodic basis?	*Not Inspected*
S272. Is viable air sampling performed?	*Not Inspected*
S273. Is viable air sampling documented by properly trained individuals for all risk levels every 6 months?	*Not Inspected*
S271. Are environmental sampling results evaluated and addressed (i.e., action levels followed)?	*Not Inspected*

Records of CSPs

S252. Does the pharmacy maintain records relating to CSPs for a minimum of 2 years?	*Not Inspected*
S253. Do compounding records include the date and time of preparation of a CSP?	*Not Inspected*
S254. Do compounding records include the complete formula of a CSP?	*Not Inspected*
S257. Do compounding records include the quantities of materials used in a CSP?	*Not Inspected*
S255. Do compounding records include the signature or initials of who prepared a CSP?	*Not Inspected*
S256. Do compounding records include the signature or initials of who conducted the final check of a CSP?	*Not Inspected*
S258. Do compounding records include the container used and the number of units prepared for a CSP?	*Not Inspected*
S259. Do compounding records include the criteria used to determine the beyond-use date of a CSP?	*Not Inspected*
S260. Do compounding records include the documentation of performance of quality control procedures?	*Not Inspected*
S261. Are master worksheets and preparation worksheets for batch compounding complete?	*Not Inspected*
S262. Are master worksheets developed and approved by a pharmacist?	*Not Inspected*

General Operational Requirements

S166. Is a pharmacist available at all times (24/7)?	*Not Inspected*
S187. Are written SOPs developed and implemented for all significant procedures in the compounding area to include at a minimum: the facility, equipment, personnel, preparation evaluation, quality assurance, preparation recall, packaging, and storage of CSPs?	*Not Inspected*
S188. Does the pharmacy have all required written policies (e.g., pharmaceutical care services, sampling plan, recalls)?	*Not Inspected*
S158. If the pharmacy compounds commercially available products, does the pharmacy document the need by verifying and monitoring a drug shortage list (including if the preparation is quarantined/not available once removed from the shortage list)? Or,	*Not Inspected*
S158. Does the pharmacy document the need for compounding commercially available products by individual patient needs determined by the prescribing practitioner (i.e, hypersensitivity to inactive ingredients or alternate dosage form)?	*Not Inspected*
S275. If the pharmacy dispenses prescriptions to patients in other states, does the pharmacy have proper licensure in those states?	*Not Inspected*

Office Use Compounding & Distribution of CSPs

S163. Does the pharmacy have a written agreement with the prescriber that meets all requirements to distribute compounded sterile preparations to practitioners for office use?	*Not Inspected*
S162. If the pharmacy is distributing CSPs to another pharmacy, does the pharmacy meet the requirements for such distribution?	*Not Inspected*
Is the pharmacy registered with the FDA as an Outsourcing Facility (503B)?	*Not Inspected*

Quality Control & Verification of Compounding Accuracy

S207. Does a pharmacist review all compounding records for accuracy and perform the final check of a CSP?	*Not Inspected*
S185. Are periodic in-process checks for CSPs defined in written procedures and conducted as defined?	*Not Inspected*
S191. Are all drug components USP/NF grade substances manufactured in an FDA-registered facility? If USP/NF grade substances are not available, are the drug components of chemical grade in CP, AR, ACS, or Food Chemical Codex categories?	*Not Inspected*
S191. Is a Certificate of Analysis available for all components of the preparation if materials are not purchased through an FDA-registered facility?	*Not Inspected*
S191. Are any CSPs prepared by the pharmacy listed on the federal FDA list of drug products that are withdrawn or removed from the market for safety reasons?	*Not Inspected*

Veterinary Compounding

Are APIs or other components labeled for veterinary use segregated or marked to prevent use for human compounding?	*Not Inspected*

Does the pharmacy meet the same standards for animal compounding as human compounding?	*Not Inspected*
Is the pharmacist knowledgeable or does the pharmacy have up-to-date references regarding species limits that can result in toxicity when compounding with particular drugs/excipients?	*Not Inspected*
Does the pharmacy document if the animal is a pet or used for food?	*Not Inspected*
Is the pharmacist familiar with, or does the pharmacy have the most up-to date references regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals?	*Not Inspected*
Does the pharmacy have a list of drugs and components that have been designated by state or federal authorities as prohibited ingredients in CSPs for food-producing animals?	*Not Inspected*
Is the pharmacist familiar with, or does the pharmacy have the most up-to-date reference regarding regulations for drug use in performance animals?	*Not Inspected*

Label

S209. Is the CSP properly labeled to include the generic name(s), and	*Not Inspected*
S210. For outpatient prescriptions, does the label include a statement that the CSP has been compounded by the pharmacy?	*Not Inspected*
S211. Does the label include a beyond-use date?	*Not Inspected*
S213. If the CSP is compounded as a batch, does the label contain a unique lot number assigned to the batch, and	*Not Inspected*
S214. Quantity, and	*Not Inspected*
S215. Appropriate ancillary instructions, such as storage or cautionary statements, and	*Not Inspected*
S216. Any device-specific instructions, if appropriate?	*Not Inspected*
S220. Are CSPs assigned a beyond-use date based on the specified labeling for the drug, appropriate literature sources, or direct testing?	*Not Inspected*

Training & Competency Testing

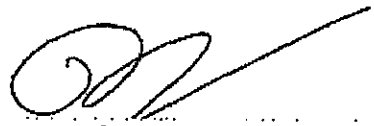
S129. Has each pharmacist completed the required education and training prior to engaging in sterile compounding?	*Not Inspected*
S130. Has each pharmacy technician completed the required education and training prior to engaging in sterile compounding?	*Not Inspected*
S142. Does the pharmacy maintain documentation to demonstrate that all compounding personnel have successfully passed initial competency evaluation/testing (e.g., media-fill testing, gloved fingertip/thumb testing)? Does the pharmacy have an on-the-job training program?	*Not Inspected*
S144. Does the pharmacy maintain documentation of on-going training and testing for all compounding personnel (e.g., observation of aseptic technique, media-fill testing, gloved fingertip/thumb testing, continuing education)?	*Not Inspected*

Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and

- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



Robert Blanford



Cedric Johnson

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *BEAKER PHARMACY* License Number: *32264*

Class of License: *AS*

Inspection Information

Type: *Compliance* Purpose: *Licensee Request*

Date: *04/02/2025* Arrival Time: *10:00 AM* Departure Time: *1:45 PM*

Action Taken: *Inspection*

General Comments:

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary	*Satisfactory*
01. Required licenses posted	*Satisfactory*
09. Active licenses/certifications	*Satisfactory*
62. No aiding and abetting	*Satisfactory*
65. Proper registration procedures	*Satisfactory*
79. Identification badges	*Satisfactory*

Inventory Records

15. Change of PIC inventory	*Not Applicable*
17. Meets inventory requirements	*Satisfactory*
59. Proper drug destruction	*Satisfactory*
68. Change of ownership controlled substance inventory	*Not Applicable*
69. Annual controlled substance inventory	*Satisfactory*

Comment

Annual controlled substance inventory completed on: 5/23/24 @ close

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?)	*Satisfactory*
34. Notifications	*Satisfactory*

76. PIC (Does the pharmacy have a pharmacist-in-charge?) *Satisfactory*

Environment/Equipment/Security

03. Orderly/Clean *Satisfactory*

04. Balance inspection *Satisfactory*

Comment

Number of balances: 9 registered and verified

05. Equipment Inspection *Satisfactory*

07. Security *Satisfactory*

08. Environment *Satisfactory*

48. Drugs (procurement, temperature, security, out-of-date, samples) *Satisfactory*

90. TSBP complaint notification *Satisfactory*

Controlled Substances

10. Prescriptions separated *Satisfactory*

24. Theft/Loss *Satisfactory*

Comment

No theft or loss has occurred.

26. Controlled substance prescription compliance ***Unsatisfactory***

291.34(b)(2)(B)(ii).
Prescriptions. Written prescription drug orders. Prescription drug orders written by practitioners in another state. A pharmacist may dispense prescription drug orders for controlled substances in Schedule III, IV, or V issued by a physician, dentist, veterinarian, or podiatrist in another state provided:

- the prescription drug order is issued by a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal DEA registration number, and who may legally prescribe Schedule III, IV, or V controlled substances in such other state;
- the prescription drug order is not dispensed or refilled more than six months from the initial date of issuance and may not be refilled more than five times; and
- if there are no refill instructions on the original prescription drug order (which shall be interpreted as no refills authorized) or if all refills authorized on the original prescription drug order have been dispensed, a new prescription drug order is obtained from the prescribing practitioner prior to dispensing any additional quantities of controlled substances

Warning Notice **Due Date for Completed Correction:** *05/02/2025*

Failure to comply regarding dispensing prescriptions from out-of-state APNs and PAs. Cease this practice and correct/resolve deficiency by date noted.

30. Controlled substance invoices dated/initialed by pharmacist	*Satisfactory*
35. Controlled substance invoices separated	*Satisfactory*
46. Drug distribution	*Satisfactory*
53. Possession of controlled substances	*Satisfactory*
Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?)	*Satisfactory*

Labeling/Prepackaging

32. Prescription label (Is prescription label complete?)	*Satisfactory*
45. Proper dispensing/labeling	*Satisfactory*
54. Proper prepackaging procedures	*Not Applicable*

Library

06. Required Library	*Satisfactory*

Training

60. Documentation of required training	*Satisfactory*
61. Supervision of supportive personnel	*Satisfactory*

Patient/Computer/Dispensing Records

18. Records available	*Satisfactory*
22. Data processing system compliance	*Satisfactory*
25. Prescriptions (complete, retrievable, auto-refills, accelerated refills)	*Satisfactory*
37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?)	*Satisfactory*
56. Prescription transfers	*Satisfactory*
67. Written drug information provided	*Satisfactory*
80. Patient counseling	*Satisfactory*
82. Patient Medication Records	*Satisfactory*
84. Drug regimen review	*Satisfactory*
86. Absence of pharmacist records	*Not Applicable*

Policies & Procedures/SOPs

70. Required policies & procedures/SOPs	*Satisfactory*
92. Automated dispensing policy & procedures/SOPs	*Not Applicable*

Non-Sterile Compounding

03. Orderly/Clean/Hand Hygiene	*Satisfactory*
04. Balance inspection (for non-sterile compounding)	*Satisfactory*
05. Equipment Inspection	*Satisfactory*
06. Non-sterile Library	*Satisfactory*
32. Non-sterile compound label (Is label complete?)	*Satisfactory*
38. Area/Environment for non-sterile compounding	*Satisfactory*
43. Records for non-sterile compounding	*Satisfactory*

Comment

Advised to maintain complete non-sterile compounding records including the criteria for the beyond use date.

60. Documentation of non-sterile required training	*Satisfactory*
70. Required policies & procedures/SOPs	*Satisfactory*
87. Quality Control/Assurance	*Satisfactory*

Compounded Dosage Forms

Allergen extracts	*No*
Parenteral solutions	*Yes*
Parenteral suspensions	*No*
Preservative-free parenterals	*No*
Ophthalmic preparations	*Yes*
Oral or nasal inhalation preparations (not topical spray)	*No*
Bath or soaks for live organs/tissues	*No*
Irrigations for wounds or body cavities	*No*
Any other sterile preparations (implants, pellets, etc) [list]	*No*
Investigational drugs	*No*
Blood products or other biological materials (wound care, autologous, eye drops, etc)	*Yes*
Any compounds using federally controlled substances Schedule I-V (list and percentage)	*Yes*

Comment

Testosterone, nandrolone

Does the pharmacy use lyophilizer?	*No*

Environment (Sterile)

S109. Is the cleanroom clean and free of objects that shed particles?	*Satisfactory*
S110. Is the cleanroom used only for sterile preparations?	*Satisfactory*
S119. Does the cleanroom contain only appropriate supplies?	*Satisfactory*
S101. Does the ante-area provide at least ISO Class 8 air quality under dynamic conditions?	*Satisfactory*
S115. Does the ante-area contain a hands-free sink with hot and cold running water?	*Satisfactory*
S102. Does the buffer area provide at least ISO Class 7 air quality under dynamic conditions?	*Satisfactory*
S106. Is the buffer area free from sources of water (e.g., sink, floor drains)?	*Satisfactory*
S108. Is there hands-free access to the buffer area?	*Satisfactory*
S113. Are floors, walls, ceilings & fixtures smooth, impervious and free from cracks & crevices?	*Satisfactory*
S112. Does the floor covering enable regular disinfection?	*Satisfactory*
S118. Are supplies stored above the floor to permit adequate floor cleaning?	*Satisfactory*
S127. Does the clean room have a pressure gauge or velocity meter to monitor pressure differential between buffer area and ante-area and between the ante-area and the general environment? Is the pressure differential at least 0.02" wc?	*Satisfactory*
S116. Are temperature and humidity monitored, documented and within the required range?	*Satisfactory*
S167. Is there a thermometer available for the cleanroom and refrigerator(s)?	*Satisfactory*

Primary Engineering Control (PECs) Device

S126. Is the laminar air flow hood located in a buffer area that has a minimum differential positive pressure of 0.02" wc?	*Satisfactory*
S121. Is the PEC able to maintain at least ISO Class 5 conditions while compounding sterile preparations?	*Satisfactory*
S246. Are hazardous drugs prepared in a Class II/III vertical flow BSC or CACI located in an ISO Class 7 area physically separated from other areas?	*Satisfactory*
S247. Does the area where the BSC or CACI is located have not less than 0.01" wc negative pressure adjacent to the positive pressure ISO Class 7 area?	*Satisfactory*
S105. Does the CAI or CACI provide unidirectional airflow?	*Not Applicable*
S104. If the CAI or CACI is used for high-risk sterile compounding, is it placed in an ISO Class 8 area?	*Not Applicable*
S122. If the CAI is not required to be placed in an ISO Class 7 area, does the pharmacy maintain documentation from the manufacturer?	*Not Applicable*
S124. Is the PEC certified by an independent contractor every 6 months and when relocated?	*Satisfactory*
S125. Are prefilters inspected periodically and replaced as needed?	*Sotisfactory*

S128. Are differential pressures monitored and documented at least every work shift (at a minimum daily) or by a continuous recording device?	*Satisfactory*

Equipment and Supplies

S174. Does the pharmacy have disposable needles, syringes, and other required or applicable supplies?	*Satisfactory*
S177. Does the pharmacy have lint-free towels or wipes?	*Satisfactory*
S180. Does the pharmacy have masks, caps, gowns with tight cuffs, shoes covers, and beard covers (if applicable)?	*Satisfactory*
S176. Does the pharmacy have handwashing agents with bactericidal action?	*Satisfactory*
S175. Does the pharmacy have disinfectant cleaning solutions and dedicated cleaning supplies?	*Satisfactory*
S179. Does the pharmacy have hazardous spill kits, if applicable?	*Satisfactory*
S171. Does the pharmacy have appropriate containers for needles and syringes?	*Satisfactory*
S170. Does the pharmacy have sterile isopropyl alcohol, sterile gloves, and waterless alcohol-based surgical hand scrub?	*Satisfactory*
S178. Does the pharmacy have appropriate filters and filtration equipment?	*Satisfactory*
S181. If an automated compounding device is used, does the pharmacy calibrate & verify the device for accuracy, and document at least daily?	*Satisfactory*
S172. Does the pharmacy have packaging or delivery containers to maintain proper storage conditions for sterile preparations?	*Satisfactory*

High-Risk CSPs

S103. If high-risk CSPs are compounded, does the buffer area provide physical separation from other compounding areas?	*Sotisfactory*
S231. Is sterility testing performed if CSPs are prepared in groups > 25, or	*Satisfactory*
S232. If MDVs are prepared for multiple patients or when exposed > 12 hours at 2-8 degrees C before sterilized, or	*Not Applicable*
S233. If exposed > 6 hours at warmer than 8 degrees C before sterilized?	*Not Applicable*
S237. Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with pyrogen-free or depyrogenated sterile water, and then thoroughly drained or dried immediately before use for high-risk sterile compounding?	*Satisfactory*
S238. Are all high-risk sterile solutions subjected to terminal sterilization prefiltered using no larger than a 1.2-micron filter to remove particulate matter? Is sterilization by filtration performed with a sterile 0.2 – 0.22 micrometer pore size filter within an ISO Class 5 environment or better?	*Satisfactory*
S165. Are filter integrity tests being performed and documented (e.g., bubble point test)?	*Satisfactory*
S239. Are pre-sterilization procedures (weighing and mixing) completed in an ISO Class 8 environment or better?	***Unsatisfactory***

291.133(d)(6)(B)(ii).

Presterilization procedures for high-risk level compounded sterile preparations, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.

Warning Notice Due Date for Completed Correction: *05/02/2025*

Failure to document the ISO classification of the positive and negative pressure preparatory rooms. Comply by date noted.

Sterile Library

S154. Does the pharmacy have a reference on injectable drugs?	*Satisfactory*
S155. Does the pharmacy have a specialty reference?	*Satisfactory*
S156. Does the pharmacy have all of the required (USP chapters 71, 85, 795, 797, 1163) and applicable USP chapters?	*Satisfactory*

Hazardous CSPs

S242. Do personnel wear protective apparel at all times when hazardous drugs are handled?	*Satisfactory*
S243. Do personnel use appropriate safety and containment techniques when preparing hazardous CSPs?	*Satisfactory*
S244. Do personnel dispose of hazardous waste in compliance with local, state, and federal regulations?	*Satisfactory*
S245. Do personnel affix a proper label, including proper precautions inside and outside of the packaging?	*Satisfactory*
S248. Does the pharmacy have a pressure indicator that can be readily monitored for correct room pressurization?	*Satisfactory*
S249. Does the pharmacy meet the requirements for low volume preparation of hazardous drugs by using a device that provides two-tiers of containment (e.g., closed-system vial transfer device within a BSC)?	*Not Applicable*
S250. Are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure?	*Satisfactory*
Does the pharmacy have a plan to comply with USP <800> by the implementation date?	*Yes*
Are hazardous drugs stored separately in compliance with USP <800> (negative pressure at least -0.01" wc to adjacent areas and with at least 12 ACPH)?	*Yes*
Is hazardous drug waste quarantined in a designated area?	*Yes*
Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)?	*Yes*

Personnel Cleansing, Garbing, Hand Hygiene

S202. Does hand sanitizing and gowning occur in the ante-area (outside of the buffer area)?	*Satisfactory*

S180. Do compounding personnel don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclose at the neck? Is the order of garbing appropriate (dirtiest to cleanest)?	*Satisfactory*
S194. Before entering the buffer area, do compounding personnel remove cosmetics?	*Satisfactory*
S195. Before entering the buffer area, do compounding personnel remove all hand, wrist, and other body jewelry/piercings?	*Satisfactory*
S196. Are natural nails kept neat and trim and no wearing of artificial nails or extenders?	*Satisfactory*
S200. Do compounding personnel remove debris from underneath fingernails using a nail cleaner under running warm water?	*Satisfactory*
S192. Are personnel with an apparent illness or open lesions compounding sterile preparations?	*Satisfactory*
S241. When compounding personnel temporarily exit the ISO Class 7 environment, are re-donning procedures properly followed?	*Satisfactory*
S201. Do compounding personnel engage in proper hand hygiene?	*Satisfactory*
S203. Do compounding personnel completely dry hands and forearms using lint-free disposable towels or hand dryer?	*Satisfactory*
S204. Is antiseptic hand cleansing performed using waterless alcohol-based surgical scrub once inside the buffer area and prior to donning sterile gloves?	*Satisfactory*
S206. Is sterile isopropyl alcohol applied to gloves throughout the day and when non-sterile surfaces are touched?	*Satisfactory*

Cleaning/Disinfection Procedures

S182. Does the pharmacy have written procedures on the cleaning and disinfecting of the direct and contiguous compounding areas (e.g., beginning of shift, every 30 minutes, before each batch, spills)?	*Satisfactory*
S230. Is cleaning performed by trained personnel using approved agents (described in written SOPs)?	*Satisfactory*
S228. Are supplies & equipment that are removed from shipping cartons wiped with a disinfecting agent (e.g., sterile IPA)?	*Satisfactory*
S226. Are work surfaces and floors in the ante-area and buffer area cleaned and disinfected daily with dedicated supplies?	*Satisfactory*
S227. Are walls, ceilings and shelving in the ante-area and buffer area cleaned and disinfected at least monthly?	*Satisfactory*
S229. Does the pharmacy maintain documentation of cleaning procedures (i.e., date/time of cleaning, type of cleaning, name of individual who performed the cleaning)?	*Satisfactory*

Environmental Sampling

S270. Is surface sampling conducted in all ISO classified areas on a periodic basis?	*Satisfactory*
S272. Is viable air sampling performed?	*Satisfactory*

Comment

Advised to maintain documentation of viable air sampling results.

S273. Is viable air sampling documented by properly trained individuals for all risk levels every 6 months? *Satisfactory*

S271. Are environmental sampling results evaluated and addressed (i.e., action levels followed)? *Satisfactory*

Records of CSPs

S252. Does the pharmacy maintain records relating to CSPs for a minimum of 2 years? *Satisfactory*

S253. Do compounding records include the date and time of preparation of a CSP? *Satisfactory*

S254. Do compounding records include the complete formula of a CSP? *Satisfactory*

S257. Do compounding records include the quantities of materials used in a CSP? *Satisfactory*

S255. Do compounding records include the signature or initials of who prepared a CSP? *Satisfactory*

S256. Do compounding records include the signature or initials of who conducted the final check of a CSP? *Satisfactory*

S258. Do compounding records include the container used and the number of units prepared for a CSP? *Satisfactory*

S259. Do compounding records include the criteria used to determine the beyond-use date of a CSP? *Satisfactory*

Comment

Advised to ensure compounding records include the criteria used to determine the beyand-use date of a compounded sterile preparation.

S260. Do compounding records include the documentation of performance of quality control procedures? *Satisfactory*

S261. Are master worksheets and preparation worksheets for batch compounding complete? *Satisfactory*

S262. Are master worksheets developed and approved by a pharmacist? *Satisfactory*

General Operational Requirements

S166. Is a pharmacist available at all times (24/7)? *Satisfactory*

S187. Are written SOPs developed and implemented for all significant procedures in the compounding area to include at a minimum: the facility, equipment, personnel, preparation evaluation, quality assurance, preparation recall, packaging, and storage of CSPs? *Satisfactory*

S188. Does the pharmacy have all required written policies (e.g., pharmaceutical care services, sampling plan, recalls)? *Satisfactory*

S158. If the pharmacy compounds commercially available products, does the pharmacy document the need by verifying and monitoring a drug shortage list (including if the preparation is quarantined/not available once removed from the shortage list)? Or, *Not Applicable*

S158. Does the pharmacy document the need for compounding commercially available products by individual patient needs determined by the prescribing practitioner (i.e, hypersensitivity to inactive ingredients or alternate dosage form)?	*Satisfactory*
S275. If the pharmacy dispenses prescriptions to patients in other states, does the pharmacy have proper licensure in those states?	*Satisfactory*

Office Use Compounding & Distribution of CSPs

S163. Does the pharmacy have a written agreement with the prescriber that meets all requirements to distribute compounded sterile preparations to practitioners for office use?	*Not Applicable*
S162. If the pharmacy is distributing CSPs to another pharmacy, does the pharmacy meet the requirements for such distribution?	*Not Applicable*
Is the pharmacy registered with the FDA as an Outsourcing Facility (503B)?	*No*

Quality Control & Verification of Compounding Accuracy

S207. Does a pharmacist review all compounding records for accuracy and perform the final check of a CSP?	*Satisfactory*
S185. Are periodic in-process checks for CSPs defined in written procedures and conducted as defined?	*Satisfactory*
S191. Are all drug components USP/NF grade substances manufactured in an FDA-registered facility? If USP/NF grade substances are not available, are the drug components of chemical grade in CP, AR, ACS, or Food Chemical Codex categories?	*Satisfactory*
S191. Is a Certificate of Analysis available for all components of the preparation if materials are not purchased through an FDA-registered facility?	*Satisfactory*
S191. Are any CSPs prepared by the pharmacy listed on the federal FDA list of drug products that are withdrawn or removed from the market for safety reasons?	*Satisfactory*

Veterinary Compounding

Are APIs or other components labeled for veterinary use segregated or marked to prevent use for human compounding?	*Not Applicable*
Does the pharmacy meet the same standards for animal compounding as human compounding?	*Not Applicable*
Is the pharmacist knowledgeable or does the pharmacy have up-to-date references regarding species limits that can result in toxicity when compounding with particular drugs/excipients?	*Not Applicable*
Does the pharmacy document if the animal is a pet or used for food?	*Not Applicable*
Is the pharmacist familiar with, or does the pharmacy have the most up-to date references regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals?	*Not Applicable*
Does the pharmacy have a list of drugs and components that have been designated by state or federal authorities as prohibited ingredients in CSPs for food-producing animals?	*Not Applicable*
Is the pharmacist familiar with, or does the pharmacy have the most up-to-date reference regarding regulations for drug use in performance animals?	*Not Applicable*

Label

S209. Is the CSP properly labeled to include the generic name(s), and	*Satisfactory*
S210. For outpatient prescriptions, does the label include a statement that the CSP has been compounded by the pharmacy?	*Satisfactory*
S211. Does the label include a beyond-use date?	*Satisfactory*
S213. If the CSP is compounded as a batch, does the label contain a unique lot number assigned to the batch, and	*Satisfactory*
S214. Quantity, and	*Satisfactory*
S215. Appropriate ancillary instructions, such as storage or cautionary statements, and	*Satisfactory*
S216. Any device-specific instructions, if appropriate?	*Satisfactory*
S220. Are CSPs assigned a beyond-use date based on the specified labeling for the drug, appropriate literature sources, or direct testing?	*Satisfactory*

Training & Competency Testing

S129. Has each pharmacist completed the required education and training prior to engaging in sterile compounding?	*Satisfactory*
S130. Has each pharmacy technician completed the required education and training prior to engaging in sterile compounding?	*Satisfactory*
S142. Does the pharmacy maintain documentation to demonstrate that all compounding personnel have successfully passed initial competency evaluation/testing (e.g., media-fill testing, gloved fingertip/thumb testing)? Does the pharmacy have an on-the-job training program?	*Satisfactory*
S144. Does the pharmacy maintain documentation of on-going training and testing for all compounding personnel (e.g., observation of aseptic technique, media-fill testing, gloved fingertip/thumb testing, continuing education)?	*Satisfactory*

Comment

Advised to ensure the aseptic technique of each person compounding or supervising personnel compounding sterile preparations be observed evaluated by written and practical tests, media fill and gloved fingertip testing, and be documented. This must be done every six months if high risk sterile compounding is being conducted.

Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



DAMASKE, DAVID PIC 41186



Terri Burrows

TEXAS STATE BOARD OF PHARMACY
1801 Congress Avenue, Suite 13.100
Austin, TX 78701-1319
(512) 305-8000

License Number: 32264

(Date PDF Version Generated: 9/18/2024)

HELPFUL PHARMACY INFORMATION

- Pharmacies are required to notify TSBP within 10 days of a discontinuance of service, change of location or closure. See the TSBP website here Pharmacy - Renew & Update (texas.gov) for changes.
- Renewals open about 60 days prior to your expiration date, renewal information can be found here Renew | Pharmacy (texas.gov).
- Change of Employment or Change of PIC information can be found here Update | Employment (texas.gov).
- Change of Ownership – Call (512) 305-8021 or see Apply | Change of Ownership (texas.gov).
- For questions or assistance regarding rules, contact TSBP Rules Queue line at (512) 305-8070 see www.pharmacy.texas.gov.
- Non-Resident Pharmacy questions call (512) 305-9127 or email NonResPhcy@pharmacy.texas.gov.

An up-to-date License Verification is always available on the Board's website: http://www.pharmacy.texas.gov/

This certifies that the pharmacy named below is hereby licensed to operate as a Class **AS** pharmacy.

License No. **32264** Expiration Date: **09/30/2026**

Balances: 9

BEAKER PHARMACY
7810 ELDORADO PKWY STE 200
MCKINNEY, TX 75070

Daniel R. Carroll, Pharm.D.,
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 32264

BEAKER PHARMACY

License Information

License Status Active
License # 32264
Expiration Date 09/30/2026
Date License Issued 09/26/2018

Address

7810 ELDORADO PKWY STE 200
MCKINNEY, TX 75070
County COLLIN
Phone (972) 972-4700

Pharmacy Details

Prior Disciplinary Orders* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy Community Sterile Compounding
Type of Ownership LLC
Type of Pharmacy Community Independent
# of Hospital beds

Employment Information

Pharmacist in Charge
DAMASKE, DAVID LAWRENCE

Pharmacy Profile ¥

Accessible to disabled persons?		Yes
Participates in the Texas Medicaid program?	**Translating services (Listed Below If Available)**	Yes

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans and/or Inspection Reports

- 971601 32264 BEAKERPHARMACY 2018-09 09-2023.pdf
- 971601 32264 BEAKERPHARMACY 2019-05 05-2024.pdf
- 971601 32264 BEAKERPHARMACY 2021-02 02-2026.pdf
- 971601 32264 BEAKERPHARMACY 2022-10 10-2027.pdf
- 971601 32264 BEAKERPHARMACY 2023-02 02-2028.pdf
- 971601 32264 BEAKERPHARMACY 2024-03 03-2029.pdf
- 971601 32264 BEAKERPHARMACY 2025-04 04-2030.pdf
- 971601 32264 BEAKERPHARMACY 2025-08 08-2030.pdf
- 971601 32264 E BEAKERPHARMACY 2025-08 08-2030.pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

Nuclear	No
Out-Patient Prescriptions	Yes
Ship Prescription Out of State	Yes
Class D (Expanded Formulary)	No
Class D (Alternative Visit Schedule)	No
Compounding Sterile-Risk Level Low	Yes
Compounding Sterile-Risk Level Med	Yes
Compounding Sterile-Risk Level High	Yes
Compounding Non-Sterile	Yes
24 Hour Service	No
Closed Door	No
Compounding, Office Use	Yes
Home Delivery	No
Infusion	No
Pharmacist Administered Immunizations	Yes
Veterinary Prescriptions	Yes
In-Patient Medication Orders	No
Out-Patient Surgery	No
Rural Hospital	No
Tech Check Tech	No
503b Outsourcing Facility	No
Other Services	No

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
BLANFORD, ROBERT T	33295	07/31/1992	09/30/2027	Staff	Active
BROWER, ALEXANDRA	57106	08/13/2015	03/31/2027	Staff	Active
CASTRO, STACEY	53969	09/12/2013	01/31/2026	Staff	Active
CLINE, SHEILA	53629	08/08/2013	01/31/2026	Staff	Active
DAMASKE, DAVID LAWRENCE	41186	10/03/2002	02/28/2027	PIC	Active
DAMASKE, AVNI	40204	08/14/2001	09/30/2027	Relief	Active
KALANGARA, GEETHU	58805	07/21/2016	11/30/2026	Staff	Active
LEE, JANE I	44197	06/09/2006	03/31/2026	Staff	Active
MATHEW, PRISCILLA	65886	10/03/2019	08/31/2027	Relief	Active
PARK, DALE	67314	08/20/2020	12/31/2026	Staff	Active
PATEL, SARAH	65944	10/10/2019	05/31/2027	Staff	Active
PIPER, VINCENT ROBERT	32098	10/04/1990	05/31/2026	Staff	Active
RODNEY, TERENCE ALLEN	63383	08/23/2018	07/31/2026	Staff	Active
TRAN, ALEXANDER Q	63413	08/30/2018	12/31/2025	Staff	Active

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Texas Registered Technicians/Trainees Employment Information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status
ALARCON, JENNIFER	328742	10/04/2021	04/30/2026	Staff	Active
ANDRADE , DANIELA SALOME	330950	11/03/2021	11/30/2025	Staff	Active
AVILA, DANIELLE HAILEY	317036	01/27/2021	08/31/2026	Staff	Active
BAKER , ALEXANDRIA	343327	08/20/2022	06/30/2027	Staff	Active
BAZALDUA, AMIA	382577	01/28/2025	01/31/2027	Staff	Active
BERDICHEVSKAYA, YELENA	101221	03/02/2004	01/31/2027	Staff	Active
BLACK, TASHA MARIE	104157	05/15/2004	03/31/2026	Staff	Active
BROWN, RONNEE	346868	10/24/2022	01/31/2026	Staff	Active
EVANS, PATRICIA DIONNE	384632	03/17/2025	03/31/2027	Staff	Active
FELTON, MARY ANN	107403	04/19/2004	02/28/2026	Staff	Active
FLORES, DANIEL SEBASTIAN	314616	11/17/2020	11/30/2025	Staff	Active
GAUVEY, KIRSTEN RENEE	315991	12/24/2020	10/31/2027	Staff	Active
HILL, OLIVIA	302372	11/04/2019	09/30/2026	Staff	Active
JARAMILLO PEREZ, CRISTOBAL	288693	10/01/2018	02/28/2026	Staff	Active
KING, JESSE TAYLOR	261105	09/27/2016	11/30/2026	Staff	Active
KUE, KAO N	201524	10/11/2011	10/31/2026	Staff	Active
LEDFORD, DYLAN TYLER	322681	06/08/2021	06/30/2027	Staff	Active
LEE, JZANE D	331063	11/05/2021	11/30/2025	Staff	Active
LEE, JZENA D	370805	05/10/2024	05/31/2026	Staff	Active
LONDON, FAITH NICOLE	349949	01/10/2023	01/31/2027	Staff	Active

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Texas Remote Pharmacy Information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode

Page 0 of 0 20 No records to view

Texas Pharmacy Owner Information

Owner Name	Owner Title	Address	City	State	Zipcode
APTEEK RX, LLC	OWNER	,			
DAMASKE, DAVID LAWRENCE	OFFICER	,			
DAMASKE, AVNI	OFFICER	,			

Page 1 of 1 20 View 1 - 3 of 3

The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Apteek Rx, LLC d/b/a Beaker Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04343

Physical Address: 7810 Eldorado Pkwy Ste 200

City: McKinney State: TX Zip: 75070

Mailing Address (if different from physical address): Same

City: State: Zip:

Telephone: (972) 972-4700 Website: https://beakerpharmacy.com/

Licensing Company Email: beakerpharmacylicensing@openloophealth.com

Section 2: Personal Information

First: Jonathan Middle: Nguyen Last: Lensing

Alias(es, nicknames, name changes, etc.):

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Iowa Carver College of Medicine		08/16 – 05/20	
Address	**City**	**State**	**Zip**
375 Newton Rd	Iowa City	IA	52242
Diploma/Degree obtained, if any			
MD			

School Name		From - To (MM/YY – MM/YY)	
Calvin University		08/12 – 05/16	
Address	**City**	**State**	**Zip**
3206 Burton Ave SE	Grand Rapids	MI	49546
Diploma/Degree obtained, if any			
B.S. Biology B.S. Biochemistry			

School Name		From - To (MM/YY – MM/YY)	
Pella Christian High School		08/08 – 05/12	
Address	**City**	**State**	**Zip**
300 Eagle Ln	~~Des Moines~~ Pella	IA	50219
Diploma/Degree obtained, if any			
High school Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/24 –	[redacted]			
12/22 – 05/24				
08/20 – 12/22				
05/16 – 08/20				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
OpenLoop Health			01/20 — Present
Business Address	**City**	**State**	**Zip**
317 6th Ave	Des Moines	IA	50309
Phone	**Title**		
641 - 780 - 1114	CEO		
Description of Duties			
CEO - Management			

Business Name			From - To (MM/YY – MM/YY)
University of Iowa Carver College of Medicine			08/16 – 05/20
Business Address	**City**	**State**	**Zip**
375 NEWTON RD	IOWA CITY	IA	52242
Phone	**Title**		
	Research Assistant		
Description of Duties			
Conducted medical research			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JONATHAN LENSING
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/15/2026
Date

Please have this section completed in the presence of a Notary Public.

State of Iowa, ss. County of Dallas

I, Jonathan Lensing, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/15/2026
Date

Subscribed and Sworn to before me this 15 day of January, 2026

Jacqueline White
Notary Public Signature

JACQUELINE WHITE
Notarial Seal - Iowa
Commission Number 864870
My Commission Expires May 21, 2028

(Seal)

4NN

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☐ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.)	☐ Other:	☒ Non-sterile Compounding
			☒ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Blue Door Pharmacies, LLC

Physical Address: 15225 Shady Grove Rd Suite 101

City: Rockville State: MD Zip: 20850

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 301-948-4222 Toll Free # (NAC 639.708, NRS 639.23286): 1-877-213-2387

Fax: 301-948-0018 Contact Email: sheila@shadygroverx.com

Website: www.shadygroverx.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Sheila Alizadeh, PharmD

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24864

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Sheila Alizadeh	NV Pharmacist Registration #: 24864
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-S) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: n/a	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: MD

Parent Company (if any): _____

Corporation/Organization Name: Blue Door Pharmacies, LLC

Mailing Address: 15225 Shady Grove Road Suite 101

City: Rockville State: MD Zip: 20850

Telephone: 301-948-4222 Email: sheila@shadygroverx.com

Contact Person Name: sheila@shadygroverx.com

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner/PIC (title) for Blue Door Pharmacies, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Sheila Alizadeh, PharmD

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

11/6/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sheila Alizadeh,PharmD

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

11/6/2025

Date

Board Use Only	Date Received: 11/14/26	Amount: $500-ck1113

- Officers and Ownership Information

  There are no stockholders or officers and I am the owner.

  Sheila Alizadeh, PharmD



STATE OF MARYLAND
Department of Assessments and Taxation

I, BOB YEAGER OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF THE STATE OF MARYLAND, DO HEREBY CERTIFY THAT THE DEPARTMENT, BY LAWS OF THE STATE, IS THE CUSTODIAN OF THE RECORDS OF THIS STATE RELATING TO LIMITED LIABILITY COMPANIES , OR THE RIGHTS OF LIMITED LIABILITY COMPANIES TO TRANSACT BUSINESS IN THIS STATE, AND THAT I AM THE PROPER OFFICER TO EXECUTE THIS CERTIFICATE.

I FURTHER CERTIFY THAT BLUE DOOR PHARMACIES LLC (W26628693) , REGISTERED OCTOBER 17, 2025, IS A LIMITED LIABILITY COMPANY EXISTING UNDER AND BY VIRTUE OF THE LAWS OF THE STATE OF MARYLAND, AND THAT THE LIMITED LIABILITY COMPANY IS AT THE TIME OF THIS CERTIFICATE IN GOOD STANDING TO TRANSACT BUSINESS.

IN WITNESS WHEREOF, I HAVE HEREUNTO SUBSCRIBED MY SIGNATURE AND AFFIXED THE SEAL OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF MARYLAND AT BALTIMORE ON THIS DECEMBER 02, 2025.

Bob Yeager
Director

700 East Pratt Street, 2nd Flr, Ste 2700, Baltimore, Maryland 21202
Telephone Baltimore Metro (410) 767-1344 / Outside Baltimore Metro (888) 246-5941
MRS (Maryland Relay Service) (800) 735-2258 TT/Voice

Online Certificate Authentication Code: Zjb5ilgBvEasfXFaiKm3cw
To verify the Authentication Code, visit http://dat.maryland.gov/verify

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Blue Door Pharmacies, LLC

Pharmacy/Wholesaler License # (if applicable): P05361 in MD

Physical Address: 15225 Shady Grove Road Suite 101

City: Rockville State: MD Zip: 20850

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 301-948-4222 Website: www.shadygroverx.com

Licensing Company Email: sheila@shadygroverx.com

Section 2: Personal Information

First: Sheila Middle: Last: Alizadeh

Alias(es, nicknames, name changes, etc.): n/a

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Univeristy of MD School of Pharmacy		08/99-05/03	
Address	**City**	**State**	**Zip**
20 N Pine St	Baltimore	MD	21201
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
University of Maryland College Pard		09/91-12/94	
Address	**City**	**State**	**Zip**
no street address	College Park	MD	20742
Diploma/Degree obtained, if any			
BS Biology			

School Name		From - To (MM/YY – MM/YY)	
St Maria Goretti		09/85-05/89	
Address	**City**	**State**	**Zip**
18614 Crestwood De	Hagerstown	MD	21742
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/15-present	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Blue Door Pharmacies, LLC			08/10-present	
Business Address		**City**	**State**	**Zip**
15225 Shady Grove Road Suite 101		Rockville	MD	20850
Phone	**Title**		**Number of Employed Hours**	
301-948-422	owner/PIC		31,200	
Description of Duties				
As the owner and PIC of I am responsible for all legal, professional, operational and financial oversight for Shady Grove Pharmacy. I ensure that all pharmacy operations comply with applicable federal and state laws.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Sheila Alizadeh, PharmD, **certify that as the designated representative for**

Blue Door Pharmacies, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sheila Alizadeh

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/12/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sheila Alizadeh

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/13/26

Date

Please have this section completed in the presence of a Notary Public.

State of MARYLAND, ss. County of MONTGOMERY

I, Sheila Alizadeh, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/13/26

Date

Subscribed and Sworn to before me this 13TH day of JANUARY 2026.

Notary Public Signature

RAYMOND WAI LEE
Notary Public - State of Maryland
Frederick County
My Commission Expires Oct 26, 2029

NOTARY PUBLIC

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Blue Door Pharmacies, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 15225 Shady Grove Rd Suite 101

City: Rockville State: MD Zip: 20850

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 301-948-4222 Toll Free # (NAC 639.708, NRS 639.23286): 1-877-213-2387

Fax: 301-948-4222 Contact Email: sheila@shadygroverx.com

Website: www.shadygroverx.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Sheila Alizadeh, PharmD

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24864

Name of Designated Person(s) as defined by revised USP-797 guidelines: Sheila Alizadeh, PharmD

Email of Designated Person(s): sheila@shadygroverx.com

Telephone of Designated Person(s): 240-731-2813

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

■ Category 1 ■ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 09.12.2025

6. What is the frequency of the recertification for the ISO classified areas? q 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? monthly

10. Will you be performing sterile hazardous drug compounding? ☐ Yes ■ No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

- dilute atropine eye drops.
- NAD^+ subcutaneous injection

12. What laboratory performs your sterility or endotoxin testing?

Name: Eagle Analytical

Address: 11111 S Wilcrest Dr S1000

City: Houston State: TX Zip: 77099

Telephone: 1-800-745-8516

13. What is your procedure for visual inspection of compounded sterile products?
We have black and white backgrounds to inspect for particulate matter in sterile compounds.

14. How often do you perform glove fingertip and medial fill testing?
Twice yearly

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
Initial training is through USP as well as onsite training at Medisca's training facility in Aventura, FL.
In addition, quarterly training modules on calculations, patient safety and medication errors are performed.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

We employ two all in one agents on a rotating basis: Tex Q and Spor-Klenz followed by 70% sterile alcohol.
Primary engineering control (LAFW) are cleaning prior to and at the completion of compounding activities. In addition it is cleaned every 30 minutes during continuous
comounding and after spills when contamination is suspected. Work surfaces are cleaned at the beginning and end of each shift and after spills.
Floors are cleaned daily at the end of each shift
Walls, doors, storage racks, shelving is cleaned monthly.
Ante room counters are cleaned daily and after spills.

17. Who performs the sterile compounding process at your facility?

Sheila Alizadeh and Amelia Sherman

18. Who is responsible and accountable for the sterile compounding process at your facility?
Sheila Alizadeh

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Yes, we use overnight priority FedEx and use insulated shipping materials with 2-3 Nordic Ice ice packs.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A n/a		
2. Are you complying with all USP 800 guidelines?	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? n/a

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

n/a

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

n/a

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

n/a

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

n/a

5. What is the frequency for completing surface sampling? n/a			
6. What is the frequency for using sporicidal agents?			
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?		Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?		Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sheila Alizadeh, PharmD

Name of Person who Completed the Form

PIC/owner

Title

Signature (copies or stamps not accepted)

11/6/25

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

Maryland
DEPARTMENT OF HEALTH

Wes Moore, Governor • Aruna Miller, Lt. Governor • Laura Herrera Scott, M.D. M.P.H., Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue, Baltimore, Maryland 21215-2299

Neil Leikach, RPh, M.Sc., Board President • Deena Speights-Napata, M.A. Executive Director

Sterile Compounding Inspection Form

The Maryland Board of Pharmacy developed this inspection form in coordination with NABP and other state boards of pharmacies in an attempt to apply a uniformed approach to inspection of sterile compounding pharmacies, wherever located, for compliance of USP 797 standards. Thus, this form includes requirements of other states, items related to best practices, and informational questions related to the Board's health oversight functions. These items are highlighted with an asterisk.

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

1.00 PERMITS AND LICENSES

Corporate Pharmacy Name: Shady Grove Pharmacy

Pharmacy Name-Doing Business as (d/b/a) or-Trade Name: _____

Address: 15225 SHADY GROVE RD, ROCKVILLE, MD, 20850

Business Telephone Number: 301-948-4222 Business Fax Number: 301-948-0018

Business Email Contact: sheila@shadygroverx.com

Maryland Pharmacy Permit Number: P05361 Expiration: 05/31/2026

CDS Registration Number: 472352 Expiration: 06/30/2025

DEA Registration Number: [redacted] Expiration: 02/28/2025

Pharmacy Hours: M-F 9:00am - 5:00pm; S,S Closed

Inspection Date: 1/23/2025 Arrival Time: 11:45 Departure Time: _____

Type of Inspection: Opening ○ Annual ◉ Follow-up ○ Previous Date: 01/18/2024

Name of Inspector: Jered Pasay

2.00 PERSONNEL (COMAR 10.34.03.05)

Name of Pharmacist/Manager who is charged with ensuring compliance with all applicable laws
Sheila Alizadeh

Pharmacist Employees	License #	Exp. Date
See Attached		

Registered Technicians	Registration #	Exp. Date
See Attached		

Support Personnel	Title	Duties
See Attached		

General Operations Information	Y	N	N/A	Follow up ☐	
3.00 The pharmacy department provides service 24 hours a day.	◉	○			COMAR 10.34.05.
4.00 The pharmacy hours of operation are prominently displayed.	◉	○	○		COMAR 10.34.05.03B
5.00 All permits, licenses, and registrations are posted conspicuously.	◉	○			HO §12-311, HO §12-408(b) and HO §12-6B-08
6.00 Does the pharmacy dispense/distribute sterile compounded preparations over state lines	◉	○			
6.01 States in which Pharmacy is Licensed/Permitted					
NJ, FL, ME, GA, VA					
7.00 Are patient profiles complete, easily accessible and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.*	◉	○	○		COMAR 10.34.19.07A
Maintained electronically					
8.00 Does the pharmacy **dispense** sterile compounded preparations pursuant to a prescription?	◉	○	○		HO § 21-220
8.01 The pharmacy fills original prescriptions received via the internet. *If yes, how do pharmacists verify that a relationship exists between the patient and the prescriber?*	○	◉	○		HG §21-220; COMAR 10.19.03.02 and .07
8.02 Are sterile compounded prescriptions picked up at the pharmacy?	◉	○	○		
8.03 Are sterile compounded prescriptions delivered/mailed to patients in their homes or residential facilities?	◉	○	○		
8.03A Proper in-transit storage is consistent with preparation labeling	◉	○	○		COMAR 10.34.19.06(A)(2)
8.04 A reasonable effort to provide tamper-evident packaging if appropriate to setting	◉	○	○		COMAR 10.34.19.06(A)(1)
9.00 Does the pharmacy **distribute** sterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*	○	◉	○		COMAR 10.34.37

9.01 Does the pharmacy distribute sterile compounded preparations to practitioners for office-use? COMAR 10.34.37

9.02 Does the pharmacy distribute sterile compounded preparations to hospitals, clinics, or surgery centers? COMAR 10.34.37

9.03 Does the pharmacy distribute sterile compounded preparations to a wholesale distributor? COMAR 10.34.37

9.04 Does the pharmacy have a sales force that distributes samples containing active ingredients? *List samples provided.* COMAR 10.34.37

9.05 Does the pharmacy provide sterile compounded preparations to other pharmacies for dispensing?

9.05A Does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations?

9.06 Proper in-transit storage is consistent with preparation labeling COMAR 10.34.19.06(A)(2)

9.07 A reasonable effort to provide tamper-evident packaging if appropriate to setting COMAR 10.34.19.06(A)(1)

10.00 Is the pharmacy registered with the FDA as an Outsourcing Facility? COMAR 10.34.37

11.00 Which of the following sterile compounds are prepared?

	Y	N		Y	N
11.01 Allergen extracts	○	●	11.07 Baths and soaks for live organs and tissues	○	●
11.02 Parenteral solutions	○	●	11.08 Irrigations for wounds and body cavities	○	●
11.03 Parenteral *suspensions*	○	●	11.09 Injectables	●	○
11.04 Preservative-free parenterals	○	●	11.10 Radiopharmaceuticals	○	●
11.05 Ophthalmic preparations	●	○	11.11 Any other sterile preparations (implants, pellets, etc.). *Provide list.*	○	●
11.06 Oral or nasal *inhalation* preparations (not topical sprays)	○	●			

12.00 Does the pharmacy prepare medication using proprietary bag and vial systems? (ADD-Vantage, Mini Bag Plus. Etc)

12.01 Are they docked in an ISO 5 environment?

12.02 Are BUDS less than or equal to manufacturers labeling?

13.00 Does the pharmacy outsource medications? *Indicate companies*

13.01 Does the pharmacy act as an outsourcer? *Indicate companies*

14.00 Does the pharmacy compound investigational drugs?

15.00 Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *Indicate name and volume/percent compounded currently.*

15.01 If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.

15.02 If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing.
NOTE: Per FDA guidance, 503B facilities may continue to distribute for 60 days following removal from drug shortage list for existing orders.

FDA shortage list checked before compounding

16.00 Does the pharmacy provide sterile compounded preparations to be administered via an implantable infusion pump?

17.00 Does the pharmacy perform compounding for **immediate use?**
Indicate percentage of immediate use sterile compounding.

18.00 Does the pharmacy perform compounding with **hazardous drugs?**
Indicate percentage of hazardous sterile compounding.
NOTE: NIOSH list of hazardous drugs including chemotherapy, hormones, etc.

18.01 Does pharmacy have a plan to comply with USP Chapter <800> by the implementation date? Describe plan.

19.00 Does the pharmacy perform compounding using **blood products** (or other biological materials)? Such as wound care, autologous eye drops, etc. *Describe.*

20.00 Does the pharmacy compound using any Federally **controlled substances I-V?**
Indicate controlled substances used and percentage of controlled substance sterile compounding.

21.00 Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)?
Verify that personnel can access them and are familiar with the format.

Hazardous Drugs CSPs
COMAR 10.34.07.03(E)

Component Selection and Use

Y N N/A Follow up

22.00 **APIs:** Does the pharmacy make any sterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?

22.01 Does the pharmacy purchase APIs directly from the manufacturer/repackager?
If not, indicate the source of APIs

22.02 Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified*

22.03 Does the pharmacy use active ingredients that are not from an FDA facility? ○◉○
If so, indicate sources.

22.04 Are on-hand quantities of APIs used for compounding tracked by computer? *** ◉○○

23.00 If the facility performs both sterile and nonsterile compounding, the areas are separated and distinct. ◉○○

24.00 If the facility performs compounding using blood products (or other biological materials), this compounding area is separate and distinct from the general compounding areas. ○○◉

24.01 Are components used in compounding with blood products restricted to the blood compounding area (not used in other compounding areas)? ○○◉

25.00 **Active Pharmaceutical Ingredients (APIs), bulk drug substances:** ◉○○ Nonsterile Ingredients and Devices
All bulk drug substances (APIs) used are:
1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or
2) A component of an FDA-approved human drug product; or
3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation
NOTE: Must comply with (1) or (2) above until the FDA list is issued

25.01 Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. ◉○○ Nonsterile Ingredients and Devices
Verification of Compounding Accuracy and Sterility
Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.
NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before being used for compounding.

25.02 USP- or NF-grade substances used, if available. ◉○○ Nonsterile Ingredients and Devices

25.03 If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities. ◉○○ High-Risk Level CSPs cross reference to 795, Component Selection Handling and Storage, Item number 4

25.04 APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only," "not for drug use," or are handwritten labels from other pharmacies. ○○◉ High-Risk Level CSPs cross reference to 795, Component Selection Handling and Storage, Item number 4
Photograph and describe if found. Request copies of the invoices for products with questionable labels

25.05 All substances and components have a complete label including a batch control or lot number, and an expiration date. ◉○○ Responsibility of Compounding Personnel
Ingredients and Devices
Storage and Beyond-Use Dating cross reference to USP Chapter 795

25.06 For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned is not greater than one (1) year, unless it is supported with data and/or testing. **NOTE: purity and quality testing may be performed to extend.** ◉○○ Nonsterile Ingredients and Devices

25.07	All APIs are labeled with the date they were received.		Nonsterile Ingredients and Devices
25.08	If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.		Nonsterile Ingredients and Devices Determining BUD cross reference to USP Chapter 795
25.09	Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones). ***		Hazardous Drugs CSPs
26.00	The Pharmacy is free of preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).		U.S. Food, Drug and Cosmetic Act List 21CFR216.64 COMAR 10.34.19.04
27.00	When manufactured products are used for compounding, all the other excipients (in addition to the active ingredient) in the manufactured product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.		Introduction Ingredients and Devices
28.00	If a pharmacy compounds stock solutions or components that are then used to compound a finished product, using APIs, these stock solutions are categorized as high-risk compounding. ***		High-Risk Level CSPs
28.01	The stock solutions are assigned BUD based on the USP<795> high risk compounded BUD OR are assigned on the basis of direct tests or extrapolation from reliable literature sources to support an extended BUD. ***		High-Risk Level CSPs
28.02	Compounded preparations using the stock solution are classified as high risk compounds with appropriate handling with regard to BUD and testing requirements. ***		High-Risk Level CSPs
29.00	If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding. ***		
29.01	For animal compounding, does the compounding meet the same standards as compounding for human patients? ***		Cross reference USP Chapter 795
29.02	The pharmacist is knowledgeable or has the most up-to-date references regarding the individual species limitations in processing and metabolic capacity that can result in toxicity when certain drugs or excipients are used. ***		Cross reference USP Chapter 795
29.03	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet. ***		Cross reference USP Chapter 795
29.04	The pharmacist is familiar with, or has the most up-to-date reference regarding drug residues in the food chain and withdrawal times if compounding for food producing animals. ***		Cross reference USP Chapter 795

29.05	The facility has a list of drugs and components not allowed when compounding for food-producing animals.***	○○●	Cross reference USP Chapter 795
29.06	The pharmacist is familiar with, or has the most up-to-date reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)***	○○●	Cross reference USP Chapter 795

Environment		Y	N	N/A	Follow up □
30.00	The anteroom contains an eyewash station or sink design suitable for flushing an eye injury.	●	○		COMAR 10.34.19.09(C)(2)(c)
31.00	Entry into the sterile compounding areas is limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel).	●	○		
32.00	Certification is performed to the Controlled Environment Testing Association (CETA) guide (USP: CETA CAG-003-2006 Certification Guide for Sterile Compounding Facilities) and is noted on the report.	●	○		
32.01	If the certification standard used and noted on the report is NOT CETA CAG-003-2006, the facility has performed a comparison and determined the standard used is the same or better than the CETA CAG-003-2006 guide.	○	○	●	
33.00	The anteroom has a line of demarcation or other segregation of the dirty to the clean side. NOTE: The line of demarcation may NOT be the doorway between the anteroom and the clean/buffer room.***	●	○	○	Additional Personnel Requirements
33.01	Carts used in the anteroom are kept on the outside of the line of demarcation.***	●	○	○	Suggested SOPs
33.02	Carts used in the clean/buffer room are kept on the clean side of the line of demarcation.***	●	○	○	Suggested SOPs
34.00	Hand drying is with lint-free disposable towels, or an electronic or HEPA filtered hand dryer.	●	○	○	Personnel Cleansing and Garbing COMAR 10.34.19.11(D)
34.01	If using a hand dryer, particle count and smoke testing validation is performed while dryer is in use (while someone is actively using to dry their hands) at certification, and the immediate area around the dryer is part of the viable air and surface testing program performed.***	○	○	●	Environmental Viable Airborne Particle Testing Program
35.00	Beverages including drinking water, chewing gum, candy, or food items are prohibited from the clean/buffer room or anteroom.	●	○	○	Additional Personnel Requirements Suggested SOPs (Item 13) COMAR 10.34.19.09
36.00	All surfaces of the sterile product compounding area carts, shelves, stools, chairs, and other items are resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low particulate generating.	●	○	○	Facility Design and Environmental Controls 10.34.19.09(B)(3)
37.00	Walls are constructed of durable material, which is cleanable, such as epoxy-coated or heavy-gauge polymer material. *If panels are used, they are locked together and sealed.*	●	○	○	Facility Design and Environmental Controls 10.34.19.09(B)(3)

38.00	The ceiling surface shall be impervious and hydrophobic. *If tiles are used, they shall be locked and the seams (between tiles and where the tiles meet with the walls) shall be caulked and sealed.*	◉○○	Facility Design and Environmental Controls 10.34.19.09(B)(3)
39.00	The floor overlaid with wide sheet flooring and seamless or with heat welded seams, with coving to the sidewall, and a sealed seam where the coving meets the wall.	◉○○	Facility Design and Environmental Controls 10.34.19.09(B)(3)
40.00	The clean/buffer room or anteroom does not have dust collecting overhangs. ***	◉○○	Facility Design and Environmental Controls
41.00	The exposed surfaces of:		
41.01	PEC are free of dirt, rust, chips and particulate matter.	◉○○	Cleaning and Disinfecting the Compounding Area COMAR 10.34.19.09(B)(3)
41.02	Light fixtures are smooth, mounted flush, and sealed.	◉○○	Facility Design and Environmental Controls COMAR 10.34.19.09(B)(3)
42.00	A working sink, located on the clean side of the line of demarcation, is available that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands and is away from/not adjacent to any PEC(s).	◉○○	Additional Personnel Requirements COMAR 10.34.19.09(C)(2)
43.00	The permit holder shall ensure that the clean room in the controlled environment contains no sinks or floor drains;	◉○○	Facility Design and Environmental Controls Appendix 1 COMAR 10.34.19.09(B)(2)
44.00	All air ducts controlling air flow into the sterile compounding clean/buffer room and anteroom are equipped with High Efficiency Particulate Air filtered air that maintains the cleanroom with an ISO Class 7 environment and the anteroom with an ISO Class 7 (when adjacent to HD cleanroom) or ISO Class 8 environment.	◉○○	ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas
45.00	Supply air ducts through HEPA filters and ceiling diffusers and return ducts are known to the walls in the anteroom and clean/buffer room. ***	◉○○	Facility Design and Environmental Controls
46.00	If there are particle generating equipment/appliances in the clean/buffer room or anteroom (e.g., computers, printers, refrigerators, dishwashers, etc.), they are located downstream of the air flow over and out of the room using particle velocity and the air flow has been confirmed by smoke testing when in use. ***	◉○◉	ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas
47.00	If compounding occurs using nonsterile ingredients, products, components, or devices (for example compounding with non-sterile APIs or using nonsterile vials and closures), the pharmacy has appropriate equipment to sterilize the finished product.	○○◉	Verification of Compounding Accuracy and Sterility
47.01	Pre-sterilization procedures for high-risk level CSPs (such as weighing and mixing) are performed in no worse than an ISO Class 8 environment.	○○◉	Placement of Primary Engineering Controls Appendix 1
48.00	Completely enclosed anteroom and clean/buffer room (with a door) are equipped with monitors or gauges to measure differential pressure.	◉○○	Pressure Differential Monitoring Facility Design and Environmental Controls

48.01 Anteroom is at least 0.02" wc positive pressure to general pharmacy areas.

Facility Design and Environment Controls

48.02 Clean/buffer room is at least 0.02" wc positive pressure to Anteroom.

Facility Design and Environment Controls

48.03 Hazardous compounding room and drug storage area is at least 0.01" wc negative pressure to ISO Class 7 anteroom.

Hazardous Drugs CSPs

48.04 Pressures are reviewed and documented on a log at least every work shift (minimum of once daily) or monitored by a continuous recording device.
View logs

Pressure Differential Monitoring

48.05 Written plan in place to detect and react to pressure differentials outside of limits.

Facility Design and Environmental Controls Equipment

Logged manually

49.00 Is the clean/buffer room and anteroom not fully enclosed (open or with plastic strips - no door that closes):

Facility Design and Environment Controls

49.01 Airflow is measured across the openings.

49.02 Airflow is at least 40 feet per minute across the entire opening.

Facility Design and Environment Controls

49.03 Airflow is read and recorded each shift (minimum of once daily) or continuously recorded. *View logs.*

Pressure Differential Monitoring

49.04 Written plan in place to detect and react to airflow measurements outside of limits

Facility Design and Environmental Controls Equipment

49.05 This area is used only for low- and medium-risk compounding
NOTE: HD and high-risk not allowed.

Facility Design and Environment Controls

50.00 **Temperature:** The temperature of all compounding and drug storage areas shall be maintained in accordance with standards, and a written plan shall be in place and followed to address any excursions.

Facility Design and Environment Controls
Monitoring Controlled Storage Areas
USP Chapter 659
COMAR 10.34.19.09(3)(b)

50.01 [redacted]

Facility Design and Environment Controls

50.02 [redacted]

Monitoring Controlled Storage Areas

50.03	Temperature monitoring is also performed in **drug storage areas** (if separate from the compounding areas). Temperature is maintained at controlled room temperature of 20° - 25° C (68° - 77° F) or as specified by FDA approved labeling for drug product storage.	◉○○	Nonsterile Ingredients and Devices COMAR 10.34.19.09(A), 10.34.19.15(A), 10.34.19.12(B),
50.04	Temperature monitoring in the **drug storage area** is performed at least once daily and documented. *Temperature records are maintained for at least 5 years.*	◉○○	Monitoring Controlled Storage Areas
50.05	Temperature in the **refrigerator or cooler** is maintained to provide controlled cold temperature of 2° to 8°C (36° to 46°F) or as specified by FDA approved labeling for drug product storage.	◉○○	Monitoring Controlled Storage Areas COMAR 10.34.19.10(A)
50.06	Temperature monitoring in the **refrigerator** is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration. Alternatively, continuous monitoring or retroactive detection using min/max may be used. *Temperature records are maintained for at least 5 years.*	◉○○	Monitoring Controlled Storage Areas COMAR 10.34.19.10(A), 10.34.19.15(B), 10.34.19.07(B)(1)(b)
50.07	Temperature in the **freezer** is maintained to provide controlled frozen temperature of -25° to -10°C (-13° to 14°F) or as specified by FDA approved labeling for drug product storage.	◉○○	Monitoring Controlled Storage Areas
50.08	Temperature monitoring in the **freezer** is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration. *Temperature records are maintained for at least 5 years.*	◉○○	Monitoring Controlled Storage Areas COMAR 10.34.19.07(B)(1)(b), 10.34.19.10(A), 10.34.19.15(B)
50.09	Action plan in place for any temperature excursions including evaluating excursion effects on drug product integrity for all temperature-monitored areas. ***	◉○○	Monitoring Controlled Storage Areas

Logged manually

51.00	Humidity, if required by specific drug products, is kept in the compounding area, maintained to provide humidity within the specified ranges. If drug products require storage in a "dry place," humidity is not to exceed 40%. (General recommended range is 35-60% for participating sterile compounding.) ***	◉○○	Nonsterile Ingredients and Devices USP Chapter 659 (definition of dry place)
51.01	If applicable, humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained. ***	◉○○	Nonsterile Ingredients and Devices
51.02	If applicable, and if not in action plan, including evaluating excursion effects on drug product integrity. ***	○○◉	Nonsterile Ingredients and Devices
51.03	If applicable, humidity monitoring is also performed in drug storage areas (if separate from the compounding areas). ***	○○◉	Nonsterile Ingredients and Devices

Logged manually

52.00	Blowers on ISO 5 PECs are operated continuously during compounding activity, including during interruptions of less than eight hours. ***	◉○○	Suggested SOPs
53.00	When the ISO 5 PEC blower is turned off, and before other personnel enter to perform compounding activities, only one garbed person is allowed to enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and of sanitizing the work surfaces. ***	◉○○	Suggested SOPs

54.00	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*	◉○○	Facility Design and Environmental Controls
55.00	The inside and outside doors of a pass-through are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*	◉○○	Facility Design and Environmental Controls
56.00	**If the PEC is a BSC or LAFW that is NOT located in an ISO Class 7 clean/buffer room:**		
56.01	BSC or LAFW has been certified to maintain ISO Class 5 during compounding activities.	○○◉	Low-Risk Level CSPs COMAR 10.34.19.15(D)
56.02	Used only for low-risk compounded preparations with a 12-hour or less BUD assigned. *If yes, list percentage.*	○○◉	Low-Risk Level CSPs
56.03	All garbing requirements are adhered too.	○○◉	Low-Risk Level CSPs
56.04	Located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.	○○◉	Low-Risk Level CSPs
56.05	Location does not contain any unsealed windows or doors that connect to the outdoors or areas of high traffic flow, and is not adjacent to construction sites, warehouses, or food preparation areas.	○○◉	Low-Risk Level CSPs
56.06	The sink is separated from the immediate area of the ISO Class 5 BSC or LAFW (not adjacent).	○○◉	Low-Risk Level CSPs
57.00	**If the PEC is a CAI/CACI that is NOT located in an ISO Class 7 clean/buffer room:**		
57.01	CAI/CACI has been certified to maintain ISO Class 5 under dynamic conditions including transferring of ingredients, components and devices, and during preparation of CSP.	○○◉	Placement of Primary Engineering Controls Low-Risk Level CSPs COMAR 10.34.19.15(D)
57.02	The pharmacy has documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse than ISO Class 7 environments.	○○◉	Placement of Primary Engineering Controls Low-Risk Level CSPs
57.03	The CAI or CACI is located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.	○○◉	Placement of Primary Engineering Controls Low-Risk Level CSPs
57.04	The sink is separated from the immediate area of the CAI or CACI (not adjacent).	○○◉	Placement of Primary Engineering Controls Low-Risk Level CSPs
57.05	For NIOSH hazardous compounding in a CACI that is NOT located in a clean/buffer room, the CACI is located in a physically separated area that maintains a negative pressure of 0.01" water column pressure to adjacent areas and a minimum of 12 ACPH.	○○◉	Hazardous Drugs as CSPs

58.00 Supplies are stored in a manner that maintains integrity of an aseptic environment.

59.00 The facility must contain appropriate waste containers to isolate sharps, hazardous waste, biological, and chemotherapy waste.

COMAR 10.34.19.09(B)(6), 10.34.19.15(F), 10.34.19.10(A)(3)

Cleaning and Disinfection

Y N N/A Follow up ☐

60.00 Are all personnel performing cleaning appropriately garbed?

Personnel Cleansing and Garbing

61.00 The sterile compounding area is equipped with appropriate nonshedding cleaning equipment and supplies.
All cleaning tools, such as wipers, sponges, and mops, must be nonshedding; dedicated to and labeled for use in either the buffer or clean area (no wooden handles are allowed).

Cleaning and Disinfecting the Compounding Area Appendix 2
USP General Chapter 1072
COMAR 10.34.19.13(3)

62.00 If cleaning tools are reused, is there a procedure to rinse and sanitize the tools and an appropriate clean storage area?

Cleaning and Disinfecting the Compounding Area

63.00 [redacted]

Cleaning and Disinfecting the Compounding Area

64.00 [redacted]

Cleaning and Disinfecting the Compounding Area Appendix 2
USP General Chapter 1072

65.00 [redacted]

Cleaning and Disinfecting the Compounding Area Appendix 2
USP General Chapter 1072

66.00 [redacted]

Cleaning and Disinfecting the Compounding Area Appendix 2
USP General Chapter 1072
COMAR 10.34.19.11(C), 10.34.19.12(4)

67.00 Are 3rd party cleaners and/or cleaning staff utilized to perform cleaning of rooms?
List company/unit and frequency they perform cleaning.

6701 Are they trained to enter the cleanroom and perform cleaning? *Review training documents.*

Cleaning and Disinfecting the Compounding Area Appendix 2
USP General Chapter 1072
COMAR 10.34.19.07B(1)(d)

68.00 The ISO 5 PEC is cleaned at the beginning of each shift, between compounding activities, at least every 30 minutes while compounding and after spills or suspected surface contamination.

68.01 If heavily soiled, cleaning includes the appropriate agent. *List agent(s) used.*

SporKlenz, TexQ

Cleaning and Disinfecting the Compounding Area Appendix 2
USP General Chapter 1072

69.00	Sanitizing of the ISO 5 PEC includes sanitizing with sterile 70% IPA using a non-linting wipe.	◉○○	Cleaning and Disinfecting the Compounding Area Appendix 2 USP General Chapter 1072 COMAR 10.34.19.11(C)
70.00	Daily cleaning and sanitizing include counters and easily cleanable work surfaces.	◉○○	Cleaning and Disinfecting the Compounding Area COMAR 10.34.19.15(e)
71.00	Daily cleaning includes the floors starting from the clean/buffer room and working outwards. *Floor cleaning is not to occur during compounding.*	◉○○	Cleaning and Disinfecting the Compounding Area COMAR 10.34.19.15(e)
72.00	If fatigue mats are used, are they cleaned daily and allowed to dry on both sides?	○○◉	Cleaning and Disinfecting the Compounding Area
73.00	Is a tacky mat used, and if so, is there a procedure in place regarding replacement?	◉○○	Cleaning and Disinfecting the Compounding Area
74.00	The ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the primary engineering controls (PECs) thoroughly cleaned monthly. (*This includes removing everything from shelves and bins before cleaning, cleaning the undersides of cart surfaces and stools, wheels, etc.) Check inside bins and shelving for dust if you are garbed.*	◉○○	Cleaning and Disinfecting the Compounding Area COMAR 10.34.19.15(e)
75.00	Enough time is allocated for cleaning activities, including contact/dwell times for the cleaning/disinfection agents.	◉○○	Cleaning and Disinfecting the Compounding Area Appendix 2 USP General Chapter 1072
76.00	Cleaning is documented and retained for 5 years	◉○○	COMAR 10.34.19.07B()(1)(d)

Tacky mat in front of hood in cleanroom

Training	Y	N	NA	Follow-up
77.00 Pharmacies must establish and follow a written program of training performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly.	◉	○	○	COMAR 10.34.19.14E(1)
77.01 Personnel competency must be re-verified at least every 12 months (every 6 months for high-risk), whenever the quality assurance program yields an unacceptable result, or whenever improper aseptic technique is observed.	◉	○	○	COMAR 10.34.19.14E(1)(a)
77.02 Records of training and demonstrated competence shall be available for each individual and shall be retained for five (5) years beyond the period of employment.	◉	○	○	COMAR 10.34.19.14(c), COMAR 10.34.19.07(B)(1)(a)
78.00 There is documentation that compounding personnel are appropriately trained including policies and procedures, documentation, cleaning/disinfection/spills, garbing/gowning/hand hygiene, aseptic technique, and general conduct in the controlled area. **NOTE: "Compounding personnel" includes personnel performing compounding, supervising compounding, and performing verification of compounding.** *List number of personnel training files viewed.*	◉	○	○	Responsibility of Compounding Personnel Personnel Training and Evaluation in Aseptic Manipulation Skills Hazardous Drugs as CSPs Personnel Cleansing and Garbing Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and

			Cleaning/Disinfection Procedures Appendices 3, 4, & 5 COMAR 10.34.19.14E(1)
78.01	Equipment and closure system selection if applicable		COMAR 10.34.19.14E(1)(j)
78.02	Hazardous drug handling if applicable		
78.03	Sterilization techniques if applicable		COMAR 10.34.19.14E(1)(i)
79.00	No personnel performing compounding are allowed to compound until training and initial testing is successfully completed.		Personnel Training and Evaluation in Aseptic Manipulation Skills Personnel Cleansing and Garbing Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures Appendices 3, 4, & 5 COMAR 10.34.19.14(B)
80.00	No personnel that SUPERVISE compounding and/or perform verifications of other's compounding are allowed to supervise or verify compounding until training and initial testing is successfully completed.		Personnel Training and Evaluation in Aseptic Manipulation Skills Personnel Cleansing and Garbing Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures Appendices 3, 4, & 5 COMAR 10.34.19.14(B)
81.00	All personnel of reproductive capability who handle or compound hazardous drugs or chemicals have confirmed in writing that they understand the risks of handling hazardous drugs. *Teratogenicity; carcinogenicity; reproductive issues.* ***		Hazardous Drugs as CSPs
82.00	There is documentation, such as an observational checklist, that all personnel (including housekeeping or other outside personnel) that perform cleaning activities in the compounding areas including hazardous compounding areas are appropriately trained in garbing, cleaning and disinfection.		Personnel Training and Evaluation in Aseptic Manipulation Skills Hazardous Drugs as CSPs Personnel Cleansing and Garbing Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures Appendices 3, & 5 COMAR 10.34.19.14(E)(1)(f), 10.34.19.14(E)(2)

83.00 There is documentation of training on the operation of any equipment that may be used when preparing compounded sterile products.
Documentation needs to include training on operation, and troubleshooting



Personnel Training and Evaluation in Aseptic Manipulation Skills
Personnel Cleansing and Garbing
Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures
Appendices 3, 4, & 5
COMAR 10.34.19.14E(1)(h) & (j)

84.00 If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, training and certifications are verified.
View documentation.



Personnel Training and Evaluation in Aseptic Manipulation Skills
Personnel Cleansing and Garbing
Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures
Appendices 3, 4, & 5

85.00 There is documentation that all compounding personnel (including those supervising or performing verifications) have passed an initial written exam, and subsequent annual written exams for the appropriate compounding risk levels and NIOSH hazardous drugs when applicable. *Indicate frequency, if testing more than annually*



Personnel Training and Evaluation in Aseptic Manipulation Skills
Hazardous Drugs as CSPs
Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures
Appendix 1
COMAR 10.34.19.14(B), COMAR 10.34.19.14E(3)

85.01 There is documentation that all compounding personnel (including those supervising or performing verifications) have passed an initial pharmaceutical calculation exam, and subsequent annual pharmaceutical calculation exams.



COMAR 10.34.19.14E(1)(b)

86.00 There is documentation that all compounding personnel have passed an initial and subsequent annual competency assessments of aseptic compounding skills using observational audit tools including handling NIOSH hazardous drugs when applicable. Compounding skills evaluation to include use of equipment. *Indicate frequency, if testing more than annually.*



Personnel Training and Evaluation in Aseptic Manipulation Skills
Hazardous Drugs as CSPs
Personnel Cleansing and Garbing
Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures
Appendices 3, 4, & 5
COMAR 10.34.19.14(B)

87.00 There is documentation that new compounding personnel have passed an initial observed gowning procedure and three gloved fingertip sampling tests. *Personnel must pass the tests upon initial validation before being allowed to compound. Action required if the tests yield any garbing deficiencies, or if the sampling results are >0 colony-forming units (CFU)/plate on the three initial validations. Indicate frequency, if testing more than annually.*



Personnel Training and Evaluation in Aseptic Manipulation Skills
Personnel Cleansing and Garbing
Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures
Action Levels, Documentation, and Data Evaluation
Appendices 1, 3, 4, & 5

88.00 There is documentation that compounding personnel preparing low- or medium-risk level products have passed an annual observed gowning procedure and gloved fingertip sampling test. *Action required if the tests yield any garbing deficiencies, or if the fingertip sampling results are >3 CFU (total both hands, all 10 fingers). Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results.*
Indicate frequency, if testing more than annually.



Low-Risk Level CSPs
Medium-Risk Level CSPs
Personnel Training and Evaluation in Aseptic Manipulation Skills
Hazardous Drugs as CSPs
Personnel Cleansing and Garbing
Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures
Appendices 3, 4, & 5

89.00 There is documentation that a media fill test procedure is performed for each compounding employee at least annually for individuals that prepare low- or medium- risk level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days. Indicate frequency, if testing more than annually.*



Low-Risk Level CSPs
Medium-Risk Level CSPs
Personnel Training and Evaluation in Aseptic Manipulation Skills
Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedure (includes all sub-headings)
COMAR 10.34.19.12(C)(11), 10.34.19.15(C)

90.00 The media-fill testing procedures include:

Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)

90.01 Media selection (including obtaining COAs or growth promotion certificates from suppliers)



Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)
NABP 80.01

90.02 Fill Volume



Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)
NABP 80.02

90.03	Incubation time and temperature (Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature.)		Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings) COMAR 10.34.19.15(c)
90.04	Inspection of filled units		Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)
90.05	Documentation		Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)
90.06	Interpretation of results		Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)
90.07	Action levels set with the corrective actions required		Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)
91.00	**High-Risk Sterile Compounding:** There is documentation that compounding personnel have passed an observed gowning procedure and gloved fingertip sampling test every six (6) months. *Action required if the tests yield any garbing deficiencies, or if the sampling results are >3 CFU on both hands upon revalidation. Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results.* *Indicate frequency, if testing more than every 6 months.*		High-Risk Level CSPs Appendix I COMAR 10.34.19.14(E)(1)(a)
91.01	**High-Risk Sterile Compounding:** There is documentation that a media fill test procedure is performed for each compounding employee at least every six (6) months for individuals that prepare high-risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding.* *Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature.*		High-Risk Level CSPs Appendix I COMAR 10.34.19.14(E)(1)(a)

92.00 **Failed testing:** Employees who have failed any testing are prohibited from compounding until training is performed/reviewed and subsequent testing is performed successfully.

Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)

92.01 Glove fingertip tests that have failed have the organism identified down to the genus to determine the most likely source of the contamination. This data is used to develop plans to prevent contamination. ***

Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)
Action Levels, Documentation, and Data Evaluation

92.02 There is a plan to evaluate the sterile compounds prepared by employees with failed gloved fingertip tests or media fills to detect potential contamination of the sterile preparations compounded. ***

Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)
Action Levels, Documentation, and Data Evaluation

Garbing	Y	N	N/A	Follow up
93.00 Personnel are prohibited from compounding, or entering the clean/buffer room or anteroom if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection.				Personnel Cleansing and Garbing
94.00 Personnel are required to remove all personal outer garments such as hats, scarves, sweaters, vests, coats, or jackets and any makeup or cosmetics before entering compounding areas. *Include observations in the comments.*				Personnel Cleansing and Garbing COMAR 10.34.19.13(A)(7)
95.00 Personnel are required to remove all jewelry				Personnel Cleansing and Garbing COMAR 10.34.19.13(A)(5)
96.00 Personnel are prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed.				Personnel Cleansing and Garbing
97.00 Garbing with dedicated shoes or shoe covers that are donned as the line of demarcation is crossed (with the dedicated or covered shoe never touching the same side of the line of demarcation as the dirty shoe). ***				Personnel Cleansing and Garbing COMAR 10.34.19.13(A)(3), 10.34.19.13(A)(4)
98.00 Garbing includes head and facial hair covers and masks. **NOTE: Facial hair requires both a facial hair cover AND a mask. Eye shields are optional unless using cleaning agents or preparing hazardous drugs. There is a method available to assure that all hair is covered.**				Personnel Cleansing and Garbing COMAR 10.34.19.13(A)(3)(b), 10.34.19.13(3)(c)
99.00 Hand cleaning is performed in the anteroom and includes removing debris from under the nails with a nail cleaner followed by a vigorous washing of the hands and forearms with soap for at least 30 seconds with hands and arms then dried with a non-linting disposable towel or a hand dryer. *Scrub brushes are NOT recommended as they cause skin irritation and damage.*				Personnel Cleansing and Garbing COMAR 10.34.19.13(2)
100.00 The gown is non-shedding with sleeves that fit snugly around the wrists and enclosed at the neck.				Personnel Cleansing and Garbing COMAR 10.34.19.13(A)(3)

101.00	The gloves are sterile and made of non-shedding materials.	◉○○	COMAR 10.34.19.11(A)
102.00	All bare skin is covered on the arms and the legs (no bare ankles, wrists, etc.).	◉○○	Personnel Cleansing and Garbing
103.00	Prior to donning sterile gloves, a waterless alcohol based surgical hand scrub with persistent activity is used and hands are allowed to dry.	◉○○	Personnel Cleansing and Garbing
104.00	Upon leaving the sterile product compounding area, gowns are taken off and disposed of, or if used for nonhazardous compounding they are left in the anteroom and not reused for longer than one shift.	◉○○	Personnel Cleansing and Garbing COMAR 10.34.19.13(A)(4)
105.00	Pharmacists or other personnel do NOT enter the anteroom and cross the line of demarcation without donning shoe covers or dedicated shoes. *Watch for personnel traversing back and forth across the line of demarcation without doffing and donning new shoe covers or dedicated shoes.*	◉○○	Personnel Cleansing and Garbing 10.34.19.13A(4)
106.00	Pharmacists or other personnel do NOT enter the clean/buffer room without fully washing and garbing (wearing just a mask to check technician's work, for example)	◉○○	Personnel Cleansing and Garbing COMAR 10.34.19.13(A)
107.00	When preparing cytotoxic agents, appropriate personal protective equipment including gowns and gloves are worn.	○○◉	COMAR 10.34.19.12(C)(17), 10.34.19.14(B)
108.00	When working in a CAI/CACI are sterile gloves donned over the CAI/CACI gloves prior to compounding and changed in accordance with USP 797 or manufacturers recomendations	○○◉	Personnel Cleansing and Garbing

Environmental Monitoring

Y N N/A Follow up ☐

109.00	The most recent PEC and room certification report is available.	◉○○	Viable and Nonviable Environmental Sampling (ES) Testing
109.01	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last 6 months.	◉○○	Viable and Nonviable ES Testing
109.02	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, and barrier isolators) have been certified within the last 6 months.	◉○○	Viable and Nonviable ES Testing COMAR 10.34.19.03(B)(5) & (10), 10.34.19.15(D)
109.03	Certification is performed at least every six months (view date of previous certification) and whenever a device or room is relocated, altered, or major service to the facility is performed. *Record the date of the previous certification.*	◉○○	Viable and Nonviable ES Testing COMAR 10.34.19.03(B)(5), 10.34.19.15(e)

LFC performed semiannual certification and environmental sampling on 9/12/2024

110.00	Certification of the testing of the sterile compounding environment is retained for 5 years	◉○○	COMAR 10.34.19.07(B)(1)(c)
111.00	The PIC/compounding supervisor is familiar with what testing is required and interpretation of results, ensures all testing is performed appropriately (under dynamic conditions where appropriate), has action levels identified, evaluates results to detect issues or trends, and action levels are further customized based on trended data of performance.	◉○○	Viable and Nonviable ES Testing COMAR 10.34.19.07(B)(1)

112.00	The certification report includes information about the equipment used for performing each test including, identification of the equipment used by model, serial number, last calibration date (or date when next calibration is due).	●○○	Viable and Nonviable ES Testing cross reference CETA guide
112.01	The equipment used had not exceeded its calibration date at the time of certification.	●○○	Viable and Nonviable ES Testing cross reference CETA guide
113.00	The HEPA filtered air changes per hour (ACPH) were measured for the compounding rooms.	●○○	Facility Design and Environmental Controls
113.01	ISO Class 7 sterile compounding room is certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources. *Recirculated air from the PECs may account for up to 15 ACPH in nonhazardous classified rooms only.*	●○○	Facility Design and Environmental Controls
113.02	ISO class 7 anteroom is certified as having a minimum of 30 ACPH. *Anteroom must be ISO class 7 if connected to a NIOSH hazardous compounding clean/buffer room.*	●○○	Facility Design and Environmental Controls
113.03	ISO class 7 hazardous sterile compounding room is certified as having a minimum of 30 ACPH. *Typically all of the air will be from outside.*	○○●	Hazardous Drugs CSPs
113.04	If a CACI is used in a non-HEPA filtered room, the room is certified to maintain a minimum of 12 ACPH.	○○●	Hazardous Drugs CSPs
114.00	Air pattern analysis using smoke testing was performed under dynamic conditions (people working in the PECs and rooms). The smoke flow is described in the report for the various tests such as turbulent, sluggish, smooth, etc.	●○○	Facility Design and Environmental Controls
114.01	Air pattern analysis was conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate **unidirectional** airflow and sweeping action over and away from the product under dynamic conditions (personnel compounding or simulating compounding in PEC).	●○○	Facility Design and Environmental Controls
114.02	Air pattern analysis was conducted to confirm positive pressure and negative pressure into hazardous compounding rooms at all points around all openings, doorways, and pass-throughs.	○○●	Facility Design and Environmental Controls Hazardous Drugs CSPs
114.03	Air pattern analysis conducted around particle generating equipment while the equipment was in operation to confirm airflow.	○○●	Facility Design and Environmental Controls Viable and Nonviable ES Testing
115.00	Differential air pressure between rooms was measured.	●○○	Facility Design and Environmental Controls
115.01	The differential pressure measured was at least 0.02" water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed.	●○○	Facility Design and Environmental Controls
115.02	The differential pressure measured was at least 0.01" water column negative from the hazardous clean/buffer room to the anteroom with the doors closed.	○○●	Facility Design and Environmental Controls

116.00	Displacement airflow between rooms or areas was measured. This is for a clean/buffer room without a door that closes to the anteroom - may be an open space or may have plastic strips in doorways.		Facility Design and Environmental Controls
116.01	Displacement airflow (for low- and medium-risk non-hazardous rooms only) was measured at a minimum differential velocity of 40 feet per minute from the cleanroom to the anteroom. **NOTE: It is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings.**		Facility Design and Environmental Controls
117.00	Particle counts of particles 0.5um and larger were measured under dynamic conditions.		Facility Design and Environmental Controls
117.01	ISO Class 5 areas and PECs are certified as having less than 3,520 particles per cubic meter of air (100 particles per cubic foot).		Facility Design and Environmental Controls Table 1
117.02	ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air (10,000 particles per cubic foot).		Facility Design and Environmental Controls Table 2
117.03	ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air (100,000 particles per cubic foot).		Facility Design and Environmental Controls Table 3
118.00	HEPA filter tests were performed.		Facility Design and Environmental Controls
118.01	All room HEPA filters were leak tested and if leaks found, they were fixed		Facility Design and Environmental Controls
118.02	All PEC HEPA filters were leak tested and if leaks found, they were fixed		Facility Design and Environmental Controls
119.00	PECs with failed tests are not used for compounding until the conditions are corrected and verified by subsequent testing.		Viable and Nonviable ES Testing (includes all subheadings)
120.00	Viable air (every six months) and surface sampling (periodically) tests have been conducted as required. *Document frequency.*		Viable and Nonviable ES Testing (includes all subheadings) Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/ Disinfection Procedures (includes subheadings) COMAR 10.34.19.15(C)
120.01	Appropriate growth media used (containing tryptic soy agar medium with polysorbate and lecithin (TSApl) added to neutralize cleaning agents for surface sampling) with appropriate corresponding incubation time and temperature used. *Required to use media that supports both bacterial and fungal growth for high-risk compounding.*		Competency Evaluation of Garbing and Aseptic Work Practice Cross reference USP Chapter 1116 COMAR 10.34.19.15(C)

120.02 Viable air sampling by active impaction using a volumetric air-sampling device.
NOTE: Passive air sampling or settling plates are not compliant with USP Chapter <797>.



Environmental Viable Airborne Particle Testing Program
COMAR 10.34.19.15(C)

120.03 Air samples were taken in each ISO Class 5 PEC and in each sterile compounding room and anteroom and volume sufficient volume of air (400-1000L) was collected.
NOTE: 1000L must be collected in ISO Class 5 PECs to be able to detect the action level. Room samples can be 400-1000L.



Environmental Viable Airborne Particle Testing Program
10.34.19.15(C)

120.04 Surface samples performed on all direct compounding areas inside of each ISO 5 PEC, in each ISO classified room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc.



Environmental Viable Airborne Particle Testing Program
COMAR 10.34.19.15(C)

120.05 Viable air and surface samples did not exceed USP action levels (or internal action levels if more restrictive).

Classification	Air Sample	Surface Sample
ISO Class 5	>1 CFU/m^3	>3 CFU/plate
ISO Class 7	>10 CFU/m^3	>5 CFU/plate
ISO Class 8	>100 CFU/m^3	>100 CFU/plate

CFUs are TOTAL of bacterial plus fungal/mold plates. If air sampling volume is less than 1000 liters (one cubic meter), the raw total microbial count must be multiplied by the appropriate factor to determine the number of CFU/cubic meter.



Environmental Viable Airborne Particle Testing Program, Table 2
Action Levels, Documentation, and Data Evaluation, Table 4
COMAR 10.34.19.15(C)

120.06 CFUs detected (viable air or surface sampling failed sterility tests, etc.) are identified to the genus level. *All CFUs detected must be identified even if the number of CFUs does not exceed an action level.*



Environmental Viable Airborne Particle Testing Program
COMAR 10.34.19.15(C)

120.07 If the number of CFUs detected **in the rooms** exceeds action levels, begin immediate remediation (e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.



Environmental Viable Airborne Particle Testing Program
COMAR 10.34.19.15(C)

120.08 If the number of CFUs detected **in the PECs** exceeds action levels, begin immediate remediation, (e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.



Environmental Viable Airborne Particle Testing Program
COMAR 10.34.19.15(C)

120.09 If any highly pathogenic microbes (e.g. mold, yeast, coagulase positive staphylococcus, or gram-negative rods) were detected (whether or not the number of CFUs exceeds action levels), begin immediate remediation (e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.



Environmental Viable Airborne Particle Testing Program

Semiannual viable air and monthly surface sampling

121.00 Samples that exceed USP action levels (or internal action levels if more restrictive) or have highly pathogenic microbes detected have been reported to the Board within 5 days of receiving report.



COMAR 10.34.19.18(B)

122.00	Facilities performing routine air or surface sampling with internal qualified personnel routinely verify sampling procedures. *Indicate the outside vendor used to verify procedures and frequency of verifications.* ***	Y N	Viable and Nonviable ES Testing (includes all subheadings)

Equipment

		Y N N/A	Follow up ☐
123.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (autoclaves, ovens, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines.*	Y N N/A	Equipment USP Chapter 1176 COMAR 10.34.19.10(B)
124.00	All environmental monitoring equipment and gauges (differential pressure gauges or probes, airflow and velocity measuring equipment for rooms not fully enclosed, etc.) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented.	Y N N/A	Equipment
125.00	All temperature and humidity (where applicable) monitoring devices (thermometers, hygrometers, probes, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented	Y N N/A	Equipment USP Chapter 659; USP Chapter 1079 COMAR 10.34.19.10(B)(5)
126.00	Does the pharmacy use scales/balances for sterile compounding?	Y N	Accuracy
126.01	If so, what type of scale/balanced is used? *List manufacturer and model number.*		
126.02	If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency.*	Y N N/A	
127.00	Does the pharmacy have a **lyophilizer**?	N Y	
127.01	Where is the lyophilizer located? *Indicate location and ISO class of room.*		
127.02	Note the products lyophilized, and the volume or percent of products per week produced using the lyophilizer.		
127.03	The lyophilizer is part of the viable air and surface sampling; media fill testing procedures, and cleaning schedules and procedures.	N N/A Y	
128.00	Automated Compounding Devices (ACDs) are used for sterile compounding and there is a P&P for the use and calibration. (TPN Preparations, Repeater Pumps, Robots, HD Preparations [Diana ACS], etc.)	N Y	Equipment; Verification of Automated Compounding Devices for Parenteral Nutrition Compounding (and subsections) COMAR 10.34.19.10(B)

128.01 There is documentation of the ACD tubing being changed or discarded every 24 hours — Y N N/A

Equipment;
Verification of Automated Compounding Devices for Parenteral Nutrition Compounding (and subsections)
manufacturer's guidance for tubing

128.02 The ACD is used when performing media fill testing. — Y N N/A

Equipment;
Verification of Automated Compounding Devices for Parenteral Nutrition Compounding (and subsections)

129.00 Does the pharmacy have an **incubator**? — Y N N/A

129.01 The temperature is documented at least daily when in use — Y N N/A

COMAR 10.34.19.10(B)(6)

Pharmacy utilizes an auto pipette which is calibrated annually

Compounding Procedures — Y N N/A — Follow up ☐

130.00 Does the pharmacy perform **low-risk** compounding? — Y N N/A
Indicate percentage of low-risk sterile compounding.

Low-Risk Level CSPs

130.01 All low-risk compounds are assigned BUDs within USP guidelines (48 hours at controlled room temperature, 14 days refrigerated, 45 days frozen). — Y N N/A

COMAR 10.34.19.06(D)

130.02 If low-risk, the compounds located in segregated area are BUD 12 hours or less. — Y N N/A

130.03 If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.

130.04 If extended BUDs are used, further testing is being performed to justify the use of extended BUDs. *List the types of testing performed (potency, sterility, stability, etc.).* — Y N N/A

131.00 Does the pharmacy perform **medium-risk** compounding? — Y N N/A
Indicate percentage of medium-risk sterile compounding.

Medium-Risk Level CSPs

131.01 All medium-risk compounds are assigned BUDs within USP guidelines (30 hours at controlled room temperature, 9 days refrigerated, 45 days frozen). — Y N N/A

COMAR 10.34.19.06(D)

131.02 If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.

131.03 If extended BUDs are used, further testing is being performed to justify the use of extended BUDS. — Y N N/A
List the types of testing performed (potency, sterility, stability, etc.).

approximately 45 CSPs are prepared daily, 100% of CSPs are Category 2

132.00 Does the pharmacy perform **high-risk** compounding? — Y N N/A
Indicate percentage of high-risk sterile compounding.

High-Risk Level CSPs

132.01 All high-risk compounds are assigned BUDs within USP guidelines (24 hours at controlled room temperature, 3 days refrigerated, 45 days frozen). — Y N N/A

COMAR 10.34.19.06 (D)

132.02	If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.		
132.03	If extended BUDs are used, further testing is being performed to justify the use of extended BUDs. *List the types of testing performed (potency, sterility, stability, etc.).*	○○◉	
133.00	Hazardous drugs are segregated and stored in a room that is negative pressure (at least -0.01" wc) to adjacent areas and with at least 12 ACPH. ***	○○◉	
133.01	Hazardous drug waste is quarantined in a designated area and disposed of in compliance with local, state, and federal regulations.	○○◉	COMAR 10.34.19.12C(18), 10.34.19.09B(6) 10.34.19.15(F), 10.34.19.10(A)(3)
134.00	Closed system vial transfer devices (CSTD) are employed when handling cytotoxic drugs.	○○◉	COMAR 10.34.19.12(17)
135.00	Gloves are disinfected with adequate frequency with an approved disinfectant, such as sterile 70% isopropyl alcohol (IPA).	◉○○	Suggested SOPs Exposure of Critical Sites
136.00	Nonessential objects that shed particles are prohibited in the buffer or clean area, including pencils, cardboard cartons, paper towels, reading material, and cotton items (e.g., gauze pads).	◉○○	Suggested SOPs
137.00	Essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) are wiped down with sterile 70% IPA before being brought into the buffer or clean area.	◉○○	Suggested SOPs
138.00	Supplies required for the scheduled operations of the shift are prepared by wiping the outer surface with sterile 70% IPA (or removing the outer wrap as the item is introduced into the aseptic work area) and brought into the buffer or clean area in a bin or on a movable cart.	◉○○	Suggested SOPs
139.00	Compounding employees are using appropriate aseptic technique. *May require inspector to garb and enter clean/buffer room. Pay attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitization of gloves, appropriate cleaning and cleanliness of the direct compounding area (DCA).*	○○○	Responsibility of Compounding Personnel Competency Evaluation of Garbing and Aseptic

No compounding taking place,

140.00	Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality by reading vendors' labels, and a unit-by-unit physical inspection of the product before use.	◉○○	Responsibility of Compounding Personnel Identity and Strength Verification of Ingredients and Devices (and subsections)
141.00	All rubber stoppers, of vials and bottles and the necks of ampules are disinfected with sterile 70% IPA waiting for at least 10 seconds before they are used to prepare CSPs.	◉○○	Suggested SOPs Exposure of Critical Sites

142.00	Single-dose vials exposed to ISO Class 5 or cleaner air are used within six (6) hours of the initial puncture and any remaining contents discarded. *If exposed to less than ISO Class 5 air, used within 1 hour and discarded.*	Single Dose and Multiple Dose Containers
143.00	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. *May not be stored for any period of time.*	Single Dose and Multiple Dose Containers
144.00	Multiple-dose vials formulated for removal of portions on multiple occasions are used within 28 days (or the manufacturer's specific BUD if less) after the initial entry or puncture and any remaining contents discarded.	Single Dose and Multiple Dose Containers Determining BUD
145.00	The compounding record is complete. *View several completed compounding records and answer each of the following questions. List records reviewed.*	Inspection of Solution Dosage Forms and Review of Compounding Procedures Compounding Accuracy Checks COMAR 10.34.19.07(B)(1)
145.01	Official or assigned name, strength and dosage of the preparation	Inspection of Solution Dosage Forms and Review of Compounding Procedures COMAR 10.34.19.07(B)(1)
145.02	Names, lot numbers and expiration dates of all components *(lot numbers for high risk and batch compounding)*	Inspection of Solution Dosage Forms and Review of Compounding Procedures COMAR 10.34.19.07(B)(1)
145.03	Total quantity or number of units compounded	Inspection of Solution Dosage Forms and Review of Compounding Procedures
145.04	Person compounding the preparation	Inspection of Solution Dosage Forms and Review of Compounding Procedures Compounding Accuracy Checks
145.05	Person performing the quality control procedures	Inspection of Solution Dosage Forms and Review of Compounding Procedures Compounding Accuracy Checks
145.06	Person who approved the preparation	Inspection of Solution Dosage Forms and Review of Compounding Procedures Compounding Accuracy Checks COMAR 10.34.19.07(B)(1)(f) & (g)
145.07	Date of compounding	Inspection of Solution Dosage Forms and Review of Compounding Procedures
145.08	Assigned internal identification number or prescription number	Inspection of Solution Dosage Forms and Review of Compounding Procedures

145.09	Assigned BUD and reference if extended beyond USP guidelines	Inspection of Solution Dosage Forms and Review of Compounding ProceduresCOMAR 10.34.19.07(B)(1)
145.10	Duplicate label***	Responsibility of Compounding Personnel Inspection of Solution Dosage Forms and Review of Compounding Procedures Identity and Strength Verification of Ingredients
145.11	Sterilization method (if applicable)	Inspection of Solution Dosage Forms and Review of Compounding Procedures Sterility Testing
145.12	Indication of the quality control procedures to perform (testing, filter integrity, etc.) and results of the testing, quality control issues, and investigation/recall if applicable	Inspection of Solution Dosage Forms and Review of Compounding Procedures Elements of Quality Control (and subparagraphs) COMAR 10.34.19.12C(6)(h)
146.00	Procedure for in-process checks is followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is* ***recommended*** *to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage.*	Responsibility of Compounding Personnel Verification of Automat4ed Compounding Devices for Parenteral Nutrition Compounding
147.00	Preparation records including the master work sheet, the preparation work sheet and records of end-product evaluation, if applicable. (Documentation to be retained for 5 years)	COMAR 10.34.19.07(B)(1)(f)
148.00	Labels on BATCH preparations include the name and quantity of all contents, date, and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.	Responsibility of Compounding Personnel Inspection of Solution Dosage Forms and Review of Compounding Procedures Compounding Accuracy Checks Identity and Strength Verification of Ingredients COMAR 10.34.19.07(B)(2)
149.00	Labels on PATIENT-SPECIFIC compounded sterile preparations contain the following: **NOTE: Some requirements may not be applicable if items are dispensed for inpatient use only.**	Responsibility of Compounding Personnel Inspection of Solution Dosage Forms and Review of Compounding Procedures Compounding Accuracy Checks Identity and Strength Verification of Ingredients COMAR 10.34.19.06(B)
149.01	Date of preparation unless otherwise readily retrievable from prescription records	COMAR 10.34.19.06(B)(1)
149.02	Serial number of the prescription	HG § 21-221(a)(2)

149.03	Pertinent requirements for proper storage	●○○	COMAR 10.34.19.06(B)(3)
149.04	Name of the prescriber, unless in an inpatient hospital setting	●○○	COMAR 10.34.19.06(B)(4)
149.05	Name of the patient	●○○	COMAR 10.34.19.06(B)(5)
149.06	Directions for use	●○○	COMAR 10.34.19.06(B)(6)
149.07	Name of the base solution for infusion preparations	●○○	COMAR 10.34.19.06(B)(7)
149.08	Name and concentration or amount of active drugs contained in the final sterile preparation	●○○	COMAR 10.34.19.06(B)(8)
149.09	Reviewing pharmacist and data-entry technician initials	●○○	COMAR 10.34.08.01
149.10	Name or identifying initials of the pharmacist who checked or prepared the compounded sterile preparation unless otherwise readily retrievable from prescription records	●○○	COMAR 10.34.19.06(B)(9)
149.11	Name, address, and telephone number of the pharmacy unless in an inpatient hospital facility	●○○	COMAR 10.34.19.06(B)(10)
149.12	Beyond-use/expiration dating and time of the compounded sterile preparation	●○○	COMAR 10.34.19.06(B)(11)
149.13	Ancillary and cautionary instructions as needed	●○○	COMAR 10.34.19.06(B)(12)
149.13A	Cytotoxic agents include a special label, which states: "Chemotherapy-Dispose of Properly."	○○●	COMAR 10.34.19.06(B)(13)
149.13B	Short dated preparations labeling must include: Time and Cautionary Label	●○○	COMAR 10.34.19.06(B)(2)

150.00	Inspect several different finished products and look for any particulates. Are the inspected finished products free of particulates? *If so, list the products including lot and expiration date and obtain photos (if possible).* **REQUEST THE PRODUCT BE QUARANTINED**	●○○	Responsibility of Compounding Personnel Inspection of Solution Dosage Forms and Review of Compounding Procedures
151.00	Preparations without additional stability testing or supported by data are assigned BUDs within USP<797> guidelines. **Low Risk:** 48 hours room temp, 14 days refrigerated, 45 days frozen **Medium Risk:** 30 hours room temp, 9 days refrigerated, 45 days frozen **High-Risk:** 24 hours room temp, 3 days refrigerated, 45 days frozen	●○○	CSP Microbial Contamination Risk Levels (and subsections) Determining BUD COMAR 10.34.19.06(D)
152.00	There must be current and appropriate reference materials regarding the compounding of sterile preparations located in or immediately available to the pharmacy.	●○○	COMAR 10.34.19.16
153.00	If extended BUDs are assigned, are they assigned based on stability data extrapolated from reliable literature sources? *View records, preparation must exactly match the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.*	●○○	Determining BUD COMAR 10.34.19.12(C)(5)(e)

154.00	If extended BUDs are assigned, has the facility performed its own stability testing? *View records; preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc. If so, view records for at least three products and list the products reviewed below. List the products reviewed.* ***	◉○○	Determining BUD
155.00	Compounded multiple-dose vials with extended BUDs assigned have additional instruction provided that indicates remainder must be discarded 28 days after first puncture or use.	○○◉	Single-Dose and Multiple-Dose Containers

Sterilization		Y N N/A	Follow up ☐
156.00	**Is Filter sterilization performed** in an ISO 5 environment? Documentation includes:	○○○	Verification of Compounding Accuracy and Sterility Sterilization of High-Risk Level CSPs by Filtration Appendix I
156.01	If the compounded preparation contains large particles, a prefilter is placed upstream from the sterilizing filter.	◉○○	Sterilization of High-Risk Level CSPs by Filtration Appendix I
156.02	The 0.2micron sterile microporous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP; and the filter is intended for human-use applications for sterilizing CSPs (labeling on the filter does not indicate "research only" or "laboratory only", for example).	◉○○	Sterilization Methods Sterilization of High-Risk Level CSPs by Filtration Appendix I
156.03	Is the appropriate capacity filter being used for the volume being filtered?	○◉○	Sterilization of High-Risk Level CSPs by Filtration Appendix I
156.04	Filtering is completed rapidly without filter replacement.	◉○○	Sterilization of High-Risk Level CSPs by Filtration Appendix I
156.05	Confirmation of filter integrity/bubble testing is performed and value documented for each filter used with each batch sterilized by filtration. View documentation on compounding records of items sterilized by filtration to confirm.	◉○○	Sterilization of High-Risk Level CSPs by Filtration Appendix I

Current filter is too large for the volume being filtered

157.00	**Is steam sterilization performed?** Documentation includes:	○◉	Verification of Compounding Accuracy and Sterility Sterilization of High-Risk Level CSPs by Steam
157.01	The autoclave has been verified for the exposure time and mass of the items to be sterilized	○○◉	Sterilization of High-Risk Level CSPs by Steam Equipment
157.02	Ensures live steam contacts all ingredients and surfaces to be sterilized, effectiveness verified with biological indicators and temperature sensing devices	○○◉	Sterilization of High-Risk Level CSPs by Steam
157.03	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization	○○◉	Sterilization of High-Risk Level CSPs by Steam

157.04	That the CSP will not be adversely affected by the steam and heat		Sterilization of High-Risk Level CSPs by Steam
157.05	The description of steam sterilization includes conditions and duration for specific CSPs		Sterilization of High-Risk Level CSPs by Steam
157.06	That the effectiveness of steam sterilization is verified each time using appropriate biological indicators of Bacillus stearothermophilus and other confirmation methods such as temperature-sensing devices.		Sterilization of High-Risk Level CSPs by Steam
158.00	**Is dry heat sterilization performed?** Documentation includes:		Verification of Compounding Accuracy and Sterility Sterilization Methods Sterilization of High-Risk Level CSPs by Dry Heat
158.01	Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture		Sterilization Methods Sterilization of High-Risk Level CSPs by Dry Heat
158.02	Sufficient space is left between materials to allow for air circulation		Sterilization Methods Sterilization of High-Risk Level CSPs by Dry Heat
158.03	The description of dry heat sterilization includes conditions and duration for specific CSPs		Sterilization Methods Sterilization of High-Risk Level CSPs by Dry Heat
158.04	That the effectiveness of dry heat sterilization is verified each time using appropriate biological indicators of Bacillus subtilis and other confirmation methods such as temperature-sensing devices.		Sterilization Methods Sterilization of High-Risk Level CSPs by Dry Heat
158.05	Heated filtered air is evenly distributed throughout the chamber with a blower and the oven is equipped with a system for controlling and recording temperature and exposure period.		Sterilization of High-Risk Level CSPs by Dry Heat Equipment
159.00	**Is depyrogenation by dry heat performed?** Documentation includes:		Verification of Compounding Accuracy and Sterility Sterilization Methods Depyrogenation by Dry Heat
159.01	Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes		Sterilization Methods Depyrogenation by Dry Heat
159.02	The description of the cycle and duration for specific load items		Sterilization Methods Depyrogenation by Dry Heat
159.03	The effectiveness of the cycle is verified using endotoxin challenge vials (ECVs)		Sterilization Methods Depyrogenation by Dry Heat Equipment

159.04	Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a 3-log reduction in endotoxins	○○●	Sterilization Methods Depyrogenation by Dry Heat
160.00	Other methods of sterilization are used with documented procedures and validation performed. *Indicate method.*	○○●	Verification of Compounding Accuracy and Sterility Equipment Appendix I

Finished Preparation Release Checks and Tests		Y	N	N/A	Follow up ☐	
161.00	The verification and re-verification process must be documented to be retained for 5 years	●	○	○		COMAR 10.34.19.07B(3)
162.00	Products are visually checked for particulates or other foreign matter against both a light and a dark colored background as a condition of release. *To be enforced FY2023*	●	○	○		Physical Inspection COMAR 10.34.19.10(A)(7)
163.00	Are there checks for container, closure integrity and any other apparent visual defects?	●	○	○		Physical Inspection
164.00	Compounding accuracy is documented by verification of steps.	●	○	○		Compounding Accuracy Checks
165.00	Ingredient identity and quantity is verified. *Is there a reconciliation of components?*	●	○	○		Identity and strength Verification of Ingredients
verification by second pharmacist						
166.00	Labels are verified as being correct and is a copy of the label included in the record. *Complies with regulation, contains the correct names and amounts or concentrations of ingredients, total volumes, BUDs, storage conditions, and route of administration.*	●	○	○		Responsibility of Compounding Personnel Inspection of Solution Dosage Forms and Review of Compounding Procedures Identity and Strength Verification of Ingredients
167.00	Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in house?*	○	●	○		
168.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed*	●	○	○		
169.00	**Is sterility testing performed(USP <71>)?** *If testing is performed to a higher standard than the minimums below, describe.*	●	○			Sterility Testing COMAR 10.34.19.15(H)
169.01	Sterility testing includes both bacterial and fungal testing.	●	○	○		Sterility Testing
169.02	Sterility testing is performed for all CSPs that have extended BUDS.	●	○	○		Sterility Testing

169.03 Sterility testing is performed for high-risk CSPs prepared in batches of more than 25 identical containers. ○○◉ Sterility Testing

169.04 Sterility testing is performed for CSPs exposed longer than 12 hours at 2°C-8°C or longer than six hours at warmer than 8°C before being sterilized. ◉○○ Sterility Testing

169.05 The appropriate quantities of units are sterility tested. ◉○○ Sterility Testing
cross reference USP Chapter 71
Parenterals, number of units in the batch is:

1. Not more than 100, test 10% or four units, whichever is greater
2. More than 100 but more than 500, test 10 units
3. More than 500 test 2% or 20 units, whichever is less
   For large volume parenterals: 2% or 10 containers, whichever is less.
   For non-parenterals (eye drops, inhalation, etc.):
4. Not more than 200 containers test 5% or 2 containers, whichever is greater
5. More than 200, test 10 containers
6. If the product is packaged in unit doses, use the parenteral testing above.

169.06 For products failing testing, product is quarantined, and an investigation is performed including microbial identification and action taken. ◉○○ Sterility Testing
View testing records and note any products with failed results and actions taken.

169.07 If items are dispensed or distributed prior to sterility testing completion, there is a written procedure requiring daily observation of the incubated media. If there is any evidence of microbial growth, there is an immediate recall and both the patient and the physician/prescriber of the patient to whom a potentially contaminated CSP was administered are notified of the potential risk. ◉○○ Sterility Testing
View testing records and note any products with failed results and actions taken.

170.00 **Is endotoxin testing performed (USP <85>)?** ◉○ Bacterial Endotoxin (Pyrogen) Testing
COMAR 10.34.19.15(H)
If testing is performed to a higher standard than the minimums below, describe.

170.01 Is endotoxin testing performed for all high-risk level CSPs for administration by injection prepared in groups of more than 25 single-dose packages (such as ampules, bags, syringes, vials) ○○◉ Bacterial Endotoxin (Pyrogen) Testing

170.02 High-risk CSPs prepared in multiple dose vials for administration to multiple patients ○○◉ Bacterial Endotoxin (Pyrogen) Testing

170.03 High-risk CSPs exposed longer than 12 hours at 2°C-8°C (25°F-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before they are sterilized ○○◉ Bacterial Endotoxin (Pyrogen) Testing

170.04 For products failing testing, product is quarantined, and an investigation is performed and action taken. *View testing records and note any products with failed results and actions taken.* ◉○○ Sterility Testing

Standard Operating Procedures	Y N N/A	Follow up ☐	
171.00 The pharmacy has policies/procedures on:			
171.01 The compounding, filling, and labeling of sterile compounds.	● ○ ○		COMAR 10.34.19.12(C)(6)(a), (c) and (d)
171.02 Proper labeling of the compounded sterile preparation including the intended route of administration and recommended rate of administration.	● ○ ○		COMAR 10.34.19.12(C)(6)(d)
171.03 Availability of equipment and supplies.	● ○ ○		COMAR 10.34.19.12(C)(3), 10.34.19.12(C)(17)(a)
171.04 The training of staff in the preparation of compounded sterile preparations.	● ○ ○		COMAR 10.34.19.12(C)(10), 10.34.19.14(B)
171.05 Staff competency evaluations.	● ○ ○		COMAR 10.34.19.14(E)
171.06 The Quality Assurance Program.	● ○ ○		COMAR 10.34.19.12(C)(9), 10.34.19.15
171.07 All record keeping requirements.	● ○ ○		COMAR 10.34.19.12(C)(7)
171.08 A written process, verified by a pharmacist, describing ingredients and the compounding process for each preparation.	● ○ ○		COMAR 10.34.19.05(B)(4), 10.34.19.07(B)(1) & (2)
171.09 Written policies and procedures for implementing the immediate use exemption for admixtures.	● ○ ○		
171.10 Documentation demonstrating that all personnel involved have read the policies and procedures.	● ○ ○		COMAR 10.34.19.12B
171.11 Documentation of communication of policy and procedure for additions and deletions.	● ○ ○		
171.12 The storage and handling of products and supplies.	● ○ ○		COMAR 10.34.19.12(C)(6)(b)
171.13 The storage and delivery of final preparation.	● ○ ○		COMAR 10.34.19.12(6)(b) & (f)
171.14 Media fill process verification testing.	● ○ ○		COMAR 10.34.19.12(C)(11)
171.15 The criteria for Beyond Use Dating (BUD).	● ○ ○		COMAR 10.34.19.12(C)(6)(e)
171.16 Personnel access and movement of materials into and near the compounding area.	● ○ ○		COMAR 10.34.19.12(C)(2)
171.17 The use and maintenance of environmental control devices used to create the critical area for manipulation of sterile preparations (e.g. laminar airflow workstations, biological safety cabinet, ISO Class 7 clean room, and/or CAIs.	● ○ ○		COMAR 10.34.19.12(C)(3)
171.18 A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants (pharmacies subject to an institutional infection control policy may follow that policy).	● ○ ○		
171.19 The method used to monitor the environment for bacterial microorganisms.	● ○ ○		COMAR 10.34.19.12(C)(4)
171.20 The disposal of packaging materials, used syringes, containers, and needles to avoid accumulation and maintain sanitation in the controlled area.	● ○ ○		COMAR 10.34.19.12(C)(18), 10.34.19.15(F)
171.21 Written policies and procedures for the use of established master formulas and worksheets for sterile batch compounding, if applicable.	● ○ ○		
171.22 Procedures must include cleanup of spills and shall be in conformance with local health jurisdictions.	● ○ ○		COMAR 10.34.19.12(C)(4)

171.23	Pharmacies compounding sterile preparations shall have written policies and procedures for disposal of infectious materials and/or materials containing cytotoxic residue or hazardous waste.	◉○○	COMAR 10.34.19.12(C)(18)
171.24	Established sterilization procedures including documentation of results, if applicable.	◉○○	COMAR 10.34.19.12(C)(4)
171.25	End-product evaluation and testing, if applicable.	◉○○	COMAR 10.34.19.12(C)(11), 10.34.19.15(H)

Policies and procedures last reviewed on 4/24/2024

Quality Assurance and Patient Counseling		Y N N/A	Follow up
172.00	**Quality Assurance/Quality Improvement**: Does the pharmacy continuous quality improvement program include sterile compounding measures?	◉○○	Quality Assurance Program COMAR 10.34.19.12(C), 10.34.19.15
172.01	Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products?	◉○○	COMAR 10.34.19.14(E)(1), 10.34.19.12C(9), 10.34.19.17(B)(1)
172.02	Does the pharmacy continuous quality improvement program include nonviable environmental monitoring and testing?	◉○○	
172.03	Does the pharmacy continuous quality improvement program include viable environmental testing?	◉○○	COMAR 10.34.19.15(C)
172.04	Does the pharmacy continuous quality improvement program include personnel testing and verification?	◉○○	COMAR 10.34.19.14
172.05	Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc.?	◉○○	COMAR 10.34.19.15(D), 10.34.19.10(B)
172.06	Does the pharmacy continuous quality improvement program include sterilization method testing and validation?	◉○○	
172.07	Does the pharmacy continuous quality improvement program include end-product testing (such as potency, particulates, sterility, endotoxin, etc.)? Written documentation that the end-product has been tested on a periodic sampling basis for microbial contamination and steps taken in the event that testing for contamination proves positive, if applicable.	◉○○	COMAR 10.34.19.15C
172.08	Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding CSPs?	◉○○	COMAR 10.34.26.04(A), 10.34.19.12(C)(9), 10.34.19.17(B)(1)
172.09	Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?	◉○○	COMAR 10.34.19.12(C)(6)(h)
172.10	Does the recall system include communication with both the patient and the physician/prescriber regarding the potentially contaminated CSP administered and the potential risks?	◉○○	COMAR 10.34.19.12(C)(6)(h)
172.11	Are QREs involving CSPs that may have been contaminated or are recalled reported to the appropriate agency such as the Board of Pharmacy and/or FDA?	◉○○	COMAR 10.34.19.12C(6)(h)
172.12	Records documenting inspection for expired or recalled pharmaceutical preparations or raw ingredients(Documentation to be retained for 5 years)	◉○○	COMAR 10.34.19.07(B)(1)(e)

172.13	Are all CFUs detected by any personnel, environmental, or product testing; or any other checks or tests including endotoxin, purity, potency, etc. remediated, appropriately investigated, cause determined, and processes implemented to prevent in the future, where applicable? *Review QA trends.*	◉○○	
172.14	A 24-hour telephone number is provided to allow its patients or other health care providers who may be administering its prescriptions to contact its pharmacists	◉○○	COMAR 10.34.19.06(C)
173.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?	◉○○	Patient or Caregiver Training COMAR 10.34.19.14(A)
174.00	Are the above required printed drug information materials (drug information, PPI, MedGuides, etc.) provided for the compounded products?	◉○○	Patient or Caregiver Training COMAR 10.34.19.14(A)
175.00	Patients are instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy.	◉○○	Patient or Caregiver Training COMAR 10.34.19.14(A)
176.00	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated CSP was administered are notified of the potential risk.	◉○○	Patient Monitoring and Adverse Events Reporting COMAR 10.34.19.12(C)(6)(h)

Final Comments:

Conducted the Inspection with Sheila Alizadeh and Amelia Sherman. Pharmacy will be developing a compounded NAD+ Injectable, and will be becoming licensed in all 50 states. Pharmacy is also looking to create a new separate compounding space, this second location will require a separate pharmacy permit. Pharmacy is compounding semiglutide, shortage is being documented and following FDA Mandates. Pharmacy has contracted a CGMP consultant.

Pharmacy has partially transitioned to new USP 797 revisions, most recent update 4/2024

Clean room consists of a positive pressure anteroom and buffer room with an LAFW

Discussed/Recommend
Recommend combining compounding records and end product testing results and/or adding a cross reference/link to link the two documents

Observations
- Tacky mat in front of hood in cleanroom - revised 797 prohibits tacky mats from being within the controlled space, you can have one in front of the entrance to the anteroom - removed during inspection
- USP 797 requires 2 incubation temperatures for viable samples, the 2 controlled temperature require 2 incubators - pharmacy ordered a second incubator during inspection.
- Pharmacy is performing filter sterilization with large hopper filters which don't easily allow for bubble point testing, and its not being conducted - discussed process with pharmacy and looked at products to perform bubble point verification - bubble point tests need to he documented on the compounding log.
- Current filters are too large for the volume of CSPs being prepared - pharmacy is looking at smaller filters
- pH testing results are not included on compounding records
- Sink did not get hot water - maintenance was called during inspection

Please provide by 2/7/2024
Proof of hot water
Updated compounding logs
Action plan for sterile filtering CSPs and filter verification (bubble point testing)

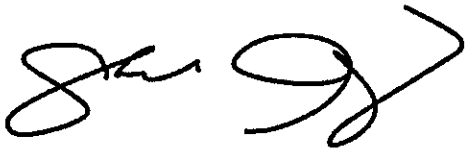
All documents can be sent to Jered Pasay by email at jered.pasay@maryland.gov or faxed to 410-384-4137. Unresolved matters will be brought to the Board for review.

Inspector Signature:

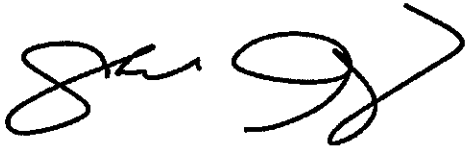


Pharmacist Name			
	17034	**Sheila Alizadeh**	01/23/2025

Signature:



Received a copy of this inspection report:



MARYLAND
Department of Health
Wes Moore, Governor - Aruna Miller, Lt. Governor - Laura Herrera Scott, M.D., M.P.H. Secretary

MARYLAND BOARD OF PHARMACY
4201 Patterson Avenue, Baltimore, Maryland 21215-2299
Kristopher Rusinko, PharmD, Board President, Deena Speights-Napata, Executive Director

SUPPLEMENTAL STERILE PROCESSING INSPECTION FORM

Maryland Pharmacy Permit Number	:	P05361
Corporate Pharmacy Name	:	Shady Grove Pharmacy
Pharmacy Name-Doing Business as (d/b/a) or Trade Name	:	
Street Address	:	15225 SHADY GROVE RD, ROCKVILLE, MD, 20850
Business Telephone Number	:	3019484222
Business Fax Number	:	3019480018
Inspection Date	:	01/23/2025
Arrival Time	:	11:51
Departure Time	:	13:19
Type of Inspection	:	○Opening ◉Annual ○Follow-up ○Others Select
Previous Date	:	01/18/2024
Name of Inspector	:	Jered Pasay

Pharmacy Hours							
Monday:	9:00am - 5:00pm	Tuesday:	9:00am - 5:00pm	Wednesday:	9:00am - 5:00pm	Thursday:	9:00am - 5:00pm
Friday:	9:00am - 5:00pm	Saturday:	Closed	Sunday:	Closed		

Maryland Pharmacy Permit Number	P05361	Expiration Date	05/31/2026
CDS Registration Number	472352	Expiration Date	06/30/2025
DEA Registration Number	[redacted]	Expiration Date	02/28/2025

○ Yes ○ No The pharmacy department provides service 24 hours a day. COMAR 10.34.05.

○ Yes ○ No ○ N/A The pharmacy hours of operation are prominently displayed. COMAR 10.34.05.03B

○ Yes ○ No All permits, licenses, and registrations are posted conspicuously. HO §12-311, HO §12-408(b) and HO §12-6B-08

○ Yes ○ No The pharmacy fills original prescriptions received via the internet. If yes, how do pharmacists verify that a relationship exists between the patient and the prescriber?

HG §21-220; COMAR 10.19.03.02 and .07

○ Yes ○ No The pharmacy wholesale distributes to another pharmacy. COMAR 10.34.37

○ Yes ○ No The pharmacy wholesale distributes to a wholesale distributor. COMAR 10.34.37

○ Yes ○ No ○ N/A The wholesale distribution business exceeds 5% of the pharmacy annual sales. COMAR 10.34.37

Comments:

2. PERSONNEL

17034 | 17034 : SHEILA ALIZADEH

Pharmacist Employee	License #	Status	Exp. Date	Vaccine Certification #	Status	Exp. Date	
SHEILA ALIZADEH	17034	Active	12/31/2026				

Registered Technicians	Registration #	Status	Exp. Date	
Amelia T. Sherman	T19944	Active	11/30/2026	

Unlicensed Personnel (non-registered)	Title	Duties	

Comments:

3. FACILITY AND EQUIPMENT STANDARDS FOR COMPOUNDING STERILE PREPARATIONS

Documentation shows:

O Yes O No Certification that each LAFW (Laminar Air Flow Workbench), BSC (Biological Safety Cabinet), and CAI (Compounding Aseptic Isolator) is functioning properly and meets the air quality requirement of ISO Class 5, and is performed by a qualified operator(s) using current, state-of-the-art electronic air sampling at least every six months and whenever the LAFW, BSC, or CAI is relocated. COMAR 10.34.19.03B(5) & (10); COMAR 10.34.19.15D

O Yes O No The air quality of the clean room and anteroom area is evaluated by a qualified operator(s) for conformance to ISO Class 7 and ISO Class 8 requirements, as appropriate, at least every six months and when renovations occur. COMAR 10.34.19.03B(5); COMAR 10.34.19.15E

O Yes O No Records of clean room testing are maintained and reviewed by the supervising pharmacist. COMAR 10.34.19.07B(1)

O Yes O No Evidence of daily calibration and routine maintenance on the following equipment, if applicable, for use:

O Yes O No O N/A Autoclave

O Yes O No O N/A Electronic Balance

O Yes O No O N/A Convection Oven

O Yes O No O N/A Incubator

O Yes O No O N/A Automated Compounding Devices (pumps) COMAR 10.34.19.10B

O Yes O No A refrigerator and freezer, if applicable, with sufficient capacity to meet the storage requirements for all material requiring refrigeration/freezing must be available in the facility. Evidence of maintenance of acceptable temperature ranges must be available. COMAR 10.34.19.10A

O Yes O No The facility must contain appropriate waste containers to isolate sharps, hazardous waste, biological, and chemotherapy waste. COMAR 10.34.19.09B(6) & .15F; COMAR 10.34.19.10A(3) Access to designated areas and clean rooms is limited to those individuals who are properly attired. COMAR 10.34.19.09A

O Yes O No All equipment used in the designated area or clean room must be made of a material that can be easily cleaned and disinfected. COMAR 10.34.19.09B(3)

O Yes O No O N/A Closed system vial transfer devices (CSTD) are employed when handling cytotoxic drugs. COMAR 10.34.19.12(17)

Comments:

4. COMPOUNDING AREA COMAR 10.34.19.09

O Yes O No Clean room walls, ceilings, counters, lighting fixtures and floors are made of non-porous, nonshedding, cleanable surfaces. COMAR 10.34.19.09B(3)

O Yes O No Supplies are stored in a manner that maintains integrity of an aseptic environment.

O Yes O No The anteroom contains a sink with hot and cold running water. COMAR 10.34.19.09C(2)(a)

Comments:

5.POLICIES AND PROCEDURES MUST ADDRESS: COMAR 10.34.19.12

Policies and procedures address at least the following:

O Yes O No The compounding, filling, and labeling of sterile compounds. COMAR 10.34.19.12C(6)(a), (c) and (d)

O Yes O No Proper labeling of the compounded sterile preparation including the intended route of administration and recommended rate of administration. COMAR 10.34.19.12C(6)(d)

O Yes O No Availability of equipment and supplies. COMAR 10.34.19.12C(3); COMAR 10.34.19.12C(17)(a)

O Yes O No The training of staff in the preparation of compounded sterile preparations. COMAR 10.34.19.12C(10); COMAR 10.34.19.14B

O Yes O No Staff competency evaluations. COMAR 10.34.19.14E

O Yes O No Quality Assurance Program. COMAR 10.34.19.12C(9); 10.34.19.15

O Yes O No All record keeping requirements COMAR 10.34.19.12C(7)

O Yes O No A written process, verified by a pharmacist, describing ingredients and the process for each preparation. COMAR 10.34.19.05B(4); COMAR 10.34.19.07B(1) and (2)

O Yes O No Documentation demonstrating that all personnel involved have read the policies procedures before compounding sterile preparations. COMAR 10.34.19.12B

O Yes O No Documentation of communication of policy and procedure for additions and deletions

O Yes O No The storage and handling of products and supplies. COMAR 10.34.19.12C(6)(b)

O Yes O No The storage and delivery of final preparation. COMAR 10.34.19.12(6)(b) and (f)

O Yes O No Media fill process verification testing. COMAR 10.34.19.12C(11)

O Yes O No The criteria for Beyond Use Dating (BUD). COMAR 10.34.19.12C(6)(e)

O Yes O No Personnel access and movement of materials into and near the compounding area. COMAR 10.34.19.12C(2)

O Yes O No The use and maintenance of environmental control devices used to create the critical area for manipulation of sterile preparations (e.g. laminar air flow workstations, biological safety cabinet, ISO Class 7 clean room, and/or CAIs. COMAR 10.34.19.12C(3)

O Yes O No A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants (pharmacies subject to an institutional infection control policy may follow that policy).

O Yes O No The method used to monitor the environment for bacterial microorganisms. COMAR 10.34.19.12C(4)

O Yes O No The disposal of packaging materials, used syringes, containers, and needles to avoid accumulation and maintain sanitation in the controlled area. COMAR 10.34.19.12C(18); COMAR 10.34.19.15F

O Yes O No Written policies and procedures for the use of established master formulas and worksheets for sterile batch componnding, if applicable

O Yes O No O N/A Established sterilization procedures including documentation of results, if applicable. COMAR 10.34.19.12C(4)

O Yes O No O N/A End-product evaluation and testing, if applicable. COMAR 10.34.19.12C(11); COMAR 10.34.19.15H

Comments:

6. LABELING REQUIREMENTS COMAR 10.34.19.06

All labeling must include the following:

O Yes O No The name and concentration or amount of each ingredient contained in the preparation. COMAR 10.34.19.06B(7) and (8)

O Yes O No Instructions for storage and handling. COMAR 10.34.19.06B(12)

O Yes O No O N/A Cytotoxic agents include a special label which states "Chemotherapy-Dispose of Properly". COMAR 10.34.19.06B(13)

O Yes O No Beyond Use Dating. COMAR 10.34.19.06B(11)

O Yes O No For short dated preparations, labeling must include:

O Yes O No O N/A Time

O Yes O No O N/A Date

O Yes O No O N/A Caution label/start-up time

Comments:

7. RECORD KEEPING REQUIREMENTS COMAR 10.34.19.07

The following records must be maintained:

O Yes O No A readily retrievable medication profile for each patient. COMAR 10.34.19.07A

O O Yes No Compounding worksheets for preparations for future use, indicating the drug name and amount/dose, ingredient lot numbers, quantity prepared, preparation date and BUD. COMAR 10.34.19.07B(2)

O O O Yes No N/A Documentation for 3 years to include: COMAR 10.34.19.07B – 5 years

O O Yes No Training and competency evaluation of employees in sterile preparation procedures. COMAR 10.34.19.07B(1)(a)

O O Yes No Refrigerator and freezer temperatures. COMAR 10.34.19.07B(1)(b)

O O O Yes No N/A Certification of the testing of the sterile compounding environment.COMAR 10.34.19.07B(1)(c)

O O O Yes No N/A Other facility quality control logs specific to the pharmacy's policies and procedures (e.g. cleaning logs for facilities and equipment). COMAR 10.34.19.07B(1)(d)

O O O Yes No N/A Preparation records including the master work sheet, the preparation work sheet and records of end product evaluation, if applicable. COMAR 10.34.19.07B(1)(f)

O O O Yes No N/A Daily, weekly and monthly records of disinfection of workbench surface, walls, floors, ceilings, shelving, tables and stools, and after any unanticipated event which increases the risk of contamination. COMAR 10.34.19.07B(1)(d)

Comments:

8. INVENTORY CONTROL PROCEDURES

O O O Yes No N/A The pharmacy maintains records of wholesale distribution to other pharmacies separately from its other records. COMAR 10.34.37.03

O O O Yes No N/A The pharmacy maintains records of wholesale distribution to wholesale distributors separately from its records of wholesale distribution to other pharmacies. COMAR 10.34.37.03

Comments:

9. ATTIRE 10.34.19.13

O O O Yes No N/A Clean room garb consists of a non-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times. COMAR 10.34.19.13A(3)

O O O Yes No N/A Clean room garb must be donned and removed outside the designated area. COMAR 10.34.19.13A(4)

O O O Yes No N/A Hand, finger, and wrist jewelry must be removed. COMAR 10.34.19.13A(5)

O O O Yes No N/A Head and facial hair must be covered. COMAR 10.34.19.13A(3)(b)

O O O Yes No N/A Makeup must not be worn in clean room. COMAR 10.34.19.13A(7)

O O O Yes No N/A Protective gloves made of non-shedding materials are required. COMAR 10.34.19.11A

O O O Yes No N/A When preparing cytotoxic agents, appropriate personal protective equipment including gowns and gloves are worn. COMAR 10.34.19.12C(17); COMAR 10.34.19.14B

Comments:

Requirements may not apply if a barrier isolator is used to compound sterile preparations.

10. TRAINING OF STAFF, PATIENT, AND CAREGIVER COMAR 10.34.19.14

O O O Yes No N/A In non-hospital environments: Consultation shall be available to the patient and/or primary caregiver concerning proper use of compounded sterile preparations and related supplies furnished by the pharmacy. COMAR 10.34.19.14A

O O O Yes No N/A The supervising pharmacist shall ensure all personnel engaging in compounding sterile drug preparations shall have training and demonstrate on-going competence in the safe handling and compounding of sterile drug preparations including cytotoxic agents if applicable. COMAR 10.34.19.14B

O O O Yes No N/A Pharmacies must establish and follow a written program of training performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. COMAR 10.34.19.14E(1)

O O O Yes No N/A The program of training and evaluation addresses the following:

O O O Yes No N/A Aseptic technique

O O O Yes No N/A Pharmaceutical calculations/terminology

O O O Yes No N/A Sterile preparations compounding documentation

O O O Yes No N/A Quality assurance procedures

O O O Yes No N/A Aseptic preparation procedures

O O O Yes No N/A Proper cleansing and garbing techniques

O O O Yes No N/A General conduct in the controlled area

O O O Yes No N/A Cleaning/sanitizing and maintaining equipment used in the controlled area

O O O Yes No N/A Sterilization techniques if applicable See COMAR 10.34.19.14E(1)(a) – (i) for above

O O O Yes No N/A Handling, storage, and delivery of sterile compounded preparations

O O O Yes No N/A Equipment training COMAR 10.34.19.14E(1)(j)

O O O Yes No N/A Competency assessment COMAR 10.34.19.14B

O O O Yes No N/A Equipment and closure system selection COMAR 10.34.19.14E(1)(j)

O O O Yes No N/A Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. COMAR 10.34.19.14E(2)

O O O Yes No N/A Evaluations must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. COMAR 10.34.19.14E(3)

O O O Yes No N/A Each person's proficiency and continuing training needs must be reassessed every 12 months (every 6 months for high-risk compounding). COMAR 10.34.19.14E(1)(a)

O O O Yes No N/A Records of training and demonstrated competence shall be available for each individual and shall be retained for three (3) years beyond the period of employment. 5 years for employees. COMAR 10.34.19.14C

Comments:

11. DISPOSAL OF WASTE MATERIAL

O O O Yes No N/A Pharmacies compounding sterile preparations shall have written policies and procedures for disposal of infectious materials and/or materials containing cytotoxic residue or hazardous waste. COMAR 10.34.19.12C(18)

O O O Yes No N/A Procedures must include cleanup of spills and shall be in conformance with local health jurisdictions. COMAR 10.34.19.12C(4)

Comments:

12. QUALITY ASSURANCE AND PROCESS VERIFICATION COMAR 10.34.19.15

O O O Yes No N/A Each pharmacy shall have a documented, ongoing quality assurance program that monitors personnel performance, equipment and facilities. COMAR 10.34.19.12C; COMAR 10.34.19.15

O O O Yes No N/A The Quality Assurance Program shall include documentation of monitoring to assure successful:

O O O Yes No N/A Cleaning and sanitization of the parenteral medication preparation area. COMAR 10.34.19.15E

O O O Yes No N/A The storage of compounded parenteral preparations in the pharmacy and periodic documentation of refrigeration/freezer temperature. COMAR 10.34.19.15B

O O O Yes No N/A Steps taken in the event of a drug recall. COMAR 10.34.19.12C(6)(h)

O O O Yes No N/A Written justification including literature references of the chosen beyond use dates for compounded sterile preparations.

O O O Yes No N/A Written policies and procedures for implementing the immediate use exemption for admixtures.

O O O Yes No N/A Each individual involved in the preparation of compounded sterile preparations must successfully complete a verification process before being allowed to prepare sterile preparations. COMAR 10.34.19.14B

Yes	No	N/A	
O	O	O	The verification process shall be carried out using the same personnel, procedures, equipment, and materials as normal production, except that an appropriate microbiological growth medium is used in the compounding process to verify the sterility of the final preparation. COMAR 10.34.19.12C(11); COMAR 10.34.19.15C
O	O	O	Completed media samples must be incubated according to currently accepted standards. COMAR 10.34.19.15C
O	O	O	If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the verification process repeated.
O	O	O	Personnel competency must be re-verified at least every 12 months (every 6 months for highrisk), whenever the quality assurance program yields an unacceptable result, or whenever improper aseptic technique is observed.
O	O	O	The verification and re-verification process must be documented. COMAR 10.34.19.07B(3)
O	O	O	Other personnel monitoring requirements as required by current standards must be performed, such as fingertip touch testing.
O	O	O	There must be current and appropriate reference materials regarding the compounding of sterile preparations located in or immediately available to the pharmacy. COMAR 10.34.19.16
O	O	O	Written documentation that the end product has been tested on a periodic sampling basis for microbial contamination and steps taken in the event that testing for contamination proves positive, if applicable. COMAR 10.34.19.15C

Comments:

CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

Pharmacy: Shady Grove Pharmacy
Permit#: P05361
Date: 01/23/2025

Rx#:
Date Filled:

DRUG	NDC Number	ON HAND INVENTORY	PERPETUAL INVENTORY	
				Clear
				Clear
				Clear
				Clear

Comments:

SCHEDULE II AUDIT

Drug:
NDC Number:
Date of last Inspection/Biennial: 01/18/2024

Amount at last inspection/biennial	0.00	(A)
Purchased since inspection/biennial	0.00	(B)
Total inventory	0	(C) = A + B
Quantity Dispensed	0.00	(D)
Expected Inventory	0	(E) = C - D
Quantity on Hand	0.00	(F)
Discrepancy	0	(G) = (F-E)excess or (E-F) shortage

INVOICE REVIEW

CII:

CIII - CV:

PRESCRIPTION REVIEW

CII#:

Date:

Comments:

CIII - CV#:

Date:

Comments:

Pharmacist Signature for Controlled Dangerous Substances Audit:

INSPECTOR'S COMMENTS:

Observations
- Tacky mat in front of hood in cleanroom - revised 797 prohibits tacky mats from being within the controlled space, you can have one in front of the entrance to the anteroom - removed during inspection
- USP 797 requires 2 incubation temperatures for viable samples, the 2 controlled temperature require 2 incubators - pharmacy ordered a second incubator during inspection.
- Pharmacy is performing filter sterilization with large hopper filters which don't easily allow for bubble point testing, and its not being conducted - discussed process with pharmacy and looked at products to perform bubble point verification
- bubble point tests need to be documented on the compounding log.
- Current filters are too large for the volume of CSPs being prepared - pharmacy is looking at smaller filters
- pH testing results are not included on compounding records
- Sink did not get hot water - maintenance was called during inspection

Please provide by 2/7/2024
Proof of hot water
Updated compounding logs
Action plan for sterile filtering CSPs and filter verification (bubble point testing)

Inspector Signature:

Pharmacist Name (Print):

Date: 01/23/2025

Signature:	
Received a copy of this inspection report:	

Supporting Documents.

410-764-4755 - Fax 410-384-4137 - Toll Free 800-542-4964
MDH 1-877-463-3464 - Maryland Relay Service 1-800-735-2258
Web site: https://health.maryland.gov/pharmacy/Pages/index.aspx

Following Task Completed or in progress

Please provide by 2/7/2024
Proof of hot water -Task completed with photo 1-24-25
Updated compounding logs- Task completed PDF 1-24-25
Action plan for sterile filtering CSPs and filter verification (bubble point testing)--In Progress 1-24-25



Formula Worksheet
09/26/2019 12:20pm

Shady Grove Pharmacy
15225 Shady Grove Rd Ste 101
Rockville, MD 20850-3263
(301) 948-4222

Rx #: _____

C-ATROPINE 0.05% EYE DROPS

Flavor: None
Total Quantity: 1800.000 ML
Date Made: ___/___/___
Lot Number: _____
BUD: ___/___/___ Time: ___:___ Time to expiration: 14.000 Days
Pharmacist: _____ Initials: ____
Technician: _____ Initials: ____

Schedule:
Class: Rx

Route: Ophthalmic
Dosage Form: Solution

Warnings: For the eye.

Ingredient Name	NDC	Quantity	Qs (actual)	Active	Optional
Atropine 1% Eye Drops	60219-1750-08	90.0000 ML	☐	☑	☐
Mfg: _____ Lot #: _____ Exp. Date: ___/___/___ Supplier: _____					
Checked: ☐ By: _____					
Sensitive Eyes Plus Saline	10119-0002-38	1710.0000 ML	☐	☑	☐
Mfg: _____ Lot #: _____ Exp. Date: ___/___/___ Supplier: _____					
Checked: ☐ By: _____					

Mixing Directions:

1. pH Testing Results

NDC	Quantity	Qs (actual)	Active	Optional
10119-0002-38	1710.0000 ML	☐		

Mfg _____ Lot # _____ Exp. Date ___/___/___
Checked ☐ By _____ pH Results _____

2. CSP filter verifcations (Bubble point testing) results

NDC	Quantity	Qs (actual)	Active	Optional
10119-0002-38	1710.0000 ML	☐		

Mfg _____ Lot # _____ Exp Date: ___/___/___
Checked ☐ By: _____ PSI _____

This formula is a trade secret of Shady Grove Pharmacy

Gmail

Amelia Sherman <amelia@shadygroverx.com>

Fwd: Annual Sterile Inspection FY25 P05361

Amelia Sherman <amelia@shadygroverx.com> Fri, Jan 24, 2025 at 4:41 PM
To: jered.pasay@maryland.gov, Sheila Alizadeh <sheila@shadygroverx.com>

Following Task Completed or in progress

Please provide by 2/7/2024
Proof of hot water -Task completed with photo 1-24-25
Updated compounding logs- Task completed PDF 1-24-25
Action plan for sterile filtering CSPs and filter verification (bubble point testing)--In Progress 1-24-25



[Quoted text hidden]

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Amelia Sherman
Compounding & Regulatory Specialist
Shady Grove Pharmacy
301.948.4222

---

2 attachments

P05361 FY25 Sterile Inspection - FINAL.pdf
3414K

01242025.pdf
261K

Jered Pasay -MDH- <jered.pasay@maryland.gov> Fri, Feb 7, 2025 at 8:46 AM
To: Sheila Alizadeh <sheila@shadygroverx.com>
Cc: Amelia Sherman <amelia@shadygroverx.com>

got it, thank you

Jered Pasay, MS
Laboratory Scientist Surveyor
Maryland Board of Pharmacy
Maryland Department of Health
4201 Patterson Avenue
Baltimore, MD 21215
Cell: [redacted]
Board: 410-764-4755
Office: 410-764-3970
Jered.Pasay@maryland.gov

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Jered Pasay -MDH- <jered.pasay@maryland.gov> Fri, Feb 7, 2025 at 9:28 AM
To: Sheila Alizadeh <sheila@shadygroverx.com>
Cc: Amelia Sherman <amelia@shadygroverx.com>

Thank you Sheila

Jered Pasay, MS
Laboratory Scientist Surveyor
Maryland Board of Pharmacy
Maryland Department of Health
4201 Patterson Avenue
Baltimore, MD 21215
Cell: [redacted]
Board: 410-764-4755
Office: 410-764-3970
Jered.Pasay@maryland.gov

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[Quoted text hidden]

Gmail

Sheila Alizadeh <sheila@shadygroverx.com>

Final requirement for sterile inspection

3 messages

Sheila Alizadeh <sheila@shadygroverx.com> Thu, Feb
To: Jered Pasay -MDH- <jered.pasay@maryland.gov>
Cc: Amelia Sherman <amelia@shadygroverx.com>

Hi Jered,
I apologize for the delay in getting this line item completed. My intention was to purchase a bubble point apparatus however the one I wanted to purchase from ThermoFisher is on backorder 6,2025. The other option we found was pretty pricey. Medisca finally restocked their Bubble Wizard today and the order was placed. Should arrive in 2 business days.

Dear Jered,

Please accept my apologies for the delay in completing this line item. I had intended to purchase a bubble point apparatus from ThermoFisher, but it is currently on backorder until August 6, 2 alternative options we found were unfortunately quite expensive.

Medisca restocked their Bubble Wizard today, and I have placed an order. It should arrive within two business days.
Order Status

Received by Medisca	Confirmed	In Warehouse	Shipped
Feb 6, 2025	Feb 6, 2025	Feb 6, 2025	Feb 6, 2025

Order Information

Order ID
04020780

PO
sheila

Order Date
Feb 6, 2025

Ship Date
Feb 6, 2025

Sold To
Shady Grove Pharmacy

Shipped To
15225 Shady Grove Road
Suite 101
Rockville, MD 20850

Order Summary
Subtotal:
$412.20
Shipping Cost:
$0.00
Order Total:
$412.20

Items to be Shipped

PRODUCT NO	PRODUCT NAME	TOTAL	BACK ORDERS	UNIT PRICE	SUBTOTAL	LOT
7054-01	BUBBLE POINT TESTER, WIZARD	1	0	$412.20	$412.20	

Thank you for your understanding.

Sincerely,
Sheila

Sheila Alizadeh, PharmD
Owner/Pharmacist in Charge
Shady Grove Pharmacy
T 301.948.4222
F 301.948.0018
www.shadygroverx.com
Follow on Facebook!

169680

State of Maryland

DEPARTMENT OF HEALTH

SIGNATURE OF BEARER

THE MARYLAND STATE BOARD OF PHARMACY
CERTIFIES THAT **Shady Grove Pharmacy**
IS A REGISTERED **Active**
License Expiration Date
Pharmacy 05/31/2026

IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. REG. PERM. NO.	EXPIRATION DATE
P05361	05/31/2026

SECRETARY MDH

WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES

Changing from Shady Grove to Blue Door

State of Maryland 169680

DEPARTMENT OF HEALTH

SIGNATURE OF BEARER

THE MARYLAND STATE BOARD OF PHARMACY
CERTIFIES THAT Shady Grove Pharmacy
IS A REGISTERED **Active**
License Expiration Date
Pharmacy 05/31/2026

IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. REG. PERM. NO.	EXPIRATION DATE
P05361	05/31/2026

SECRETARY MDH

WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Blue Door Pharmacies, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) NV Pharmacist license 24864

Physical Address 15225 Shady Grove Road Suite 101

City Rockville State MD Zip 20850

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 301-948-4222 Website www.shadygroverx.com

Licensing Company Email sheila@shadygroverx.com

Section 2: Personal Information

First Sheila Middle _____ Last Alizadeh

Alias(es, nicknames, name changes, etc.) n/a

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	n/a	n/a

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of MD School of Pharmacy		08/1999-05/2003	
Address	**City**	**State**	**Zip**
20 N Pine Street	Baltimore	MD	21201
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
University of MD College Park		09/1991-12/1994	
Address	**City**	**State**	**Zip**
NO STREET ADDRESS	College Park	MD	20742
Diploma/Degree obtained, if any			
BS Biology			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
09/2015-present				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Blue Door Pharmacis, LLC			08/2010-present	
Business Address		**City**	**State**	**Zip**
15225 Shady Grove Rd Suite 101		Rockville	MD	20850
Phone	**Title**			
301-948-4222	Owner/PIC			
Description of Duties				
Director of Operations and compounding pharmacist. Oversee staff, maintain Q/A, inventory and staff training.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sheila Alizadeh, PharmD

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/6/2025

Date

Please have this section completed in the presence of a Notary Public.

State of MARYLAND, ss. County of MONTGOMERY

I, Sheila Alizadeh, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/6/2025

Date

Subscribed and Sworn to before me this 6th day of NOVEMBER, 2025.

Notary Public Signature

RAYMOND WAI LEE
Notary Public - State of Maryland
Frederick County
My Commission Expires Oct 26, 2029

(Seal)

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Sheila Ailzadeh hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PIC/owner (title) for Blue Door Pharmacies, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT,

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 17TH day of NOVEMBER, 2025

Notary Public

RAYMOND WAI LEE
Notary Public - State of Maryland
Frederick County
My Commission Expires Oct 26, 2029

RAYMOND WAI LEE NOTARY PUBLIC STATE OF MARYLAND

Details

Demographic Information

Name: Shady Grove Pharmacy

Address Information

Address: **15225 SHADY GROVE RD**
SUITE 101

City: ROCKVILLE **State:** MD **Zip:** 20850

Maryland License\Permit Information

Number: P05361 **Type:** Pharmacy **Subtype:** **Status:** Active

Original Issued: 8/18/2010 **Date Renewed:** 5/7/2024 **Expires:** 5/31/2026

Specialty: Independent

Board Orders

Clicking on the corresponding link will allow documents to be viewed.

No Related Documents

****Please refer to the Board's Formal Disciplinary Action page for the listing of all disciplinary actions.****

400

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☑ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☑ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.)	☐ Other:	☑ Non-sterile Compounding
			☑ Sterile Compounding
			☑ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 35751		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☑ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: BLUE STONE 4 PHARMACY LLC dba GREEN STONE RX

Physical Address: 861 SW 8TH ST. SUITE # 101

City: MIAMI State: FL Zip: 33130

Mailing Address (if different from physical address): SAME

City: _____ State: _____ Zip: _____

Telephone: (707)240-5096 Toll Free # (NAC 639.708, NRS 639.23286): (855)625-7588

Fax: (855)223-6454 Contact Email: pharmacylicenses@greenstonerx.com

Website: www.greenstonerx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Nicole Kruczek

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22452

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Nicole Kruczek	NV Pharmacist Registration #: 22452
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): N/A

Corporation/Organization Name: Blue Stone 4 Pharmacy LLC

Mailing Address: 861 SW 8th St. Suite #101

City: Miami State: FL Zip: 33130

Telephone: (707) 240-5096 Email: pharmacylicenses@greenstonerx.com

Contact Person Name: Rossana Vilar

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner (title) for Blue Stone 4 Pharmacy LLC dba Green Stone RX (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Rossana Villar

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

12/1/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rossana Rodriguez Vilar

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

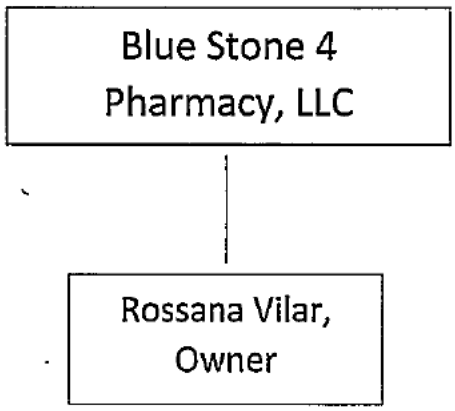
12/1/2025

Date

Board Use Only	Date Received: 2/3/26	Amount: $500 CK 1065

Organization Chart

Blue Stone 4 Pharmacy, LLC dba Green Stone Rx



Name: Rossana Vilar

Ownership: 100% - Non-Pharmacist Owner of Blue Stone 4 Pharmacy, LLC

[redacted]

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Blue Stone 4 Pharmacy LLC** as a FOREIGN LIMITED-LIABILITY COMPANY duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 01/14/2026, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 01/16/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202601166422392
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Blue Stone 4 Pharmacy LLC dba Green Stone RX

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 861 SW 8 St Suite #101

City Miami State FL Zip 33130

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (707) 240-5096 Website greenstonerx.com

Licensing Company Email pharmacylicenses@greenstonerx.com

Section 2: Personal Information

First Nicole Middle _____ Last Kruczek

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Pttsburgh, Katz School of Business		03/2018-04/2019	
Address	**City**	**State**	**Zip**
4200 Fifth Ave	Pittsburgh	PA	15260
Diploma/Degree obtained, if any			
Masters in Pharmacy Business (MPBA)			

School Name		From - To (MM/YY – MM/YY)	
Temple University, School of Pharmacy		08/1990-06/1993	
Address	**City**	**State**	**Zip**
1801 N. Broad St.	Philadelphia	PA	19122
Diploma/Degree obtained, if any			
B.S. Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Luzerne County Community College		01/1989-06/1990	
Address	**City**	**State**	**Zip**
521 Trailblazer Dr.	Nanticoke	PA	18634
Diploma/Degree obtained, if any			
Pre-Pharmacy Program			

School Name		From - To (MM/YY – MM/YY)	
Greater Nanticoke Area High School		08/1984-06/1988	
Address	**City**	**State**	**Zip**
425 Kosciuszko St	Nanticoke	PA	18634
Diploma/Degree obtained, if any			
High School Diploma Academic Study			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/1998-present	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Bluestone 4 Pharmacy LLC dba Greenstone Rx			08/2025-present	
Business Address		**City**	**State**	**Zip**
861 SW 8 St Suite #101		Miami	Fl	33130
Phone	**Title**		**Number of Employed Hours**	
(707) 240-5096	Pharmacist		200	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
CVS Health			09/2008-12/2025	
Business Address		**City**	**State**	**Zip**
1 Great Valley Blvd		Wilkes-Barre	PA	18702
Phone	**Title**		**Number of Employed Hours**	
570-820-2700	Pharmacy Director		>30,000	
Description of Duties				
Responsibilities for prescription verification pharmacists working remotely across multiple states, product verification pharmacists, and team of central fill pharmacists and technicians.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	—	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Nicole Kruczek, **certify that as the designated representative for**

Blue Stone 4 Pharmacy LLC dba Green Stone RX,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. NK I am at least 21 years of age;
3. NK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. NK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. NK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. NK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. NK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Nicole Kruczek

Print Name (First, Last)

Nicole Kruczek

Original Signature (electronic, copies or stamps not accepted)

12/23/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nicole Kruczek

Print Name (First, Last)

Nicole Kruczek — 12/23/25

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Luzerne

I, Nicole Kruczek, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Nicole Kruczek — 12/23/25

Original Signature — **Date**

Subscribed and Sworn to before me this 23rd day of Dec. 2025.

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
ANGELA E. CRUZ, Notary Public
Luzerne County
My Commission Expires September 17, 2027
Commission Number 1292848

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Blue Stone 4 Pharmacy LLC dba Green Stone RX

NV Pharmacy or Outsourcing facility license # (if applicable): N/A

Physical Address: 861 SW 8 St Suite #101

City: Miami State: FL Zip: 33130

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (707) 240-5096 Toll Free # (NAC 639.708, NRS 639.23286): (855) 625-7588

Fax: (855) 223-6454 Contact Email: pharmacylicenses@greenstonerx.com

Website: greenstonerx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Nicole Kruczek

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22452

Name of Designated Person(s) as defined by revised USP-797 guidelines: Nicole Kruczek

Email of Designated Person(s): pharmacylicenses@greenstonerx.com

Telephone of Designated Person(s): (707) 240-5096

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ☑ Category 2 ☐ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☑ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☐ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ☑ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 11/3/25

6. What is the frequency of the recertification for the ISO classified areas? 6 Months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ☑ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☑ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? At least once monthly

10. Will you be performing sterile hazardous drug compounding? Yes ☑ No

If you marked "Yes", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Semaglutide
Tirzepatide

12. What laboratory performs your sterility or endotoxin testing?

Name: Pharmetric Laboratory
Address: 7265 Ulmerton Rd.
City: Largo State: FL Zip: 33771
Telephone: (727) 209-5778

Other Labs:
Eagle Source-Based Solutions :- 11111 S. Wilcrest Drive. Houston, TX 77099 (800) 745-8916
ARC Bio Pharma : 840 Research Parkway Ste. 544 · Oklahoma City, OK 73104
Telf: (405) 271-1194

13. What is your procedure for visual inspection of compounded sterile products?

ANSWER ATTACHED

14. How often do you perform glove fingertip and medial fill testing?

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

ANSWER ATTACHED

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

ANSWER ATTACHED

17. Who performs the sterile compounding process at your facility?

ANSWER ATTACHED

18. Who is responsible and accountable for the sterile compounding process at your facility?

ANSWER ATTACHED

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

ANSWER ATTACHED

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A		
2. Are you complying with all USP 800 guidelines?	Yes	✓ No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

N/A

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

N/A

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

N/A

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

N/A

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

N/A.

5. What is the frequency for completing surface sampling? N/A			
6. What is the frequency for using sporicidal agents? N/A			
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	N/A	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	N/A	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rossana Villar

Name of Person who Completed the Form

Owner

Title

Signature (copies or stamps not accepted)

12/1/2025

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

Sterile Compounding Questionnaire 3 of 6 / Question # 13 1
Question # 14 2
Question # 15 3
Question # 16 5
Question # 17 7
Question # 18 8
Question # 19 9

Sterile Compounding Questionnaire 3 of 6 / Question # 13

What is your procedure for visual inspection of compounded sterile products?

Based on your document titled "**9.015- Visual Inspection of Compounded Sterile Solutions.docx**", the procedure for visual inspection of compounded sterile solutions is as follows:

Equipment/Supplies Required:

- Final compounded sterile product
- Light Box with black and white background and fluorescent and UV light source
- Magnifying Lens

Procedure:

1. Turn on both fluorescent and UV lights in the light box.
2. Utilizing each light independently, grip the top of the container and slowly swirl the contents in a circular motion, avoiding rigorous swirling. Any air bubbles created should rise to the top of the container.
3. Hold the container four inches above or below the light source (depending on which is being utilized at the time).
4. In a motion from left to right, pass the container in front of the black background first, then the white, and back again.
5. Invert the container and pass it again before both backgrounds.
6. Utilize a magnifying glass during this procedure for closer visual inspection as needed.

What to Monitor and Check:

- **Particulate matter** usually remains at an even level or drops to the bottom of the container.
    - Black UV light aids in the visualization of glass or crystalline particulates and some types of bacteria.
    - White fluorescent light aids in visualizing solid particulates such as rubber cores, lint, chemical precipitant, hair, or dust.
- Monitor other aspects of the preparation such as **color** or **visual signs of microbial growth**.
- Check for signs of **precipitates, flocculation, undissolved substances, solvent impurities, and carmelization**.

Rejection Criteria and Follow-up:

- Preparations showing any signs of **particulates, phase separation, or incomplete ingredient mixing** will not be released for use.
- Failures due to particulate matter will be reviewed with the technician or pharmacist responsible for the preparation to determine the source of contamination.
- Failures will be reported to the quality assurance team for review.

Question # 14

Designated Person - Annually
Compounding Personnel - Every 6 Months

Question # 15

Based on your documentation, the training program for all personnel performing sterile compounding is comprehensive, including initial core skills training and ongoing competency assessments.Initial Training and Competency Assessment

Before personnel can independently compound or have direct oversight, they must complete initial training and demonstrate knowledge and competency in core skills.

Core Skills Training Checklist:

Initial training records must document completion of a checklist that covers:

- Hand hygiene
- Garbing
- Cleaning and disinfection
- Calculations, measuring, and mixing
- Aseptic technique
- Achieving and maintaining sterility
- Use of equipment
- Documentation procedures
- Principles of HEPA filtration and Primary Engineering Control (PEC) use
- Movement of materials and personnel

Initial Garbing Competency:

- Personnel must successfully complete an initial gloved fingertip (GFT) competency a minimum of **three separate times**.
- Each attempt includes a **documented visual audit** while performing hand hygiene and garbing procedures.
- GFT samples are collected *before* applying sterile 70% isopropyl alcohol (IPA) to gloves.
- The action level for a passing result is **zero Colony-Forming Units (CFU)**. All three assessments must be passed in succession.

Initial Aseptic Manipulation Competency:

This assessment is completed by personnel who compound or have direct oversight and consists of:

- **Media-Fill Testing**: The test must simulate the most complex flow of materials, manipulations, and time to compound. A passing result is the absence of turbidity after incubation.

- **Visual Observation**
- **Post-Media-Fill Gloved Fingertip and Thumb Sampling**: This is performed immediately after the media fill. The action level for a passing result is **less than or equal to 3 CFU total** for both hands combined.
- **Surface Sampling** of the Direct Compounding Area (DCA).

Ongoing Training and Competency Assessment

Ongoing training and knowledge assessment of sterile compounding principles or core skills must be completed at least **every 12 months**. Additionally, topic-specific training is required when procedures change.

Ongoing Competency Assessments (Category 2 CSPs):

- **Compounding Personnel** (who compound): Assessment is completed **every 6 months**. This includes:
  - Garbing competency and Gloved Fingertip (GFT)
  - Aseptic technique competency
  - Media fill
  - Surface sampling of DCA
- **Direct Oversight Personnel** (who do not compound): Assessment is completed **every 12 months**. This includes:
  - Garbing competency and GFT
  - Media fill

Failure Investigation and Remediation:

Any failure of an initial or ongoing competency assessment must be investigated, remediated, and documented in a Corrective Action Plan.

All information is based on the documents found in your Workspace, including "SOP 1.020 Documentation Requirements for Sterile Compounding"

Question # 16

The cleaning and sanitization procedure for your Primary Engineering Controls (PECs) and Secondary Engineering Controls (SECs) involves specific agents and frequencies, which vary depending on the area and the type of compounding (non-hazardous or hazardous). ***Cleaning, Disinfectant, and Sporicidal Agents***

The following approved agents are used for cleaning and disinfection:

Agent Category	***Product Name***	***Use***	***Contact Time/Dwell Time***
Disinfectant Cleaner	*Contec® Sterile* ***TB1-3300*** *Disinfectant*	*EPA-registered one-step disinfectant cleaner, used on all cleanroom surfaces.*	*1-minute bactericidal, virucidal, tuberculocidal, and fungicidal contact time.*
Sporicidal Agent	***Sterile PeridoxRTU™***	*EPA-registered one-step sporicidal disinfectant cleaner. Also used for* ***deactivation*** *of hazardous chemicals.*	*3-minute sporicidal application contact time.*
General Disinfectant	***Sterile 70% Isopropyl Alcohol (IPA)***	*Applied to remove residue, immediately before compounding, and in between cleaning/sporicidal steps.*	*Allow to dry completely.*

Cleaning Frequency and Procedure1. Primary Engineering Control (PEC) - ISO Class 5

Frequency	***Cleaning/Disinfecting Activity***	***Procedure***
Daily *(on days with compounding)*	*Clean and disinfect all interior surfaces and equipment.*	*Completed in the morning before any aseptic compounding activities.* *Sterile TB 1-3300 as a one step disinfectant cleaner top, back, sides, bottom, cleaned in the order from cleanest to dirtiest.*

Throughout Shift	*Apply Sterile 70% IPA.*	*Applied to the horizontal work surface:* ***Immediately before initiating compounding, at least every 30 minutes*** *of continuous compounding,* ***after each compounded sterile preparation (CSP)*** *is made, and* ***whenever liquids are spilled*** *or contamination is suspected.*
Monthly	*Cleaning of the removable work tray and all surfaces underneath. Also Sterile Peridox RTU followed by Sterile 70% IPA*	

2. Secondary Engineering Controls (SECs) - ISO Class 7/8 (Buffer/Anteroom)

Frequency	***Area***	***Cleaning/Disinfecting Activity***
Daily *(on days with compounding)*	*Work surfaces outside the PEC*	*Cleaning and disinfecting.*
Daily - Evening *(on operational days)*	*Floors (Buffer/Ante-area)*	*Cleaned and disinfected using* ***TB1-3300*** *and then followed by* ***Sterile IPA*** *if needed to remove residue.*
Monthly	*Ceilings, Walls, Doors, Door frames, Storage shelving and bins, Equipment outside of PECs.*	*Sporicidal agent application (e.g.,* ***PeridoxRTU™****).*

Question # 17

The sterile compounding process at your facility is performed by ***trained pharmacists and pharmacy technicians****.*

The Standard Operating Procedure (SOP) also applies to the ***Pharmacist-in-Charge, Designated Person(s), and all compounding personnel*** *involved in sterile preparation activities. Entry into the controlled areas (ISO 5, 7, and 8) is limited to these trained individuals, or personnel in training under the direct supervision of certified personnel.*

7.000.4- Conduct of Personnel in Sterile Compounding Lab.docx

SOP 1.011 – Scope of Sterile Compounding Services.docx

Sterile Compounding Inspections

SOP 1.020 Documentation Requirements for Sterile Compounding.docx

Question # 18

The primary responsibility and accountability for implementing and maintaining the sterile compounding process rest with the **Pharmacist-in-Charge** and the **Designated Person(s)**.

Specifically:

- **Pharmacist-in-Charge and Designated Person(s)**
  - They are responsible for implementing and maintaining all sterile compounding procedures.
  - The **Designated Person** has the overall responsibility for ensuring facility certification and recertification are performed on schedule, reviewing certification reports, and approving corrective actions.
  - The **Designated Person** also signs off on the final clearance for personnel to return to compounding after any failed competency assessment and subsequent retraining.
  - The **Pharmacist-in-Charge** is listed as an approval signature on SOPs.
- **Compounding Personnel**
  - Personnel who perform compounding are responsible for participating in dynamic testing as assigned and reporting air quality issues to the Designated Person.

SOP 1.011 – Scope of Sterile Compounding Services.docx

SOP 5.007 Certification and Recertification of Sterile Compounding Areas.docx

SOP 1.020 Documentation Requirements for Sterile Compounding

SOP 5.001 Certification and Recertification of Sterile Compounding Areas

SOP 4.001 Facility Design and Environmental Controls for Sterile Compounding Areas

Sterile Compounding Inspections

Question # 19

The shipping conditions and procedures for compounded sterile products are designed to ensure controlled storage temperatures and product integrity for up to 48 hours in transit.

Packaging and Materials:

- **Packing:** Preparations must be packed according to the storage requirements on the Master Formulation Sheet.
- **Temperature Control:** Ship with **ice packs (2 packages) per container** to reasonably ensure controlled storage conditions for **48 hours** from packaging until delivery.
- **Protection:** The product must be isolated from potential moisture or soil placed into **sealed plastic bags**.
- **Packaging Materials:** Use an appropriate mailer designated to ship cold temperature products, or other appropriate packing material, along with **bubble wrap**.

Shipping Schedule:

- **Refrigerated Items:** Will be shipped for **next day delivery**.
- **Schedule Restriction:** Do **not** ship on Saturday or any day where the preparations may remain on shipping docks, warehouses, or in mailboxes, where they may be exposed to hot or cold temperatures.
- **Handling:** Shipping personnel are instructed to minimize jostling, shaking, or inverting CSPs.

Validation:

- Shipping packaging and methods are validated by sending test shipments to pre-arranged sites across the anticipated delivery area during the hottest and coldest parts of the year to confirm package condition and verify any temperature excursions.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV355 - Community Pharmacy (New Business / Change of Owner)

www.FloridaHealth.gov

File # 30146
Insp # 201356

NAME	PERMIT NUMBER	DATE OF INSPECTION
BLUE STONE 4 PHARMACY, LLC		10/11/2024
DOING BUSINESS AS		
BLUE STONE 4 PHARMACY		
STREET ADDRESS	**TELEPHONE #**	**EXT**
861 SW 6TH ST #101		
CITY	**COUNTY**	**STATE/ZIP**
MIAMI	MIAMI-DADE	FL/33130

Additional Information

Business Operation Hours

M-T-W-TH-F N	Weekly Hours 9:00 am to 4:00 pm
Monday N	Monday Hours
Tuesday N	Tuesday Hours
Wednesday N	Wednesday Hours
Thursday N	Thursday Hours
Friday N	Friday Hours
Saturday N	Saturday Hours Closed
Sunday N	Sunday Hours Closed

Registered Pharmacist / Intern / Tech

License # PS 38702	Licensee Name Kaila M. Charran
License Type Registered Pharmacists	
License # PS 66704	Licensee Name David Bland Hance, Jr
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # N/A	

License Relations

Pharmacy Affiliate

VILAR, ROSSANA R	License #

RX DPT MGR/COR/POR

CHARRAN, KAILA MARITZA	License # 38702

INV355 - Community Pharmacy (New Business / Change of Owner)

COMMUNITY REQUIREMENTS GENERAL SECTION

Rx Department is open for a minimum of 20 hours per week and signage stating the hours the pharmacy department is open. [64B16-28.1081, F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-28.1035, F.A.C]	Yes
Private Consultation Area available. [64B16-28.1035, F.A.C]	Yes
Generic equivalent sign is posted. [465.025(7), F.S]	Yes
Prescription department is clean and safe, has a sink with running water convenient to the prescription department, and references and equipment necessary for the practice of pharmacy. [64B16-28.102 F.A.C.]	Yes

INV355 - Community Pharmacy (New Business / Change of Owner)

Insp # 201356

BLUE STONE 4 PHARMACY, LLC

File # 30146

Pharmacy has a designated Prescription Department manager with a current and active Florida license. [465.018, F.S.]	Yes
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16 -27.410(2)(a) F.A.C.]	Yes
Continuous Quality Improvement Program described in Policy and Procedure manual [64B16-27.300 F.A.C.] [766.101(1)(a)(l) F.S.]	Yes
Policy and Procedure to prevent the fraudulent dispensing or controlled substances. [465.022 (4) F.S]	Yes
Prescription Department is securable from unauthorized access. [64B16-28.109 F.A.C.]	Yes
All medications to be purchased from a Florida licensed wholesaler [499-F.S.]	Yes
The following rules have been reviewed with the applicant: 64B16-30.003, F.A.C. (Citations), 64B16-28.140(4) F.A.C. (Compounding Records), 64B16-28.1081, F.A.C. (Regulation of Daily Operating Hours; Commencement of Operation-s), 64B16-28.202, F.A.C (Closing of a Pharmacy)	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	Yes
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	Yes

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Remarks:

This is a new business inspection for a Community Pharmacy Permit conducted with Kayla M. Charran, PS 38702 and David Bland Hance, Jr PS 66704. Pharmacy was found clean/safe and is ready to obtain a permit.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

BARREIROS, DANAY

Date:10/11/2024

Representative:

Kaila M Charran PS 38702

Date:10/11/2024

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797 USP Sterile Compounding

File # 30147
Insp # 204041

NAME	PERMIT NUMBER	DATE OF INSPECTION
BLUE STONE 4 PHARMACY, LLC		04/14/2025
DOING BUSINESS AS		
GREEN STONE RX		
STREET ADDRESS	**TELEPHONE #**	**EXT**
661 SW 8th st #101		
CITY	**COUNTY**	**STATE/ZIP**
MIAMI	MIAMI-DADE	FL/33130

Additional Information

Business Operation Hours

M-T-W-TH-F N	Weekly Hours 9 am to 5 pm
Monday N	Monday Hours 9 am to 5 pm
Tuesday N	Tuesday Hours 9 am to 5 pm
Wednesday N	Wednesday Hours 9 am to 5 pm
Thursday N	Thursday Hours 9 am to 5 pm
Friday N	Friday Hours 9 am to 5 pm
Saturday N	Saturday Hours CLOSED
Sunday N	Sunday Hours CLOSED

Registered Pharmacist / Intern / Tech

License # PS38702	Licensee Name Kaila Charran
License Type Registered Pharmacists	
License # PS66704	Licensee Name David Bland Hance
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

License Relations

Pharmacy Affiliate

VILAR, ROSSANA R	License #

RX DPT MGR/COR/POR

CHARRAN, KAILA MARITZA	License # 38702

Special Sterile Compounding

BLUE STONE 4 PHARMACY, LLC	License # 35351

INV797 - USP Sterile Compounding
(Revision 1, USP 797 2022. August 2024)
A. INTRODUCTION & SCOPE – ALL CATEGORIES

DESIGNATED PERSON: A designated person(s) is identified who is responsible and accountable for the performance and operation of the facility and personnel involved in the preparation of CSPs. [USP 797 Section 1.1.3]	Yes

IMMEDIATE USE COMPOUNDING: When preparing immediate use preparations, written SOPs are in place for all requirements and all criteria are met including 1. aseptic technique, processes, and procedures; and, 2. personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and SOP's, 3. the preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs, 4. the preparation involves not more than 3 different sterile products, 5. Any unused starting component from a single-dose container is discarded, 6. Administration begins within 4 hours following the start of preparation and, 7. Unless directly administered by the preparer or administration is witnessed by the preparer, the CSP is labeled with the names and amounts of all active ingredients, the name or initials of the preparer and the 4 hour period within which administration must begin. [USP 797 Section 1.3]	N/A
BAG & VIAL SYSTEM: Docking of vial and bag systems for future activation and administration is performed in an ISO 5 environment and BUDs are not longer than those specified in the manufacturer's labeling. [USP 797 Section 1.4]	N/A
REPACKAGING: Repackaging of sterile products or preparations from its original container into another container are prepared according to all applicable USP 797 requirements. [USP 797 Section 1.1.2]	N/A

B. COMPONENT BUDs (Single and Multi-dose Containers) – ALL CATEGORIES

SINGLE DOSE CONTAINERS (SDCs): SDCs are entered or punctured only in an ISO Class 5 or cleaner air and are used up to 12 hours after initial entry or puncture if the labeled storage requirements during that 12-hour period are maintained. [USP 797 Section 15.1] *Per policy 9.0051*	Yes
AMPULES: Opened SINGLE DOSE AMPULES are used immediately and not stored for any time period. [USP 797 Section 15.1]	N/A
MULTIDOSE CONTAINERS (MDCs): Upon initially entering or puncturing a conventionally manufactured MDC, the MDC is not used for more than 28 days unless otherwise specified by the manufacturer on the labeling. [USP 797 Section 15.2] *Per policy 9.0051*	Yes
PHARMACY BULK PACKAGES: Conventionally manufactured pharmacy bulk packages are entered or punctured only in an ISO Class 5 PEC and must be used according to the manufacturer's labeling. [USP 797 Section 15.3]	Yes
SINGLE DOSE COMPONENT CSPs & STOCK SOLUTIONS: When single-dose CSPs or CSP stock solutions are used as a component to compound additional CSPs, the original compounded single-dose component CSP or CSP stock solution is entered or punctured in ISO Class 5 or cleaner air and is stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). Once punctured, the component CSP is used for sterile compounding for up to 12 hours or its assigned BUD, whichever is shorter, and any remainder is discarded. [USP 797 Section 16.2]	N/A

C. CSP LABELING – ALL CATEGORIES

CSP LABEL REQUIREMENTS: CSP immediate container label prominently and legibly displays 1) assigned internal identification number; 2) active ingredient(s) and their amount(s), or concentration(s); 3) storage conditions if other than controlled room temperature; 4) BUD; 5) dosage form; 6) total amount or volume; 7) statement if CSP is a single dose container (when space permits) or multi-dose container. Labeling of CSP displays 1) route of administration, 2) special handling instructions, 3) warning statements, and the compounding facility name and contact information if the CSP is sent outside of the facility in which it was compounded. [USP 797 Section 13] *Reviewed sample label for Semaglutide 2.5mg/mL Solution during inspection.*	Yes
ADDITIONAL REQUIREMENTS FOR A CLASS II OR III FACILITY: 1) Identification of responsible compounding personnel and/or dispensing pharmacist;2) labels for batch-prepared CSPs must also include: Control or lot number, auxiliary labeling (including precautions); and device-specific instructions. Patient specific medications must also include patient's name, location the medication is to be delivered to and directions for use. [USP 797 Section 13] [F.A.C.64B16-28.108(10)]	N/A
LABELING SOP: SOPs describe labeling procedures and are followed to prevent labeling errors and CSP mix-ups. [USP 797 Section 13] *Per SOP 9.006.1*	Yes
LABEL VERIFICATION: CSP labels are verified to ensure that they conform with the prescription or medication order, MFR (if required), and the CR. [USP 797 Section 13] *Per SOP 9.006.1*	Yes

D. PERSONNEL PREPARATION & OBSERVATION – ALL CATEGORIES

UNNECESSARY ITEMS: Personnel remove outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests); cosmetics, and all hand, wrist, and other exposed jewelry, including piercings that may interfere with effectiveness of garbing. Items not necessary for compounding (e.g., food, drinks, mints, gum, earbuds, headphones) are not introduced into the compounding environment. Accommodations are documented. [USP 797 Section 3.1]	Yes
NAILS: Nails are clean and trimmed. Nail products (e.g., polish, artificial nails, and extenders) are not worn. Personnel clean under nails under warm running water with a disposable nail cleaner. Hands and forearms are washed with soap and water for at least 30 seconds prior to entering a compounding area. [USP 797 Section 3.2]	Yes
REQUIRED PPE GARBING ORDER & STORAGE: Personnel garb (don and doff) in an order that reduces risk of contamination per SOP. Required garb, manner of storage, and order or garbing is documented in SOP's. The minimum required PPE when preparing CSPs includes a garment with sleeves that fit around wrists and enclosed neck, shoe covers, head/facial hair cover, face mask, and sterile powder-free gloves. All PPE is low lint for Category 1 & 2 compounding or sterile if Category 3. Gowns and other garb are stored in a manner that minimizes contamination (e.g., away from sinks) and within a classified area or SCA. [USP 797 Section 3.3]	Yes
INAPPROPRIATE HAND HYGIENE PRACTICES: Brushes and hand dryers are not used, and soap containers are not refilled or topped off. [USP 797 Section 3.2]	Yes
ALCOHOL-BASED HAND RUB: Hands are sanitized with alcohol-based hand rub prior to donning gloves. Handrub is used prior to donning garb when hand hygiene is done outside of a classified area. [USP 797 Section 3.3] *Pharmacy has Alcare and Avagard.*	Yes
STERILE GLOVES USED: Sterile gloves are donned in classified room or SCA. Skin is not exposed inside ISO 5 PEC (e.g., gloves are not donned or doffed). [USP 797 Section 3.3] *Pharmacy uses Contec Critigear sterile nitrile gloves.*	Yes
SANITIZATION OF STERILE GLOVES: Sterile 70% IPA is applied to gloves prior to compounding and regularly throughout the compounding process. [USP 797 Section 3.3]	Yes
SANITIZATION OF ITEMS INTRODUCED INTO PEC: Items are wiped with sterile 70% IPA and sterile low-lint wipers just prior to being introduced into the PEC and allowed to dry before use. [USP 797 Section 8.2] *Contec Sterilesorb wipes used to sanitize items before introducing to the PEC.*	Yes
CRITICAL SITES (e.g., vial stoppers, ampule necks, and intravenous bag septum's) are wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA is allowed to dry before personnel enter or puncture stoppers and septum's or break the necks of ampules. [USP 797 Section 8.3]	Yes
MATERIALS AND EQUIPMENT DISINFECTION: Before any item is introduced into the clean side of anteroom(s), placed into pass-through chamber(s), or brought into the SCA, it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. Dwell time is followed. [USP 797 Section 8.1 & 9.1]	Yes

E. EQUIPMENT, SUPPLIES, & COMPONENTS – ALL CATEGORIES

DAILY ACD ACCURACY ASSESSMENT: An accuracy assessment is conducted for Automated Compounding Devices (ACDs) or similar equipment before the first use and again each day the equipment is used to compound CSPs. A daily record of accuracy measurements is maintained. Corrective actions are implemented if accuracy measurements are outside of manufacturer's specifications. [USP 797 Section 9.1]	Yes
EQUIPMENT SOPs: Written SOPs for the calibration, maintenance, cleaning, and use of equipment are established and are based on the manufacturer's recommendations. Procedures are followed and records are maintained. [USP 797 Section 9.1] *General SOP for equipment SOP calibation and maintenance requirements: 6.004* *Specific SOP's for equipment such as Dry Heat oven and Autoclave are reivewed.* *Repeater pump come calibrated* *3 Incubators calibrated 10/25/24* *pH Meter Internal calibration date 11/20/24* *Dry Heat Oven calibrated 10/25/24* *Autoclave calibrated 10/24/24* *Adventurer Analytical Balance calibrated 10/24/24* *Ohaus Stir/hot plate calibrated 10/21/24* *Temperature/Humidity/Pressure sensors calibrated 11/26/24* *Other equipment PEC's certified 10/24*	Yes

F. SEGREGATED COMPOUNDING AREA: Category 1

CATEGORY 1 MAXIMUM BUDs & COMPOUNDING AREA REQUIREMENTS: Category 1 CSPs are compounded in an ISO class 5 PEC located within a SCA and are assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less when refrigerated. [USP 797 Section 1.5, 4.2.1]	
DEDICATED AREA FOR SCA: The SCA is separated from areas not directly related to compounding, and all surfaces (walls, floors, counters, and equipment) are clean, uncluttered, and dedicated to compounding. [USP 797 Section 4.2.1]	
SCA LOCATION: The SCA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC. SCA is not located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality of the PEC within the SCA. A sink is not located within 1 meter of PEC. [USP 797 Section 4.2.1]	
ITEMS WITHIN SCA: Only furniture, equipment, and other materials necessary for performing compounding activities are located within the SCA. [USP 797 Section 4.2.1]	

G. FACILITIES & SECONDARY ENGINEERING CONTROLS – Categories 2 and 3

STERILE SUITE CONSTRUCTION: The ISO-classified anteroom and buffer room are separated from the surrounding unclassified areas of the facility by fixed walls and doors, and controls are in place. [USP 797 Section 4.2.1] *Cat 2 compounder, with a non-hazardous cleanroom suite, ante room, buffer room and doffing room* **Last certified 10-16-24*	Yes
HEPA FILTERED AIR: Air supplied to the cleanroom suite is introduced through HEPA filters located in the ceiling of the buffer room and anteroom. [USP 797 Section 4.2.1]	Yes
AIR RETURNS: Air returns in the cleanroom suite are low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow. [USP 797 Section 4.2.1]	Yes
LINE OF DEMARCATION: The anteroom has a line of demarcation to separate the clean side from the dirty side. [USP 797 Section 4.2.1]	Yes
SURFACES & WALLS: The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area are smooth, impervious, free from cracks and crevices, and non-shedding. Walls are constructed of/or covered with durable material. [USP 797 Section 4.3.1]	Yes
CEILINGS & FLOORS: Inlaid panels of ceilings are caulked around each panel to seal them to the support frame. Junctures between the ceiling and the walls and between the walls and the floor are sealed to eliminate cracks and crevices where dirt can accumulate. Floors include coving to the sidewall, or the juncture between the floor and the wall are caulked. [USP 797 Section 4.3.1]	Yes
LEDGES & OVERHANGS: Overhangs and ledges are easily cleanable, and the exterior lens surface of ceiling light fixtures are smooth, mounted flush, and sealed. [USP 797 Sections 4.3.1]	Yes
FURNITURE, EQUIPMENT, & MATERIALS: Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. Tacky mats are not placed within ISO-classified areas. Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels. [USP 797 Sections 4.2.1 & 4.5]	Yes
TEMPERATURE & HUMIDITY MONITORING: Temperature and humidity in the cleanroom suite are controlled through a heating, ventilation, and air conditioning (HVAC) system. The temperature and humidity are monitored in each room of the cleanroom suite each day that compounding is performed, either manually or by a continuous recording device. They are documented at least once daily or stored in the continuous recording device and are retrievable and are reviewed as described in the facility's SOP. [USP 797 Section 4.2]	Yes
PRESSURE DIFFERENTIATION MONITORING & DOCUMENTATION: Facility maintains a minimum differential positive pressure of 0.020-inch water column between the nonhazardous buffer room to anteroom and anteroom to unclassified area. A pressure differential monitoring device is used to continuously monitor the pressure differentials. Quantitative results from the pressure monitoring device are reviewed and documented at least daily on the days when compounding is occurring. [USP 797 Sections 4.2.5]	Yes
PEC LOCATION: PECs are located in a buffer room in a manner that minimizes conditions that could increase the risk of microbial contamination (strong air currents, personnel traffic, or air streams from HVAC system(s)) and allows for cleaning around the PEC. [USP 797 Sections 4.2.2 & 4.2.3]	Yes
INTEGRATED VERTICAL LAMINAR FLOW ZONES: IVLFZ is separated from ISO Class 7 area with a physical barrier and there is full coverage of HEPA filters above the work surface. [USP 797 Section 4.2.3]	N/A

H. CERTIFICATION AND RECERTIFICATION – ALL CATEGORIES

PEC & SEC CERTIFICATION: PECs are certified initially and every 6 months to meet ISO Class 5 or better conditions, during dynamic operating conditions. SECs are certified initially and every 6 months to meet ISO Class 7 or 8 or better conditions, during dynamic operating conditions (including presterilization activities if applicable). Anterooms providing access to positive-pressure buffer rooms are at least ISO 8 and at least ISO 7 for anterooms providing access to negative-pressure buffer rooms. ISO Class 7 rooms maintain a minimum of 30 total HEPA-filtered ACPH during dynamic operating conditions, at least 15 ACPH come from the HVAC through HEPA filters located in the ceiling. ISO Class 8 rooms maintain a minimum of 20 total HEPA-filtered ACPH during dynamic operating conditions; 15 ACPH must come from the SEC. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH are documented on the certification report. HEPA filter integrity testing for both SECs & PECs is conducted initially and every 6 months as part of total particle testing. Classified areas are recertified when changes occur that could affect airflow or air quality [USP 797 Sections 4.1, 4.2.4, 4.2.6, & 5.0] *UMT Certification labs ceritifed cleanroom Oct 16, 2024.* *Cat 2 compounder, with a non-hazardous cleanroom suite, ante room, buffer room and doffing room.* *PEC's: Air Clean 600 Work station SN AC648LFC-55687, Purifier Verical Cleanbench SN 240610053 (ISO 5)* *Ante room (ISO 8-ACPH of 50), Buffer room (ISO 7-only total ACPH documented of 79). The certifier has documented how many air changes come from the HVAC 18 versus the PEC 61). Doffing room (ISO 8)*	Yes
DOCUMENTATION OF PERSONNEL PRESENT DURING CERTIFICATION: The number of personnel present in each PEC and SEC during total particle counts and dynamic airflow smoke-pattern tests is documented on the certification report. [USP 797 Section 5.0] *Personnel documented=3 from UMT certification report.*	Yes
PEC DYNAMIC SMOKE PATTERN TEST: Smoke pattern tests are performed under dynamic conditions initially to demonstrate minimal disruption in airflow and repeated if equipment is placed in a different location. Smoke pattern tests are performed under dynamic conditions every 6 months to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s). [USP 797 Section 5.0] *Smoke study repeated with Aire Eze Jan, 6 2025, this had to be repeated after UMT did not complete a dynamic smoke study Oct 2024.*	Yes
ROBOTICS / ROBOTIC ENCLOSURES: Robotic enclosures used as a PEC or placed within a PEC have a dynamic airflow smoke pattern test is performed initially and at least every 6 months that confirms 1) the robotic device is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the DCA(s). [USP 797 Section 4.2.3]	N/A
MONITORING DEVICE CERTIFICATION: Temperature and humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. [USP 797 Section 4.2] *Sensor push real time documentation for temp, humidity and pressure sensors documented calibration date of 11-26-24*	Yes
CONTAINMENT DEVICES USED FOR PRESTERILIZATION PROCEDURES: CVEs, BSCs, or CACIs used for presterilization procedures are certified at least once every 6 months. Presterilization procedures do not adversely affect the required air quality of the SEC as demonstrated during certification under dynamic operating conditions. [USP 797 Section 4.2.6] *Flowsclence CVE certified by UMT Oct 2024*	Yes
CERTIFICATION REPORT REVIEW BY DESIGNATED PERSON: All certification and recertification records are reviewed by the designated person(s). A corrective action plan is implemented and documented in response to any out-of-range results on certification report and data reviewed to confirm that the actions taken have been effective. [UPS 797 Section 5.0] *UMT certification reviewed by Designated person Kaila 11-18-24*	Yes

I. RABS

LOCATION: If used to prepare Category 2 or Category 3 CSP's RABS are located in a cleanroom suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom. [USP 797 Section 4.2.3]	
RECOVERY TIME: When a RABS is used, the recovery time after opening the transfer chamber to achieve ISO Class 5 air is documented and internal procedures are developed to ensure that adequate recovery time is allowed after opening and closing the RABS. [USP 797 Section 4.2.3]	
STERILE GLOVES: are worn over gloves attached to RABS sleeves. [USP 797 Section 3.3]	

J. CATEGORY 2 CSPs WITHOUT STERILITY TESTING

CATEGORY 2 COMPOUNDING ENVIRONMENT: Category 2 CSPs are compounded in an ISO class 5 PEC located within an ISO classified anteroom and buffer room. [USP 797 Sections 4.1 & 14.3]	N/A
CATEGORY 2 BUDs FROM STERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from all sterile starting components and in the absence of sterility testing do not exceed the following BUDs: 4 days room temperature, 10 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3]	N/A
CATEGORY 2 BUDs FROM NONSTERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from one or more nonsterile starting components and in the absence of sterility testing do not exceed the following BUDs: 1 day room temperature, 4 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *per SOP 9.005 'Beyond Use Date' policy.*	N/A

K. CATEGORY 2 EXTENDED BUD REQUIREMENTS

CATEGORY 2 BUDs FOR ASEPTICALLY PROCESSED CSPs WITH STERILITY TESTING: Category 2 CSPs compounded aseptically, and which have passed sterility testing do not exceed the following BUDs: 30 days room temperature, 45 days refrigerated, or 60 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *BUD assigned to Semaglutide 2.5mg/ml Inj solution prepared of 11-20-24 assigned a BUD of 1/4/2025 (45 days refrigerated) per SOP 9.005 on 'Beyond Use Date'*	N/A
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITHOUT STERILITY TESTING: Category 2 CSPs terminally sterilized and in the absence of sterility testing do not exceed the following BUDs: 14 days room temperature, 28 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *Pharmacy is not currently terminally sterilizing CSP's but does intend to send CSP's to an outsourced lab for sterility and endotoxin testing first done for the 11/20/24 Semaglutide Inj*	N/A
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITH STERILITY TESTING: Category 2 CSPs terminally sterilized, and which have passed sterility testing do not exceed the following BUDs: 45 days room temperature, 60 days refrigerated, or 90 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *No Intentions to terminally sterilize.*	N/A
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmics) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1] *Not completed, New business, has not compounded for release of CSP's at this time.*	N/A
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved CSPs), container integrity testing is performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5] *No formulations compounded for release or testing at this time.*	N/A

MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are assigned are prepared as a Category 2 CSP, for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	N/A
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1]	N/A
OUTSOURCED STERILITY TESTING: Sterility testing is performed for all Category 2 CSPs assigned a BUD requiring sterility testing according to USP <71> or a validated alternative and noninferior method. Membrane Filtration as described in USP <71> is the preferred method when the formulation allows. [USP 797 Section 12.2] *Pharmacy has demonstrated that the Semaglutide 2.5mg/ml compounded on 11-20-24 did pass the sterility and endotoxin test sent to ARL, requested by owner as a confirmation of aseptic technique practice.* *Pharmacy submitted 6x2ml vials*	Yes
INHOUSE STERILITY TESTING: Sterility testing is according to USP <71> or a validated alternative and noninferior method. Membrane filtration is used if appropriate and filters are rinsed according to USP <71>. Direct inoculation is done only when membrane filtration cannot be carried out. Volume inoculated does not exceed 10% of the culture media volume. Growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP <71>. TSB or SCD is incubated at 20-25C for 14 days; FTM is incubated at 30-35C for 14 days. (2 incubators present).	N/A
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method. [USP 797 Section 12.2] *Has not been started yet as testing is not initiated on formulations other than sterility and endotoxin testing.*	N/A
MAXIMUM BATCH SIZE: The maximum batch size for all CSPs requiring sterility testing is 250 final yield units. [USP 797 Section 12.2] *Semaglutide 2.5mg/ml Inj solution was compounded 11-20-24 for testing as 2ml vials from 100ml solution (50 vials).*	Yes
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2] *No documented sterility failures at this time.*	N/A
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2] *Has not sent for release, just for testing.* *Sterility testing 9.000.2 articles policy*	N/A
ENDOTOXIN TESTING: Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing are tested for bacterial endotoxins. [USP 797 Section 12.3] *Endotoxin testing confirmed as a pass from ARL for test vials sent of Semaglutide 2.5mg/ml.*	Yes
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	N/A

L. CATEGORY 3 CSPs, BUDs, & RELATED REQUIREMENTS

CATEGORY 3 REQUIREMENTS: All requirements associated with Category 3 compounding (e.g., garbing, cleaning, environmental monitoring) apply to all personnel entering the buffer room where Category 3 CSPs are compounded and always apply regardless of whether Category 3 CSPs are compounded on a given day. [USP 797 Section 14.4.2]	
STERILE/SINGLE USE GARB: When compounding Category 3 CSPs, skin is not exposed in buffer room (i.e., face and neck are covered) and all low lint outer garb is sterile, including sterile sleeves over RABS gauntlet sleeves. Disposable garb items are not reused. [USP 797 Section 3.3]	
STERILIZED/REUSABLE GARB: Non-disposable garb is not reused without being laundered and resterilized with a validated cycle. Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment. [USP 797 Section 3.3]	
CATEGORY 3 BUDs FOR ASEPTICALLY PROCESSED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 60 days room temperature, 90 days refrigerated, or 120 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for aseptically processed CSPs. [USP 797 Section 14.4.3]	
CATEGORY 3 BUDs FOR TERMINALLY STERILIZED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 90 days room temperature, 120 days refrigerated, or 180 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for terminally sterilized CSPs. [USP 797 Section 14.4.3]	
MAXIMUM BATCH SIZE: Category 3 CSP batch sizes do not exceed 250 final yield units. [USP 797 Section 12.2]	
STABILITY INDICATING ASSAYS: All Category 3 CSP formulations are supported by data obtained using a validated stability-indicating analytical method that can distinguish active ingredients from degradants and impurities and quantify the amount of active ingredient. CSPs are prepared according to the exact formulation, components, and packaged in a container closure system of the same materials of composition. Facilities have documentation of the stability study, its results, and the method validation available for review. [USP 797 Section 14.3.3]	
STERILITY TESTING: All category 3 CSPs and batches undergo sterility testing performed according to USP <71> or a validated alternative and noninferior method. [USP 797 Sections 12.2 & 14.4.4]	
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method for each formulation. [USP 797 Section 12.2]	
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	
ENDOTOXIN TESTING: Category 3 injectable CSPs compounded from one or more nonsterile component(s) are tested for bacterial endotoxins. [USP 797 Section 12.3]	
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	

PARTICULATE MATTER TESTING: Category 3 injectable CSPs undergo USP <788> (Particulate Matter in Injections) and ophthalmic solutions undergo USP <789> (Particulate Matter in Ophthalmic Solutions) test once per formulation with acceptable results. [USP 797 Section 14.3.3]	
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmic) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1]	
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved multi-dose CSPs), container closure integrity testing is also performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are prepared for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1]	

M. PERSONNEL TRAINING & COMPETENCIES - ALL CATEGORIES

TRAINING PROGRAM & SOP: Facility maintains a written training program and corresponding SOP which defines required trainings, frequency of training and the process for evaluating the performance of individuals who compound, have direct oversight of compounding personnel, perform in-process checks, final verification and dispensing of CSP's. The training program equips personnel with the appropriate knowledge and training in the required skills necessary to perform their assigned tasks. [USP 797 Section 2] *Per SOP 3.007*	Yes
INITIAL DIDACTIC TRAINING & SKILLS ASSESSMENT: Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel complete training and can demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions. [USP 797 Section 2.1] *Reviewed training documentation for DP (KC), and RPh (BH).*	Yes
INITIAL GLOVED FINGERTIP & HAND HYGIENE/GARBING COMPETENCY: Before beginning to compound independently or have direct oversight of compounding personnel, personnel successfully complete an initial gloved fingertip (GFT) competency no fewer than 3 separate times, with a documented visual audit while performing hand hygiene and garbing procedures. GFT samples are collected before applying sterile 70% IPA to gloves. [USP 797 Section 2.2] *Reviewed training documentation for DP (KC), and RPh (BH) completed on 3/21/25 during inspection.* *- GFT, Media Fill, and Surface sampling redone pursuant to initial inspection.*	Yes
INITIAL MEDIA FILL & ASEPTIC TECHNIQUE ASSESSMENT: Before beginning to compound independently or have direct oversight of compounding personnel, personnel who compound or have direct oversight of compounding successfully complete an initial aseptic manipulation competency evaluation which consists of a visual observation, media-fill testing followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area. [USP 797 Section 2.3] *Reviewed training documentation for DP (KC), and RPh (BH) completed on 3/21/25 during inspection.* *-GFT, Media Fill, and Surface sampling redone pursuant to initial inspection.*	Yes
GFT & MEDIA FILL INCUBATION: Documentation includes the name of the person evaluated, evaluation date and time, media and components used to include their manufacturer or supplier, expiration dates and lot numbers, starting temperature for each interval of incubation, dates of incubation, the results, and the names or other identification of the observer and the person who reads and documents the results. [USP 797 Section 2.3] *Reviewed training documentation for DP (KC), and RPh (BH) completed on 11-4-24 during inspection.*	Yes
ONGOING CATEGORY 1 AND 2- GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency evaluation and GFT every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2]	Yes
ONGOING CATEGORY 1 AND 2- MEDIA FILL & ASSESSMENT: After initial aseptic manipulations competency evaluations, compounding personnel complete aseptic technique competency, media fill, GFTs, and surface sampling of DCA every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete media fill every 12 months. GFTs and surface samples are appropriately incubated. [USP 797 Section 2.3]	Yes
ONGOING KNOWLEDGE & COMPENTENCY OF CORE SKILLS: Training and knowledge assessment of sterile compounding principles or core skills is completed at least every 12 months. [USP 797 Section 2.1] *Per SOP 3.007.*	N/A
FAILED COMPETENCY INVESTIGATION: Initial and ongoing competency assessment failures are investigated, remediated, and documented in a Corrective Action Plan. [USP 797 Sections 2.2 & 2.3] *Per SOP 3.007.*	N/A
STAFF TRAINING IN VIABLE AIR AND SURFACE SAMPLING: Personnel are trained and competent in air and surface sampling procedures to ensure accurate and reproducible sampling. [USP 797 Section 6.1] *Reviewed surface sampling training certificate completed by KC 6/1/24.*	Yes
CLEANING PERSONNEL: Cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures. Cleaning personnel demonstrate knowledge and competency of core skills related to cleaning, disinfection, and maintenance of environmental conditions initially and at least once every 12 months. [USP 797 Sections 7 & 2.1]	Yes

FACILITY COMPOUNDS CATEGORY 3

ONGOING CATEGORY 3 GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency and GFT every 3 months for Category 3 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2]	
ONGOING CATEGORY 3 ASEPTIC PROCESSING COMPETENCY: Aseptic competency is repeated at least one time every 3 months for personnel compounding Category 3 CSPs. The simulation must capture elements that could potentially affect the sterility of the CSP. Immediately following the media-fill test, gloved fingertip and thumb sampling is performed on both hands and surface sampling of the direct compounding area. Direct oversight personnel who do not compound must complete media fill every 12 months. [USP 797 Section 2.3]	

N. MICROBIOLOGICAL AIR AND SURFACE MONITORING: ALL CATEGORIES

ENVIRONMENTAL MONITORING PROGRAM & SOPs: The microbiological air and surface monitoring program is clearly described in the facility's SOPs, which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that trigger corrective action. [USP 797 Section 6] *Initial Viable air sampling done by Aire Eze Scientific Services 1-6-25-completed per map and SOP.*	Yes

VIABLE AIR SAMPLING: Volumetric active air sampling using an impaction air sampler collecting at least 1000L of air is conducted in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions and is completed at least every 6 months. [USP 797 Section 6.2] *Outsource to Pace labs by Aire Eze on 1-6-25.*	Yes
AIR IMPACTION DEVICE: Device is serviced and calibrated according to the manufacturer's recommendations. [USP 797 Section 6.1]	Yes
SURFACE SAMPLING: Microbiological surface sampling is conducted in all classified areas and pass-through chambers under dynamic operating conditions and performed at least once monthly. [USP 797 Section 6.3] *A4 surface sample for the bench is also documented, this pharmacy has no pass-throughs -monthly surface initiated 2-20-25 using TD-100 Cultivate media paddles.*	Yes
GROWTH MEDIA: A general microbiological growth media that supports the growth of bacteria and fungi is used and a COA from the manufacturer is available. Growth media used for surface sampling contains neutralizing agents (e.g., lecithin and polysorbate 80). [USP 797 Sections 6.2 & 6.3]	Yes
MEDIA INCUBATION: Samples are incubated at 30°C - 35°C for 48 hours and 20°C - 25°C for an additional 5 days; if dual growth media are used, incubate one media device at 30°C - 35°C for 48 hours and the second media device at 20°C - 25°C for 5 days. The incubator temperature is monitored during incubation, either manually or by a continuous recording device, and results are reviewed and documented as described in the facility's SOPs. Incubators are placed in a location outside of the sterile compounding area. [USP Sections 6.2.2 (Box 5) & 6.3.2 (Box 6)] *See incubator log for Feb on clipboard.*	Yes
ENVIRONMENTAL MONITORING TREND ANALYSIS: Regular review of sampling data is performed to detect trends and review of trending data is documented. [USP 797 Section 6.1] *New Business.*	N/A
CORRECTIVE ACTION: When microbial growth exceeds action levels, the cause is investigated, and corrective action is taken; corrective actions taken are reviewed for effectiveness. An attempt to identify microorganisms at the genus level is made. [USP Sections 6.2.3 & USP 6.3.3] *No Microbial growth exceeding action levels reported.*	N/A

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-VIABLE AIR SAMPLING: Volumetric air sampling is completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.Air sampling sites are selected in all classified areas. [USP 797 6.2.1]	
CATEGORY 3-SURFACE SAMPLING: Surface sampling for any Category 3 CSPs, is completed in all classified areas, and pass-through chambers connecting to classified areas, prior to assigning a BUD longer than BUD limits for Category 2 CSPs (defined in Table 13 of USP 797) and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. [USP 797 6.2.2]	
CATEGORY 3-BATCH SURFACE SAMPLING: Surface sampling is conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used. When a self-enclosed robotic device is used as the PEC, surface sampling is conducted at least once daily at the end of compounding operations before cleaning and disinfection occurs. [USP 797 Section 6.3.2]	

O. CLEANING AND DISINFECTING: ALL CATEGORIES

CLEANING SOPS: The frequency, method(s), documentation requirements, and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants are described in written SOPs; use of agents is in accordance with manufacturer's instructions, procedures, and in adherence with minimum wet contact times. SOPs describe the time period during which, once opened, sterile cleaning and disinfecting agents, supplies, and sterile 70% IPA may be reused. Sterile water is used to dilute concentrated cleaning agents used inside of PECs (if applicable). Cleaning and disinfecting agents are EPA-registered. If a one-step disinfectant cleaner is not used, surfaces are cleaned prior to being disinfected. [USP 797 Section 7] *SOP 5.001 'Cleaning the Controlled Environment'.* *Cleaning agents names are documented as TB1-3300 or Peridox and Sterile Isopropyl Alcohol.*	Yes
DAILY PEC CLEANING & DISINFECTION WITH STERILE AGENTS: Equipment and all interior surfaces of the PEC are cleaned and disinfected daily on days when compounding occurs and when surface contamination is known or suspected. Sterile 70% IPA is applied after cleaning, disinfecting, or after one-step disinfectant cleaner or sporicidal agent application to remove residue. [USP 797 Section 7] *Reviewed weekly cleaning logs for March and April 2025 during inspection. Pharmacy uses Sterile Peridox and 70% IPA for cleaning.* ** Pharmacy not currently compounding.*	Yes
CATEGORY 1 AND 2-MONTHLY PEC SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, are cleaned with a sporicidal agent monthly. [USP 797 Section 7] *Reviewed monthly cleaning logs for March and April 2025 during inspection. Pharmacy uses Sterile Peridox and 70% IPA for cleaning.*	Yes
DAILY SEC & SCA CLEANING & DISINFECTION: Work surfaces, floors, sink surfaces, and pass-through chambers are cleaned and disinfected daily on days when compounding occurs. [USP 797 Section 7] *Pharmacy not currently compounding. Reviewed weekly and monthly cleaning log during inspection.*	N/A
CATEGORY 1 AND 2 -MONTHLY PEC, SEC & SCA SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings*, walls, doors, and doors frames at least once monthly. SCA ceilings (if applicable) are only cleaned, disinfected, and have sporicidal agents applied when visibly soiled and when surface contamination is known or suspected. [USP 797 Section 7]	Yes
PEC SANITIZATION WITH STERILE 70% IPA: Sterile 70% IPA is applied to the horizontal work surface, including removable trays, immediately before initiating compounding and at least every 30 minutes. If a compounding process takes more than 30 minutes, the work surface is disinfected immediately after the end of the compounding process. Sterile 70% IPA is allowed to dry. [USP 797 Section 7]	Yes
CLEANING SUPPLIES & TOOLS: All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads), except for tool handles and holders, are low lint. Supplies used inside PECs are sterile. [USP 797 Section 7.1.2]	Yes
REUSABLE CLEANING TOOLS: Reusable cleaning tools (e.g., mop frames) are made of cleanable meterials and are cleaned and disinfected before and after each use. Reusable tools are dedicated for use in the classified areas or SCA and are not removed. Mops used in HD compounding areas, are dedicated for use only in those areas. [USP 797 Section 7.1.2] *Contec Easy reach tool posted in PEC.*	Yes

FACILITY COMPOUNDS CATEGORY 3

WEEKLY SPORICIDAL CLEANING OF PECs & SECs: Weekly cleaning using a sporicidal agent is performed on all internal surfaces of PEC and equipment in PEC's, on work surfaces outside the PEC, pass-through chambers, and floors. [USP 797 Section 7]	
MONTHLY SEC SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to storage shelving and bins, equipment outside of PEC's, sink surfaces, ceilings, walls, doors, and doors frames at least once monthly. [USP 797 Section 7]	

P. COMPOUNDING CSPs FROM NONSTERILE COMPONENTS OR SUPPLIES -- CATEGORY 2 & 3

PRESTERILIZATION ACTIVITY CONTAINMENT ENCLOSURES: Pre-sterilization procedures, such as weighing and mixing of nonsterile components, occur in ISO Class 8 or better environment (e.g., anteroom or buffer room) and are performed in single-use containment glove bags, CVEs, BSCs, or CACIs. [USP 797 Section 4.2.6] *ISO 8 ante room has a fume hood where API would be weighed.*	Yes
LOCATION OF STERILE & NONSTERILE PECs: PECs used for sterile and nonsterile compounding (e.g., pre-sterilization procedures) are placed in separate rooms unless the buffer room can maintain an ISO Class 7 classification during particulate generating activities. Co-located PECs are at least 1 meter apart and particle-generating activities are not performed during sterile compounding processes [USP 797 Section 4.2.1; USP 800 Section 5.3] *PEC's located in ISO 7 buffer room 3 feet apart.*	Yes
COMPONENT SOPs: Written SOPs address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components including ingredients and container closures. [USP 797 Section 9.3] *Written SOP lacks details of what to evaluate from COA and document prior to use in compounding. SOP 9.003-2 API Verification form reviewed, please obtain Container closure COA from re-packager.*	Yes
COMPONENT QUALITY & COA: APIs and components comply with the criteria in the USP-NF (if one exists for inactive components) and have a COA including specifications and test results showing the API or component meets expected quality. APIs and other components labeled "not for pharmaceutical use", "not for injectable use", "not for human use", or equivalent are not used in CSPs. [USP 7 Section 9.3.1] *Not currently compounding. Pharmacy had sealed API for Semaglutide bags, opened upon inspector request.*	N/A
API MANUFACTURERS: APIs are manufactured by an FDA-registered facility in the U.S. or comply with the laws and regulations of the applicable regulatory jurisdictions outside of the U.S. [USP 797 Section 9.3.1]	Yes
COMPONENT STORAGE: Components are handled and stored in a manner that prevents contamination, mix-ups, and deterioration and under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers and/or manufacturers. [USP 797 Section 9.3.4]	Yes
STERILE, DEPYROGENATED SUPPLIES: Supplies in direct contact with CSPs are sterile and depyrogenated. A COA or similar conformance documentation is reviewed. [USP 797 Section 9.3.1] *Pharmacy purchases sterile vials from Medisca item #620302-each tub comes packaged in 25.* *Dry heat oven is used to depyrogenate beakers, cylinders*	Yes
COMPONENT RECEIPT: Upon receipt, the external packaging of components is examined and components of unacceptable quality or showing deterioration are promptly labeled as rejected and segregated from active stock. APIs and components are inspected for a visible manufacturer expiration date. Components lacking expiration dates are assigned an expiration date no more than 1 year after receipt and both the date of receipt and facility assigned expiration date is clearly marked on the component packaging. [USP 797 Section 9.3.2] *Per SOP 9.002.*	N/A
STERILIZATION OF INJECTABLES WITHIN 6 HOURS OF COMPLETION: Injectable CSPs containing nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during compounding are sterilized within 6 hours of completion. [USP 797 Section 10] *The template of CR has a field for documentation of time compounding started and time ended* *Has not compounded for release.*	N/A

Q. STERILIZATION OF CSPs - CATEGORY 2 & 3

STERILIZING FILTERS: Sterilizing filters used are sterile, depyrogenated, have a nominal pore size of 0.22 µm or smaller, and are appropriate for pharmaceutical use. Sterilizing filters are certified by the manufacturer to retain at least 10,000,000 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area. Filters are chemically and physically compatible with all ingredients in the CSP (e.g., water-miscible alcohols may damage filter integrity); chemically stable at the pressure and temperature conditions that will be used; and have enough capacity to filter the required volumes. [USP 797 Section 10.2] *Pharmacy uses St Gobain 0.2 micron filters*	Yes
BUBBLE POINT TESTING: Sterilizing filters are subjected to the manufacturers' recommended integrity testing, such as a post-use bubble point test. If multiple filters are required for the compounding process, each of the filters passes a filter-integrity test. [USP 797 Section 10.2] For failed BP testing, CSP is discarded or, after investigating, refiltered not more than one time. [USP 797 Section 10.2] *Pharmacy uses 0.2 micron and 0.22-micron filters.* *- Observed demo of both filters during inspection.*	Yes
CSP PREFILTRATION: When CSPs are known to contain excessive particulate matter, prefiltration is performed using a filter of larger nominal pore size (e.g., 1.2 µm) or a separate filter of larger nominal pore size placed upstream of (i.e., prior to) the sterilizing filter. [USP 797 Section 10.2]	N/A
CSP TERMINAL STERILIZATION SOP Includes: 1) A description of CSP terminal sterilization process(es), including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization methods and equipment. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. [USP 797 Section 10]	N/A
STEAM OR DRY HEAT STERILIZATION CYCLES FOR CSPs: Sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of the CSP to reach and remain at the sterilizing temperature during the duration of the sterilization period. CSPs sterilized vial steam are placed in the autoclave to allow steam to reach CSPs without entrapment of air. CSPs sterilized via dry heat are placed with sufficient space between materials to allow for hot air circulation. Sterilization cycle parameters (e.g., temperature, pressure, and duration) and load configuration(s) are documented. [USP 797 Section 10.3 & 10.4]	N/A
BIOLOGICAL INDICATOR USE: The effectiveness of steam or dry heat sterilization of CSPs is verified and documented for each sterilization run or load by using appropriate biological indicators (e.g., Geobacillus stearothermophilus for steam, Bacillus atrophaeus for dry heat) and other confirmation methods. [USP 797 Section 10.3]	N/A
STEAM & DRY HEAT CSP PREFILTRATION: Immediately before filling containers that will be sterilized via steam, or dry heat, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.3]	N/A
CALIBRATED DATA RECORDER: A calibrated data recorder or chart is used to monitor each steam or dry heat sterilization cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure). The calibrated oven is equipped with temperature controls and a timer. [USP 797 Section 10.3 & 10.4]	N/A

R. STERILIZATION & DEPYROGENATION OF SUPPLIES & CONTAINER CLOSURE SYSTEMS - CATEGORY 2 & 3

STERILIZATION & DEPYROGENATION SOP's include: 1) A description of sterilization and depyrogenation process(es) used to sterilize and/or depyrogenated compounding supplies and container closure systems, including the temperature, duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. [USP 797 Section 10] *Load pattern configuration was fixed during the inspection. Pharmacy completed training on 3-6-25.*	Yes
DEPYROGENATION VIA DRY HEAT: Dry heat depyrogenation is used to render glassware, metal, and other thermostable containers and components pyrogen free. The exposure period includes sufficient time for items to reach the depyrogenation temperature; items remain at the depyrogenation temperature for the duration of the depyrogenation period. [USP 797 Section 10.1 & USP 1228.4] *URL Calibration*	Yes

DEPYROGENERATION VIA RINSING: Non-thermostable items are sterilized via a validated sterilization method and cycle: these items are also depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., Sterile Water for Injection or Sterile Water for Irrigation) and then thoroughly drained or dried immediately before use in compounding. [USP 797 Section 10 & 10.1]	N/A
DEPYROGENATION PROCESS VALIDATION: The effectiveness of the dry heat depyrogenation cycle(s) is established initially and verified annually using Endotoxin Challenge Vials (ECVs) to demonstrate the cycle achieves a greater than or equal to 3-log endotoxin reduction. The effectiveness of the depyrogenation cycle is re-established if there are changes to the cycle parameters . Cycle verifications are documented. [USP 797 Section 10.1] *Per ARL labs accomplished a 3 log reduction using Lonza ECV's.*	Yes
STERILIZATION CYCLE VALIDATION: When performed onsite, the efficacy of sterilization cycles used for supplies or container closure systems are established and documented. Each sterilization run or load is verified and documented by using appropriate biological indicators (e.g., spores of Geobacillus stearothermophilus) and other confirmation methods. [USP 797 Section 9.3.1 & USP 1229] *Pharmacy completed sterilization cycle validation using biological indicators.* **Reviewed documentation cycles completed in March and April 2025.*	Yes

S. MASTER FORMULATION AND COMPOUNDING RECORDS – ALL CATEGORIES

MASTER FORMULATION RECORD (MFR): A MFR is created for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more than one patient and any changes or alterations to an MFR are approved and documented per facility's SOPs. [USP 797 Section 11.1] *Reviewed sample MFR for Semaglutide/Cyanocobalamin 2.5mg/1mg/ml during inspection.*	Yes
MFR DOCUMENTATION: An MFR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Identities, amounts of all ingredients, and, if applicable, relevant characteristics of components; 3) Type and size of container closure system(s); 4) Complete instructions for preparing the CSP including equipment, supplies, a description of the compounding steps, and any special precautions; 5) Physical description of the of the final CSP; 6) BUD and storage requirements; 6) Stability reference; 7) Quality control procedures; 8) other information as needed to describe the compounding process and ensure repeatability. [USP 797 Section 11.1 (Box 9)] *Please update MFR to include additional references to support the formulation stability.*	Yes
COMPOUNDING RECORD (CR): A CR is created for all Category 1, Category 2, and Category 3 CSPs. A CR is created for immediate-use CSPs prepared for more than one patient. A CR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Date and time of preparation of the CSP; 3) Assigned internal identification number (e.g., prescription, order, or lot number); 4) A method to identify the individuals involved in the compounding process and individuals verifying the final CSP; 5) Name of each component; 6) Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s); 7) Weight or volume of each component; 8) Strength or activity of each component; 9) Total quantity compounded; 10) Final yield; 11) Assigned BUD and storage requirements; 12) Results of QC procedures. And, if applicable, 13) MFR reference for the CSP; and 14) Calculations made to determine and verify quantities and/or concentrations of components. [USP 797 Section 11.2] *Reviewed updated CR which was completed pursuant to initial inspection.* **Pharmacy not currently compounding.*	Yes
STERILIZATION CYCLE DOCUMENTATION: The date, run, and load numbers of the steam or dry heat sterilizer used to sterilize a CSP are documented on the CR if applicable. [USP 797 Sections 10.3 & 10.4] *Reviewed MFR with sterilization cycle documentation, during inspection.* **Pharmacy not currently compounding.*	N/A

T. RELEASE INSPECTION AND TESTING – ALL CATEGORIES

RELEASE TESTING PROCEDURES: All release testing procedures (e.g., visual inspections and testing) are included in facility documentation such as MFRs and SOPs. [USP 797 Section 12] *Per SOP 9.000.2*	Yes
VISUAL INSPECTION: CSPs are visually inspected before release and dispensing to determine whether the 1) physical appearance of the CSP is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects), 2) container closure integrity is intact (e.g., checking for leakage, cracks in the container, or improper seals), 3) CSP and its labeling match the prescription or medication order. [USP 797 Section 12.1] *Per SOP 9.015.* *- Reviewed 'Sample Compounding Worksheet or batch Record Form' [SOP 9.001.2] during inspection, where Visual inspection will be noted.*	Yes
DELAYED DISPENSING VISUAL INSPECTION: When CSPs are not released or dispensed on the day of preparation, a visual inspection is conducted immediately before its release to ensure the CSP is free from any defects such as precipitation, cloudiness, or leakage, which could develop during storage. [USP 797 Section 12.1] *Per policy 9.030 - However, pharmacy not currently dispensing CSP.*	Yes
CSP REJECTION & QUARANTINE: CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock. [USP 797 Section 12.1] *Per SOP 9.026.*	Yes
INVESTIGATION OF OOS RESULTS: Out-of-specifications results and defects indicating sterility or stability problems are investigated to determine the root cause and a corrective action plan is implemented and documented per facility SOPs. [USP 797 Section 12 & 12.1]	No

U. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, & TRANSPORT – ALL CATEGORIES

STORAGE AREA TEMPERATURE MONITORING: Temperature in CSP & component storage areas is monitored at least once daily and recorded on a log on days when the facility is open or by a continuous temperature recording device; temperature data is readily retrievable. Monitoring equipment is calibrated or verified for accuracy as recommended by the manufacturer or every 12 months. When CSPs have been exposed to temperature excursions above or below storage temperature limits for the CSP, a Designated Person determines whether the CSP has retained its integrity or quality. [USP 797 Sections 9.3 & 19.1] *temperature sensors, humidity and pressure sensors calibrated 11-26-24.*	Yes
CSP PACKAGING: CSP packaging and shipping materials are selected to protect CSPs from damage, leakage, contamination, degradation, adsorption and prevent inadvertent exposure to transport personnel. [USP 797 Section 19.2] *Per SOP 11.000.*	Yes
SHIPPING & TRANSPORTING: Modes of transport are selected that are expected to deliver properly packaged CSPs in an undamaged, sterile, and stable condition. Special handing instructions are provided and/or affixed to the exterior of the container when applicable. [USP 797 Section 19.2] *Per SOP 11.000.*	Yes

V. STERILE QUALITY PROGRAM, SOP's & DOCUMENTATION- ALL CATEGORIES

QA/QC PROGRAM & SOPs: A Quality Assurance (QA) and Quality Control (QC) program is documented in facility SOPs and formally establishes a system of 1) adherence to procedures, 2) prevention and detection of errors and other quality problems, 3) evaluation of complaints and adverse events, and 4) appropriate investigations and corrective actions. The QA/QC SOPs describe the roles, duties, and training of personnel responsible for each aspect of the QA program. [USP 797 Section 18] *SOP 9.003.1 'Finished Product Sample Testing Form' - Has the requirement for a lot#. However, the Semaglutide 2.5mg/ml Inj solution prepared on 11-20-24 CR did not contain a lot#. Further review of the ARL COA does describe the Lot# of 11202024@2. Firm states this CSP was sent for testing using 2 different vial types to determine sterility and endotoxin testing*	Yes

INVESTIGATIONS & CAPAs: A designated person(s) follows up to ensure investigations are conducted and corrective actions are taken if problems, deviations, failures, or errors are identified or when complaints or adverse reactions are reported. A complete record of each reported complaint and adverse reaction is created and retained. Investigations and corrective actions are documented. [USP 797 Sections 17, 18.2, & 18.3] *Pharmacy completed CAP on Potency failure reported on 11-25-24, for Semaglutide 2.5mg inj. lot11202024, which resulted in a potency of 89.6%.* *- Route Cause identified omission in assay calculation of Semaglutide API.*	Yes
ADR & COMPLAINT DOCUMENTATION: A complete record of each reported complaint and adverse reaction is created and retained per USP 797. [USP 797 Section 18.1] *New business, no injectables compounded for release as determined in Best Rx software.*	N/A
RECALL PROCEDURES & SOP: If CSPs are dispensed or administered before the results of release testing are known, procedures are in place to immediately notify the prescriber of a failure of specifications with a potential to cause patients harm; determine the severity of the problem and urgency for implementation/completion of recall; identify patients (or other points of distribution) who have received affected CSP; recall any unused dispensed CSPs; quarantine remaining stock in the pharmacy; investigate if other lots are affected and recalled if needed; conduct investigation and document reason for the failure. Recalls are reported to the appropriate regulatory body as required by the laws and regulations of the applicable regulatory jurisdiction. [USP 797 Section 18] *Per SOP10.002.*	Yes
ANNUAL SOP & QA/QC COMPLIANCE REVIEW: Facility sterile compounding SOPs are reviewed every 12 months by the Designated Person(s); the review is documented. Changes to SOP are made only by the Designated Person and documented. Acknowledgement of revisions to SOP's are communicated to all personnel. The overall QA/QC Program is reviewed at least once every 12 months by the Designated Person(s); the review is documented, and corrective actions are taken if needed. [USP 797 Section 17 & 18] *New Permit - SOPs created 5/31/24.*	Yes

W. HAZARDOUS DRUG HANDLING & COMPOUNDING – ALL CATEGORIES

DESIGNATED PERSON: The entity has a Designated Person who is qualified and trained to be responsible for implementing appropriate HD procedures, overseeing compliance with USP 800 requirements, ensuring environmental control of the storage and compounding areas, monitoring HD facility operations, testing, and acting on results. [USP 800 Section 4]	
HAZARD COMMUNICATION PROGRAM (HCP): Facility has SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of HDs and use of Safety Data Sheets. The HCP and HD SOPs include a written plan describing 1) how USP 800 requirements are implemented, 2) HD chemical container labeling with the identity of the material and appropriate hazard warnings, 3) readily accessible location of HD chemical SDSs known and accessible by all personnel, 4) HD risk training and information provided to all personnel with HD exposure risk before initial HD handling work assignment and whenever hazard changes, 5) personnel of reproductive capability written acknowledgement of understanding of HD handling risks. [USP 800 Section 8]	
LIST OF HAZARDOUS DRUGS & ASSESSMENT OF RISK: Facility maintains a list of HDs that includes any items on the current NIOSH that the entity handles. The list is reviewed every 12 months and whenever a new agent or dosage form is used. All HD drugs follow the requirements of USP 800 unless an assessment of risk (AOR) is performed. If an assessment of risk approach is taken, the entity must documents what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. The AOR minimally contains the type of HD, dosage form, risk of exposure, packaging, and manipulation considerations. The HD drug list & AOR is reviewed at least every 12 months and whenever a new agent or dosage form is used. [USP 800 Section 2]	
CONTAINMENT REQUIREMENTS: All antineoplastic HDs requiring manipulation and HD active pharmaceutical ingredients (APIs) on the NIOSH list follow all the requirements of USP 800. [USP 800 Section 2, Box 1]	
HD HANDLING, RECEIPT & STORAGE SOPs: SOPs are created and followed for the safe handling of HDs used by the facility. [USP 800 Section 17]	
HD HANDLING AREAS, SIGNAGE, & ACCESS: Signage designating HD handling areas are prominently displayed and access to HD handling areas is restricted to authorized personnel. Designated areas are available for receipt, unpacking, storage, and sterile compounding of HDs. [USP 800 Section 5]	
HD STORAGE: HDs are stored to prevent spillage or breakage, off floors, and in areas appropriate for natural disasters. Antineoplastic HDs and HD API are stored separately from non-HDs to prevent contamination and personnel exposure. HD storage areas are externally ventilated and negative-pressure rooms with at least 12 ACPH. Refrigerated antineoplastic HDs are stored in a dedicated refrigerator, in a negative pressure area with at least 12 ACPH. Pass through refrigerators are not used. [USP 800 Section 5.2]	
STERILE HDs COMPOUNDED IN A C-SCA: C-SCA maintains a minimum of 12 ACPH of HEPA- filtered air and has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800, sections 5.3.2 Table 3]	
C-SEC DESIGN AND ENGINEERING CONTROLS: The C-SEC has fixed walls physically separated from other preparation areas, is externally ventilated has 30 ACPH, and negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800 Section 5.3.2 Table 3]	
C-SEC ACCESS: The Ante Room used for entry into the negative pressure buffer room has fixed walls and maintains a minimum of 30 ACPH of HEPA-filtered air, positive pressure of +0.02" w.c. to all adjacent unclassified areas, and ISO7 or better classification. Alternatively, a negative-pressure HD buffer entered exclusively through a positive pressure non-HD buffer room contains a line of demarcation (LOD) within the negative-pressure buffer room for donning/doffing HD PPE and a method a transport of HDs, HD CSPs, and HD waste into and out of the HD buffer (e.g., pass-through chamber). Pass through chambers are included in semi-annual facility certification. [USP 800 Section 5.3.2]	
C-SEC SINK & SAFETY EQUIPMENT: A sink is available for hand washing and an eyewash station and/or other emergency safety precautions meeting applicable laws and regulations are readily available and located where operation does not interfere with ISO classifications. Sinks are located at least 1 meter from the entrance into the buffer room (or at least 1 meter from the C-PEC in a C-SCA). [USP 800 Sections 5.3 & 5.3.2]	
C-PEC LOCATION, VENTING, & OPERATION: All C-PECs used for sterile HD compounding (e.g., CACIs or BSCs), are located within a C-SEC or C-SCA, externally vented, and maintain an ISO 5 or better air quality. C-PECs operate continuously if supplying some or all the negative pressure in the C-SEC or if used for sterile compounding. During power outages, repairs, or relocation, C-PEC use is suspended immediately. Once C-PEC power is restored, all PEC surfaces are decontaminated, cleaned, and disinfected, and compounding is not resumed until the manufacturer's specified recovery time has elapsed. [USP 800 Section 5.3.2]	
REQUIRED HD PPE: When compounding HDs, gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are donned per facility SOPs. Chemotherapy gloves are tested to ASTM standard D6978 (or its successor) and are powder free and two pair of chemotherapy gloves are donned per SOP. Gloves are inspected for physical defects. Gloves are changed when torn, punctured, or contaminated. Personnel wash hands with soap and water after removing gloves. HD gowns are disposable, resistant to permeability by HDs, close in back, are long sleeved, closed cuff, and seamless. Gowns are changed per manufacturer's permeation information; if no data is available, HD gowns are change every 2-3 hours or immediately after a spill or splash. Gowns are limited to HD handling areas and are donned over the sterile compounding garment. When compounding, a second pair of shoe covers is donned before entering the C-SEC and doffed when exiting the C-SEC. HD PPE is disposed of appropriately prior to exiting the C-SEC. Chemotherapy gloves and sleeve covers (if used during compounding) are carefully removed and discarded immediately into an appropriate waste container inside of the C-PEC or contained in a sealable bag for discarding outside of the C-PEC. Reusable PPE is decontaminated and cleaned after each use. [USP 800 Section 7]	
EYE AND FACE PROTECTION: Appropriate eye (goggles) and face protection (face shield) are worn when there is a risk for spills or splashes or when working outside of a C-PEC. Surgical masks are not used when respiratory protection is required per SOP and/or AOR as protection from HD exposure. [USP 800 Section 7.4]	

HD TRAINING & COMPETENCY ASSESSMENT: Personnel who handle HDs are trained and demonstrate competency initially before independently handling HDs, annually, and when a new HD medication, process, SOP, or equipment is introduced. Training minimally includes an overview of the entity's HD list and their risks; review of HD SOPs; proper use of PPE, equipment, and devices; prevention of HD exposures and spills; HD exposure and spill response; use of a spill kit, PPE, and NIOSH-certified respirators; and HD disposal. Based on job duties, personnel receive additional HD training in HD acquisition and receipt, preparation, compounding, dispensing, labeling, storage, and transport. Training and competency assessments are documented. [USP 800 Sections 8, 9, 11.1, 16, & 17]	
HD ATTESTATION: Personnel of reproductive capability have a written acknowledgement attesting to their understanding of HD handling risks. [USP 800 Section 8]	
DEDICATED HD EQUIPMENT: Disposable or cleanable equipment for compounding (e.g., mortar and pestle, graduated cylinder, spatulas) is dedicated for use with HDs. [USP 800 Section 13]	
NON-HD COMPOUNDING IN A C-PEC: Non-HDs compounded in a HD C-PEC are placed in protective outer wrapping, labeled for PPE handling precautions, and treated as an HD. The C-PEC worksurface is decontaminated between compounding of different HDs. [USP 800 Section 5.3.2 and Table 3]	
DEACTIVATION, DECONTAMINATION, CLEANING & DISINFECTION (D/D/C/D): Areas where HDs are handled and all reusable equipment and devices are deactivated/decontaminated, and cleaned. Sterile compounding areas and devices are subsequently disinfected. Written procedures for decontamination, deactivation, cleaning, and disinfection are available and followed. Procedures include agents used, dilutions (if used), frequency, and documentation requirements. Agents selected are appropriate for the type of HD contamination(s), location, and surface materials. Sterile 70% IPA is used to remove residue left on sterile surfaces and compounding areas by decontaminating agents. [USP 800 Section 15]	
D/D/C/D TRAINING & PPE REQUIREMENTS: Personnel are trained in deactivation/decontamination, cleaning, and disinfection to protect themselves and the environment from contamination. Personnel wear appropriate PPE resistant to cleaning agents used, including 2 pairs of ASTM-tested chemotherapy gloves and impermeable disposable gowns. Eye protection and face shields are worn if splashing may occur. [USP 800 Section 15]	
C-PEC D/D/C/D: C-PEC is decontaminated at least daily (when used), after as spill, before and after certification, voluntary interruption, or if ventilation tool is removed. The C-PEC worksurface is decontaminated between compounding of different HDs. The area under the work tray of a C-PEC is deactivated, decontaminated, and cleaned at least monthly. [USP 800 Section 15.2]	
HD LABELING, PACKAGING, TRANSPORT & SPILLS HANDLING: Facility follows SOP for the labeling, handling, packaging, and transport of HDs which addresses the prevention of spills/exposures, training for exposure, and spill handling. HD CSPs are identified as hazardous and labeled with special handling precautions. Labeling process for compounded HD products does not introduce contaminated materials into non-HD areas. [USP 800 Section 11 & 11.2]	
SPILL KITS, & SINGAGE: Spill kits are readily available with appropriate supplies, PPE, and signs to restrict access to affected areas. restriction posted, and documentation of spills occur when needed. [USP 800 Section 16]	

X. LYOPHILIZATION

Sterile preparations prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling, and transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	
A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times. [64B16-27.797(5) F.A.C.]	
The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.]	
The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.]	
Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]	
The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.]	
SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.]	
The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.]	
Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.]	
Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin. [64B16- 27.797(5) F.A.C.]	
Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product. [64B16- 27.797(5) F.A.C.]	
A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.]	
Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.]	
Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record. [64B16-27.797(5) F.A.C.]	
Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.]	

Potency, radiochemical purity, or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight-based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.]	

Y. SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

Technicians properly identified. [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16- 27.420 F.A.C.].	
Medication is properly labeled for dispensing to patient. [64B16-28.108(2) F.A.C.]	
Outdated medications removed from active stock. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality Related Events are available for inspection. [64B 16 27.300 F.A.C.]; [766.101 (1) (a)(l) F.S.]	
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	
Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] [21CFR1304.04]	
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) F.A.C]	
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]	
A special sterile products and parenteral/enteral compounding pharmacy provides telephone accessibility to its pharmacist(s) for its patients at all hours. [64B16-28.820(3)(b)]	
A special sterile products and parenteral/enteral compounding pharmacy provides special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. [64B16-28.820(3)(b)]	

Z. Miscellaneous

BLOOD-DERIVED OR BIOLOGICAL MATERIAL MANIPULATIONS: Compounding activities that require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum), are clearly separated from other compounding activities and equipment used in CSP preparation activities and controlled by specific SOPs to avoid cross-contamination. [USP 797 Section 1.1.2]	
ALLERGENIC EXTRACTS: Licensed allergenic extracts are mixed and diluted to prepare prescription sets for administration to patients. A prescriptions set is a vial or set or vials of premixed licensed allergenic extracts for subcutaneous immunotherapy that have been diluted with an appropriate diluent for an individual patient. Compounding allergenic extracts 1) minimally complies with all aspects of USP <797> Section 21; 2) involves transfer via sterile needles and syringes of conventionally manufactured sterile allergen products and appropriate conventionally manufactured sterile added substances; and 3) manipulations are limited to penetrating stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile vials. If these conditions are not met, compounding of allergenic extracts follows all aspects of USP <797>. [USP 797 Sections 1.1.2 and 21]	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

MURRAY, CHARLENE

Date:4/14/2025

Representative:

Kaila Charran

Date:4/14/2025

AC# 11906796

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
05/10/2025	PH 35751	155514

THE PHARMACY

QUALIFICATION(S):
Special Sterile Compounding

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

Expiration Date: **FEBRUARY 28, 2027**
BLUE STONE 4 PHARMACY, LLC
Green Stone Rx
861 SW 8TH ST
#101
MIAMI, FL - 33130

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
State Surgeon General

DISPLAY IF REQUIRED BY LAW

QUALIFICATION(S):
Special Sterile Compounding

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

AC# 11906796

DATE	LICENSE NO.	CONTROL NO.
05/10/2025	PH 35751	155514

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

Expiration Date : **FEBRUARY 28, 2027**
BLUE STONE 4 PHARMACY, LLC
Green Stone Rx

REGISTRANT SIGNATURE

Your license number is PH 35351.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
OCTOBER 15, 2024	**PH 35351**	**143654**

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Schedule II & III
Community Pharmacy

EXPIRATION DATE: **FEBRUARY 28, 2027**

BLUE STONE 4 PHARMACY, LLC
Blue Stone 4 Pharmacy
861 SW 8TH ST
#101
MIAMI, FL - 33130

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
OCTOBER 15, 2024	**PH 35351**	**143654**

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

BLUE STONE 4
PHARMACY, LLC
Blue Stone 4 Pharmacy

Expiration Date: **FEBRUARY 28, 2027**

REGISTRANT SIGNATURE

Department of Health

BLUE STONE 4 PHARMACY, LLC

Green Stone Rx

License Number: PH35751

Data As Of 1/22/2026

Profession	Pharmacy
License	PH35751
License Status	Clear/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2027
License Original Issue Date	05/09/2025
Address of Record	861 SW 8th st #101 MIAMI, FL 33130
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date

BLUE STONE 4 PHARMACY, LLC

Green Stone Rx

License Number: PH35351

Data As Of 11/21/2025

Profession	Pharmacy
License	PH35351
License Status	Clear/
Qualifications	Community Pharmacy Schedule II & III
License Expiration Date	2/28/2027
License Original Issue Date	10/14/2024
Address of Record	861 SW 8TH ST #101 MIAMI, FL 33130
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

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Subordinate Practitioners

Name	Relationship	Profession	License	Effective Date
BLUE STONE 4 PHARMACY, LLC	STERILE COMPOUNDING	PHARMACY	35751	12/13/2024

Click on the License Number to view License Details for that Practitioner

BLUE STONE 4 PHARMACY, LLC

Green Stone Rx

License Number: PH35751

Data As Of 11/21/2025

Profession	Pharmacy
License	PH35751
License Status	Clear/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2027
License Original Issue Date	05/09/2025
Address of Record	861 SW 8th st #101 MIAMI, FL 33130
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

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Tallahassee, FL 32399-3251

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1. Full name and license number of the practitioner;
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Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
BLUE STONE 4 PHARMACY, LLC	PHARMACY	PHARMACY	35351	12/13/2024
CHARRAN, KAILA MARITZA	RX DPT MGR/COR/POR	PHARMACIST	38702	08/09/2024
VILAR, ROSSANA R	PHARMACY AFFILIATE	PHARMACY AFFILIATE		08/09/2024

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Blue Stone 4 Pharmacy LLC dba Green Stone RX

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 861 SW 8 St Suite #101

City: Miami State: FL Zip: 33130

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 707-240-5096 Website: greenstonerx.com

Licensing Company Email: pharmacylicenses@greenstonerx.com

Section 2: Personal Information

First: Rossana Middle: Last: Villar

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Westminster Christian			8/84 - 5/1989	
Address	City		State	Zip
6855 SW 152 ST	Miami		FL	33157
Diploma/Degree obtained, if any				
High School Degree				

School Name			From - To (MM/YY – MM/YY)	
University of Miami			8/1989 - 12/1992	
Address	City		State	Zip
1320 S Dixie Hwy	Coral Gables		FL	33146
Diploma/Degree obtained, if any				
Bachelors degree in Business				

School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/1994 - present	[redacted]			
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Join Rose			From - To (MM/YY – MM/YY): 12/2025
Business Address: 859 SW 8 ST	City: Miami	State: FL	Zip: 33130
Phone: 305-992-6191	Title: Managing Member		
Description of Duties: overall front office management			

Business Name: MD Topical			From - To (MM/YY – MM/YY): 10/2013 - 11/2019
Business Address: 11767 South Dixie Hwy	City: Miami	State: FL	Zip: 33156
Phone: 305-992-6191	Title: Managing Member		
Description of Duties: day to day accounting + operations			

Business Name: Kabs of Brandon			From - To (MM/YY – MM/YY): 10/2017 - 12/2019
Business Address: 759 West Brandon Blvd	City: Brandon	State: FL	Zip: 33511
Phone: 305-992-6191	Title: Owner		
Description of Duties: Day to Day accounting & operations			

Business Name: Gentech Pharmacy			From - To (MM/YY – MM/YY): 9/2023 - 2/2025
Business Address: 620 East Lamar Street	City: Royse City	State: TX	Zip: 75189
Phone: 305-992-6191	Title: Owner		
Description of Duties: Account Management - Operations + accounting			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rossana Villar

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/1/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Miami-Dade

I, Rossana Vilar, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/1/2025

Date

Subscribed and Sworn to before me this 1st day of December 2025

NICOLAS LOPEZ
Notary Public, State of Florida
Commission No. HH 520566
My Comm. Exp. Apr. 24, 2028

Notary Public Signature

(Seal)

4PP

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 04487	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: DM Clinical Collaborations dba InfuCare Rx of CA

Physical Address: 6108 SAN FERNANDO RD

City: Glendale State: CA Zip: 91201

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-469-6053 Toll Free # (NAC 639.708, NRS 639.23286): 877-469-6053

Fax: 877-469-6052 Contact Email: Licensing@infucarerx.com

Website: www.infucarerx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Dulari Patel

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22605

Document Ref: KIBK8-SHAAH-53VH6-TBRWW

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Dulari Patel	NV Pharmacist Registration #: 22605
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: CA

Parent Company (if any): InfuCare Rx, Inc.

Corporation/Organization Name: DM Clinical Collaborations dba InfuCare Rx of CA

Mailing Address: 6108 SAN FERNANDO RD

City: GLENDALE State: CA Zip: 91201

Telephone: 877-828-3940 Email: Licensing@infucarerx.com

Contact Person Name: Jessica Seefried

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Corporate Secretary and General Counsel (title) for DM Clinical Collaborations dba InfuCare Rx of CA (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Tiffany Scheppers

Print Name of Authorized Person

Tiffany Scheppers, Corporate Secretary

Original signature of Authorized Person (copies or stamps not accepted)

11 / 11 / 2025

Date

Document Ref: KIBK8-SHAAH-53VH6-TBRWW

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tiffany Scheppers

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Tiffany Scheppers, Corporate Secretary

Original signature of Authorized Person (copies or stamps not accepted)

11 / 11 / 2025

Date

Board Use Only	Date Received: 12/8/25	Amount: $500 CK 1000002407

Corporate Officers			
Name	**Title**	**Address**	**Phone**
Dhara Patel	President, Director, and Treasurer	695 US Hwy 46, STE 100, Fairfield, NJ 07004	877-828-3940
Tiffany Scheppers	Secretary and General Counsel	695 US Hwy 46, STE 100, Fairfield, NJ 07004	877-828-3940

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	DM CLINICAL COLLABORATIONS
Entity No.:	3345859
Registration Date:	12/30/2010
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of October 17, 2025.

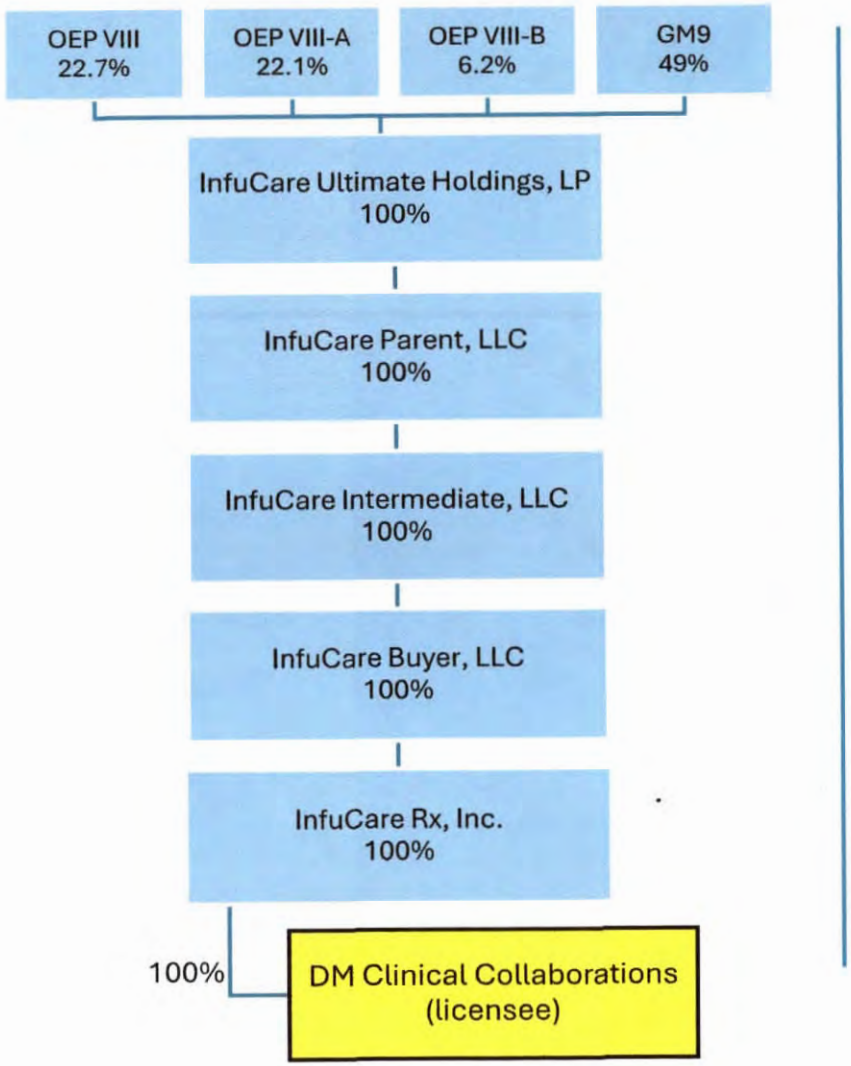
SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 379175734

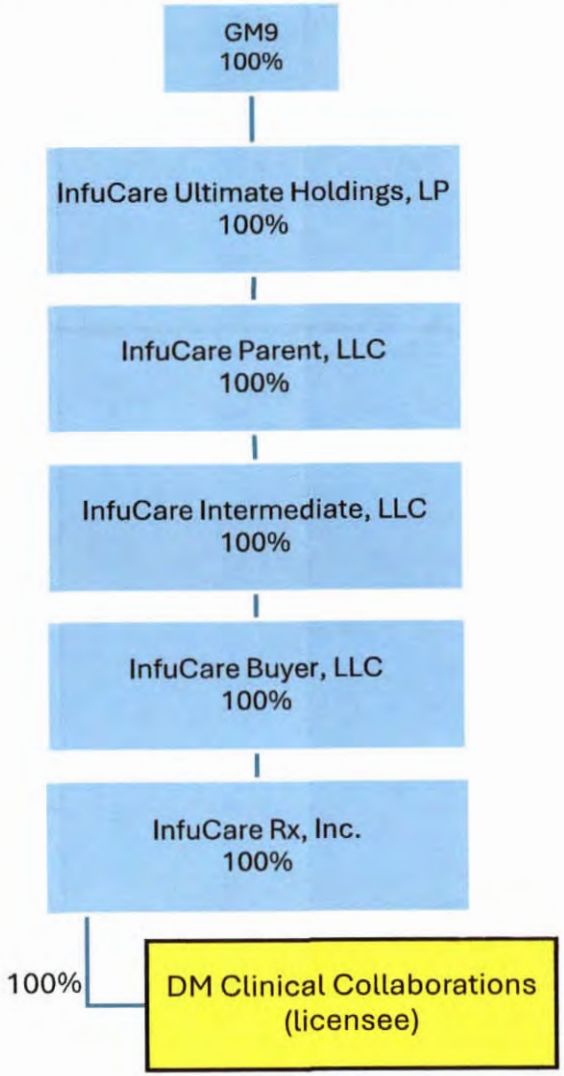
To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

Pre- and Post- Sale for DM Clinical Collaborations

Pre-Close Structure



Post-Close Structure



DM Clinical Collaborations DBA InfuCare Rx 6108 San Fernando Rd, Glendale, CA, 91201 List of Shareholders			
Name	**Address**	**Phone**	**Percent Ownership**
InfuCare Rx, Inc.	695 US Highway 46, Suite 100, Fairfield, NJ 07004	877-828-3940	100%

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler DM Clinical Collaborations dba InfuCare Rx of CA

Pharmacy/Wholesaler License # (if applicable) PH04487

Physical Address 6108 SAN FERNANDO RD

City GLENDALE State CA Zip 91201

Mailing Address (if different from physical address) P.O. Box 2578

City Secaucus State NJ Zip 07096

Telephone 877-469-6053 Website www.infucarerx.com

Licensing Company Email Licensing@infucarerx.com

Section 2: Personal Information

First Dulari Middle _____ Last Patel

Alias(es, nicknames, name changes, etc.) N/A

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Missouri-Kansas City		08/1998 to 05/2003	
Address	**City**	**State**	**Zip**
5000 Holmes St.	Kansas City	MO	64110
Diploma/Degree obtained, if any			
Doctorate of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Northern Kentucky University		08/1997 to 06/1998	
Address	**City**	**State**	**Zip**
1 Louie B Nunn Dr.	Highland Heights	KY	41099
Diploma/Degree obtained, if any			
Bachelor of Arts - Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Northern Kentucky University		08/1991 to 06/1997	
Address	**City**	**State**	**Zip**
1 Louie B Nunn Dr.	Highland Heights	KY	41099
Diploma/Degree obtained, if any			
Bachelor of Science - Biology			

School Name		From - To (MM/YY – MM/YY)	
Dixie Heights High School		08/1988 to 06/1992	
Address	**City**	**State**	**Zip**
3010 Dixie Hwy	Edgewood	KY	41017
Diploma/Degree obtained, if any			
College Prep - High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
11/2007 - Current				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
DM Clinical Collaborations dba InfuCare Rx of CA			09/2021 - Current	
Business Address		**City**	**State**	**Zip**
6108 San Fernando Rd		Glendale	CA	91201
Phone	**Title**		**Number of Employed Hours**	
877-469-6053	Pharmacist in Charge		12048	
Description of Duties				
Clinical management of patient's therapies. On-call services, production check, staff training, pharmacy technician oversight, and various projects				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4-6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
1/30/2013 and 1/31/2013	N/A	CA	Simi Valley	Ventura
Case # Citation # CI201255342 and Receipt # 450026		**Governing, licensing, Arresting Presiding Body/Agency/Court** California Board of Pharmacy		
Reason/Charge Violation Code Section CCR Title 16, S 1716 Variation from Prescription and CCR 1764 Unauthorized disclosure of prescriptions II Civil code section 56 10 Disclosure of medical information requires patient authorization				
Plaintiff/Defendant/Claimant/Respondent Walgreens #10354			**Lawsuit/Arbitration/Bankruptcy** N/A	
Name of Business/Industry/Entity Walgreens #10354, 2417 Sycamore Dr, Simi Valley, CA 93065				

Provide explanation below:

1/30/2013 Event: I, Dulari Ketankumar Patel, am providing as much information regarding an event that occurred while I was Pharmacist in Charge, which I came to know was settled out of court by Walgreens for an undisclosed amount. I was informed by the Inspector, Board of Pharmacy (California) Diann Potter, PharmD. The Inspector had notified me of the settlement out of court, as I had resigned from Walgreens Pharmacy prior to the settlement, and I was not privy to any of the proceedings. I separated from Walgreens Pharmacy #10354 on May 13, 2013, as a Retail Pharmacist and Pharmacist in Charge.

It was discovered that an error was made by a pharmacy staff member on 1/30/2013, in which a patient (K.M.) received another patients' (M.M.) medication. K.M. had ingested 1 tablet of M.M.'s medication. I had received a call from the local hospital ER nurse inquiring on the medication ingested that evening, as I was the pharmacist on duty that evening. I was the PIC, the dispensing pharmacist, and the pharmacist on duty the night the event occurred. I submitted any and all requested materials to the inspector through the end of my employment, May 13, 2013.

1/31/2013 Event: I, Dulari Ketankumar Patel, am providing as much information regarding my citation by the California Board of Pharmacy as possible.

Reason for Citation: An inquiry was made regarding Quality Assurance/ Medication Error that was reported to the board by the consumer (patient), resulting in a formal investigation.

Error: It was discovered that an error was made by the pharmacy, in which a patient received digoxin inside a bottle labeled hydralazine. The patient in question was taking both medications at the time. The caregiver noticed the mistake. Patient did not ingest the medication incorrectly, as the patient and the caregiver were familiar with the prescription regimen. I was the PIC, the dispensing pharmacist and the pharmacist on duty the night the event occurred. After the investigation was completed by the board, a citation was issued to the PIC. I am not able to provide any documentation of the report submitted to the California Board of Pharmacy, as I am no longer employed at the stated pharmacy (Walgreens Pharmacy #10354) where the incident occurred and thus no longer have access to the case.

Dulari Patel

Original Signature (electronic, copies or stamps not accepted)

11/13/2025

Date

I, Dulari Patel, **certify that as the designated representative for**

DM Clinical Collaborations dba InfuCare Rx of CA,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DP I am at least 21 years of age;
3. DP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Dulari Patel

Print Name (First, Last)

Dulari Patel

Original Signature (electronic, copies or stamps not accepted)

11/13/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dulari Patel

Print Name (First, Last)

Dulari Patel

Original Signature (electronic, copies or stamps not accepted)

11/14/2025

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Dulari Patel

Original Signature

11/14/2025

Date

Subscribed and Sworn to before me this 14th day of November

A. Valadez

Notary Public Signature

See attached CA Acknowledgment/Jurat 11-14-2025 AV

(Seal)

CALIFORNIA JURAT WITH AFFIANT STATEMENT **GOVERNMENT CODE § 8202**

☑ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], *not* Notary)

Signature of Document Signer No. 1 *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 14th day of November, 2025.
Date *Month* *Year*
by
(1) Dulari Patel
(and (2)_____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

A. VALADEZ
Notary Public - California
Los Angeles County
Commission # 2527834
My Comm. Expires Jul 21, 2029

Signature A. Valadez
Signature of Notary Public

Seal
Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document Designated
Title or Type of Document: Representative Application **Document Date:** 11-14-2025
Number of Pages: 9 **Signer(s) Other Than Named Above:** _____

©2014 National Notary Association • www.NationalNotary.org • 1-800-US NOTARY (1-800-876-6827) Item #5910

To: Nevada State Board of Pharmacy 4/7/2022

98S Damonte Ranch Parkway, Suite 206

Reno, NV 89521

I, Dulari Ketankumar Patel, am providing as much information regarding my citation by the California Board of Pharmacy as possible.

License No: RPH 00055546 Citation No: CI 2012 55342 Date of Issue: 1/31/2013

Receipt No: 33010835 Fine Amount: $500.00 Date of Incident: On or about 1/12/2012

Violation Code Section: CCR, Title 16, S 1716 Variation from Prescription

Reason for Citation:

An inquiry was made regarding Quality Assurance / Medication Error that was reported to the board by the consumer (patient), resulting in a formal investigation.

Error:

It was discovered that an error was made by the pharmacy, in which a patient received digoxin inside a bottle labeled hydralazine. The patient in question was taking both medications at the time. The caregiver noticed the mistake. Patient did not ingest the medication incorrectly, as the patient and the caregiver were familiar with the prescription regimen. I was the PIC, the dispensing pharmacist and the pharmacist on duty the night the event occurred. After the investigation was completed by the board, a citation was issued to the PIC.

I am not able to provide any documentation of the report submitted to the California Board of Pharmacy, as I am no longer employed at the stated pharmacy (Walgreens Pharmacy #10354) where the incident occurred and thus no longer have access to the case.

Should you have any further questions, please contact me at 913-269-4531.

Sincerely,

Dulari K. Patel, PharmD

To: Nevada State Board of Pharmacy 4/7/2022

985 Damonte Ranch Parkway, Suite 206

Reno, NV 89521

I, Dulari Ketankumar Patel, am providing as much information regarding an event that occurred while I was Pharmacist in Charge, which I came to know was settled out of court by Walgreens for an undisclosed amount. I was informed by the Inspector, Board of Pharmacy (California) Diann Potter, PharmD. The Inspector had notified me of the settlement out of court, as I had resigned from Walgreens Pharmacy prior to the settlement, and I was not privy to any of the proceedings. I separated from Walgreens Pharmacy #10354 on May 13, 2013, as a Retail Pharmacist and Pharmacist in Charge.

License No: PHY50221 Citation No: N/A Date of Incident: 1/30/2013

Receipt No: 450026 Settlement Awarded: Unknown to me

Violation Code Sections:

1. CCR 1764 Unauthorized disclosure of prescriptions. // Civil code section 56.10 Disclosure of medical information requires patient authorization
2. CCR 1716 Variation from Prescription

Error:

It was discovered that an error was made by a pharmacy staff member on 1/30/2013, in which a patient (K.M.) received another patients' (M.M.) medication. K.M. had ingested 1 tablet of M.M.'s medication. I had received a call from the local hospital ER nurse inquiring on the medication ingested that evening, as I was the pharmacist on duty that evening. I was the PIC, the dispensing pharmacist, and the pharmacist on duty the night the event occurred. I submitted any and all requested materials to the inspector through the end of my employment, May 13, 2013.

I am providing you with all the documentation that I have copies of regarding the incident. I do not have copies of all items submitted to the California Board of Pharmacy, as I am no longer employed at the stated pharmacy (Walgreens Pharmacy #10354) where the incident occurred and thus no longer have access to the case.

Should you have any further questions, please contact me at 913-269-4531.

Sincerely,

Dulari Patel

Dulari K. Patel, PharmD

California State Board of Pharmacy
1625 N. Market Blvd., N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFAIRS
GOVERNOR EDMUND G. BROWN JR.

April 23, 2013

PIC Dulari Patel
Walgreens #10354
2417 Sycamore Dr.
Simi Valley, CA 93065

Dear PIC Patel,

As discussed, I am issuing a Written Notice of non-compliance with CCR 1764 (in combination with Civil Code 56.10) for unauthorized disclosure of M.M.'s prescription, in the medication incident of 1/30/13, involving patient K.M. Because K.M. did consume one tablet of M.M.'s prescription, a Written Notice of non-compliance with CCR 1716, variation from prescription, was also warranted.

I have also included Official Receipt #450026, for documents you sent to me.

Please contact me if you have any questions: 661-619-6966

Respectfully,

Diann Potter, Pharm D
Inspector, Board of Pharmacy
E-mail: diann.potter@dca.ca.gov

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219 Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR

Date: 4/23/2013 Permit #: PHY50221
Time of Day: 11:10 AM

Name as shown on permit: **WALGREENS #10354**

Address: 2417 SYCAMORE DR City: SIMI VALLEY

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. **CCR 1764** Unauthorized disclosure of prescriptions.///Civil Code section 56.10 Disclosure of medical information requires patient authorization
Walgreens #10354 was not in compliance in that the contents of a prescription for a patient were revealed to someone other than the patient or authorized representative

2. **CCR 1716** Variation from Prescription

Walgreens #10354 was not in compliance in that a prescription, not authorized by the patient's prescriber, was dispensed to K.M. K.M. consumed 1 tablet of the medicaton in error.

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) Dawn Potter
Inspector (print) Dawn Potter
Date 4/23/13

Signed Sent by Postal Service
Print Name
Title

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit the following:

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

OFFICIAL RECEIPT

April 23, 2013

Receipt Number: 450026

Firm / Person: Walgreens #10354, PHY 50221

Address: 2417 Sycamore Dr., Simi Valley, CA 93065

Permit #: PHY 50221

Phone: (805) 426-3722

The following was obtained this date under provisions of the California Pharmacy Law (Chapter 9, Division 2, Business and Professions Code) or the Rules and Regulations adopted thereunder:

Qty	Units	Description
1	Ea	Electronic Prescription for cefdinir for K.M. dated 1/30/13
1	Ea	Dispensing information on Rx#194203, filled prescription of cefdinir for K.M. 1/30/13
1	Ea	QA review dated 1/30/13 for K.M. medication incident
1	Ea	PIC Patel's internal audit of events for K.M. medication incident

Voluntarily Released for Investigation

Receipt acknowledged by: Sent by Postal Service (Title)

Inspector: Dawn Potter 4/23/13

April 5, 2013

Diann Potter, Pharm D
Inspector, Board of Pharmacy
Phone: 661-619-6866
Fax: 661-758-2576
E-mail: diann.potter@dca.ca.gov

Dear Inspector Potter,

I am providing you with the information you have requested. There may be items for which we do not have records and have indicated as such in the list below, otherwise the items are attached in order. Should you have further questions or need clarification on any of the items provided, please contact me.

California Board of Pharmacy Inquiry on March 15, 2013
Re: K.M.

1. Original copy of the prescription for Omnicef for K.M. from 1/30/2013, was sent electronically to the pharmacy.
   Attached
2. Dispensing history for that prescription.
   Attached
3. The QA report on the medication.
   Attached
4. My internal audit of how error occurred.
   Attached
5. A "screen-shot" of the insurance billing timeline.
   Attached
6. Consultation records.
   We do not have consultation records for any of our patients, unless it is blocked specifically by a Pharmacist to speak with patient. In addition, I did not speak with the person picking up the prescription for K.M.. Our policy is mandatory counselling on all NEW prescriptions, unless refused by the patient or caregiver. We do not know if the patient/caregiver refused consultation as again, we do not retain records for consultations unless a specific block is placed on the prescription by the pharmacist.
7. A statement from the dispensing pharmacist, on the incident.
   Attached
8. A QA report, if one was prepared, concerning the Atripla patient.
   A QA report was not prepared for M.M. the Atripla patient, as this patient did not recieve any incorrect medications/prescriptions.
9. A statement on the Atripla patient (M.M.) on how their medication was provided.
   Attached

Again, please call me if you have any questions.

Respectfully,

Dulari Patel, Pharm D.

Dulari Patel, Pharm D
Pharmacist In Charge
Walgreens Store 10354
2417 Sycamore Drive,
Simi Valley, CA 93065
Phone: 805-426-3722
Fax: 805-426-3728

California State Board of Pharmacy
1625 N. Market Blvd., N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

March 15, 2013

PIC Dulari Patel
Walgreens #10354
2417 Sycamore Dr.
Simi Valley, CA 93065
Fax: 805-426-3728

Dear PIC Patel,

As discussed on my phone call, I have been assigned to investigate the medication error concerning patient K M Please provide me with the following documents:

1. The original prescription for Omnicef for K.M. from 1/30/13
2. The dispensing history for that prescription.
3. The QA report on the medication error.
4. Your internal audit of how the error occurred.
5. A 'screen-shot' of the insurance billing timeline, which may indicate how the error occurred.
6. Consultation records for the Omnicef prescription
7. A statement from the dispensing pharmacist, on the incident. Please include any efforts to contact the patient. (Please use the statement page attached).
8. QA report, if one was prepared, concerning the Atripla patient.
9. A statement on the the Atripla patient (pt. initials only) and how their medication was provided. (Please use statement page attached).

Please mail this information to me within 14 days: P.O. Box 53, Wasco, CA, 93280. I will send you a receipt for documents received

Please call me if you have any questions,

Respectfully,

Diann Potter, Pharm D
Inspector, Board of Pharmacy
Phone: 661-619-6966
Fax: 661-758-2576
E-mail: diann.potter@dca.ca.gov

(1) Pt stated Pharmacy showed no concern, did not contact H/parents to see how pt was doing

(2) Also complained that WAG refused to reverse claim when Rite Aid called for transfer

Mar 15 13:03:17p p.2

8

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: DM Clinical Collaborations dba InfuCare Rx of CA

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04487

Physical Address: 6108 SAN FERNANDO RD

City: GLENDALE State: CA Zip: 91201

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-469-6053 Website: www.infucarerx.com

Licensing Company Email: licensing@infucarerx.com

Section 2: Personal Information

First: Dhara Middle: Last: Patel

Alias(es, nicknames, name changes, etc.): N/A

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Armstrong Atlantic State University		From - To (MM/YY – MM/YY): Unknown	
Address: 11935 Abercorn St.	City: Savannah	State: GA	Zip: 31419
Diploma/Degree obtained, if any: BA in Liberal Arts			
School Name: Richmond Hill High School		From - To (MM/YY – MM/YY): Unknown	
Address: Unknown	City:	State:	Zip:
Diploma/Degree obtained, if any: High School Diploma			
School Name:		From - To (MM/YY – MM/YY):	
Address:	City:	State:	Zip:
Diploma/Degree obtained, if any:			
School Name:		From - To (MM/YY – MM/YY):	
Address:	City:	State:	Zip:
Diploma/Degree obtained, if any:			
School Name:		From - To (MM/YY – MM/YY	
Address:	City:	State:	Zip:
Diploma/Degree obtained, if any:			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): Unknown-Present	[redacted]			
From - To (MM/YY – MM/YY): Unknown-Present				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
InfuCare Rx, Inc.			2015 - Present	
Business Address		**City**	**State**	**Zip**
695 US Hwy 46, Ste 100		Fairfield	NJ	07004
Phone	**Title**			
877-828-3940	President			
Description of Duties				
President of InfuCare Rx, Inc.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dhara Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/2/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Passaic

I, Dhara Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/2/2025

Date

Subscribed and Sworn to before me this 2nd day of December, 2025.

Notary Public Signature

DANIEL ALBARRAN
Notary Public, State of New Jersey
My Commission Expires Dec 15, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: DM Clinical Collaborations dba InfuCare Rx of CA

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04487

Physical Address: 6108 SAN FERNANDO RD

City: GLENDALE State: CA Zip: 91201

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-469-6053 Website: www.infucarerx.com

Licensing Company Email: licensing@infucarerx.com

Section 2: Personal Information

First: Tiffany Middle: Samantha Last: Scheppers

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: University of Missouri St Louis		From - To (MM/YY – MM/YY): Unknown	
Address: 1 University Blvd.	City: St. Louis	State: MO	Zip: 63121-4400
Diploma/Degree obtained, if any: MBA not completed			
School Name: St. Louis University School of Law		From - To (MM/YY – MM/YY): 8/1996 - 5/1999	
Address: 100 N Tucker Blvd	City: St. Louis	State: MO	Zip: 63101
Diploma/Degree obtained, if any: Juris Doctor			
School Name: St. Louis University		From - To (MM/YY – MM/YY): 8/1993 - 5/1999	
Address: 1 N Grand Blvd	City: St. Louis	State: MO	Zip: 63101
Diploma/Degree obtained, if any: Nursing			
School Name: Cornelia Connelly School of the Holy Child Jesus		From - To (MM/YY – MM/YY): 1984 - 1988	
Address: 2323 W Broadway	City: Anaheim	State: CA	Zip: 92804
Diploma/Degree obtained, if any: Diploma			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 8/2015 - Present	[redacted]			
From - To (MM/YY – MM/YY): 3/2013 - 8/2015				
From - To (MM/YY – MM/YY): 1/2000 - 3/2013				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Infucare Rx Inc.			3/2021 - Present
Business Address	**City**	**State**	**Zip**
695 US Hwy 46, STE 100	Fairfield	NJ	07004
Phone	**Title**		
877-828-3940	General Counsel and Corporate Secretary		

Description of Duties

•Oversee all corporate, regulatory, employment, litigation, and compliance legal matters.

Business Name			From - To (MM/YY – MM/YY)
Asembia, LLC			07/2019 - 12/2020
Business Address	**City**	**State**	**Zip**
200 Park Ave #300	Florham Park	NJ	07932
Phone	**Title**		
973-564-8004	Senior Vice President, General Counsel and Chief Compliance Officer; Corporate Secretary		

Description of Duties

Oversee all corporate, regulatory, employment, litigation, and compliance legal matters; Current Officer acting as Corporate Secretary; Advised executive leadership and Board of Directors on complex regulatory compliance matters.

Business Name			From - To (MM/YY – MM/YY)
Outside General Counsel			07/2019 - 12/2020
Business Address	**City**	**State**	**Zip**
	Charlotte	NC	
Phone	**Title**		
314-808-3974	Outside General Counsel		

Description of Duties

Delivered outsourced general counsel and compliance services to, and temporary coverage for, in-house general counsel and chief compliance officer clients, re: health care, pharma, biotech and CRO/CSO companies on legal and regulatory.

Business Name			From - To (MM/YY – MM/YY)
SYNEOS HEALTH, INC			08/2012 - 03/2019
Business Address	**City**	**State**	**Zip**
1030 Sync Street	Morrisville	NC	27560
Phone	**Title**		
919-876-9300	Senior Associate General Counsel & Chief Compliance Officer; Commercial Division		

Description of Duties

Supervised legal and compliance teams across US, Canada, Europe and APAC, reporting directly to the General Counsel.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tiffany Scheppers

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/2025

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Mecklenburg

I, Tiffany Scheppers ~~Nimesh Patel~~, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/19/2025

Date

Subscribed and Sworn to before me this 19 day of November 2025.

Notary Public Signature

NIMESH R. PATEL NOTARY PUBLIC MECKLENBURG COUNTY, N.C.

My Commission Expires
Nov 7, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: DM Clinical Collaborations dba InfuCare Rx of CA

NV Pharmacy or Outsourcing facility license # (if applicable): PH04487

Physical Address: 6108 SAN FERNANDO RD

City: GLENDALE State: CA Zip: 91201

Mailing Address (if different from physical address): P.O. BOX 2578

City: SECAUCUS State: NJ Zip: 07096

Telephone: 877-469-6053 Toll Free # (NAC 639.708, NRS 639.23286): 877-469-6053

Fax: 877-469-6052 Contact Email: Licensing@infucarerx.com

Website: www.infucarerx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Dulari Patel

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22605

Name of Designated Person(s) as defined by revised USP-797 guidelines: Dulari Patel, Victor Reyes, Leslie Torres

Email of Designated Person(s): dkpatel@infucarerx.com, vreyes@infucarerx.com, ltorres@infucarerx.com

Telephone of Designated Person(s): 877-469-6053

Document Ref: KIBK8-SHAAH-53VH6-TBRWW

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

   ■ Category 1 ■ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? Yes ■ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? **No** ☐ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes No

5. When was the most recent certification for the ISO classified areas? 08/04/2025

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ■ Yes ☐ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? **N/A** Yes No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Monthly

10. Will you be performing sterile hazardous drug compounding? Yes ■ No

If you marked "**Yes**", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Amikacin Sulfate, Ampicillin Sodium, Avycaz, Azithromycin, Aztreonam, ceFAZolin Sodium, Cefepime HCl, cefOXitin, Sodium, cefTAZidime, cefTRIAXone , DAPTOmycin, Ertapenem, Gentamicin Sulfate, IMIPENEM/CILASTATIN, Meropenem, Micafungin Sodium, MYCAMINE, Nafcillin, Oxacillin Sodium, Penicillin G Potassium, PENICILLIN G, POTASSIUM, PFIZERPEN, PIPERACILLIN SODIUM/TAZOB, TEFLARO, Tigecycline, Unasyn, Vancomycin HCl, Zerbaxa, TPN, Hydration

12. What laboratory performs your sterility or endotoxin testing?

Name: Arl Bio Pharma

Address: 840 Research Parkway, Suite 546

City: Oklahoma City State: OK Zip: 73104

Telephone: (405) 271-1144

Document Ref: KIBK8-SHAAH-53VH6-TBRWW

13. What is your procedure for visual inspection of compounded sterile products?
We visually inspect each compounded sterile product under a black and white light. The visual inspection is done once the compounded sterile product is prepared (and again prior to shipping if stored in the refrigerator immediately after compounding).

14. How often do you perform glove fingertip and medial fill testing?
Every 6 months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
Initially, staff members are trained to ensure qualification in compounded sterile preparations. The knowledge check is done via SoleSource training and the competency is completed via hands on visual observations. Ongoing training is done annually for knowledge check via SoleSource, and visual observation competencies via Simplifi. Additionally, gloved fingertip and thumb sampling and media fill is done every 6 months.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
A daily cleaning is done using a germicidal disinfectant (sterile TB1-3300) at all ISO 5 and ISO7 area, high tough areas, interior surfaces, pass through, work surfaces, floors,and sink. All the listed areas are then wiped using sterile Isopropyl Alcohol 70%. A monthly cleaning is done using a sproficidal agent (Peridox RTU) in all the areas for daily cleaning, ceilings, walls, doors, equipment outside PEC, storage bin, and furniture surfaces.

17. Who performs the sterile compounding process at your facility?

Compounding staff includes anyone that has completed all parts of the initial and onboarding training.

18. Who is responsible and accountable for the sterile compounding process at your facility?
Designated Person

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
The products are shipped in packaging to maintain the refrigerated temperature requirements. Ice bricks and bubble wrapping is also used to maintain the product efficacy.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A - we do not dispense any hazardous compounded medications.		
2. Are you complying with all USP 800 guidelines?	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device: N/A - we do not dispense any hazardous compounded medications		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? N/A - we do not dispense any hazardous compounded medications

Document Ref: KIBK8-SHAAH-53VH6-TBRWW

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?
N/A - we do not dispense any hazardous compounded medications

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:
N/A - we do not dispense any category 3 compounds

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?
N/A - we do not dispense any category 3 compounds

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes ■ No

4. What is the frequency for completing volumetric active air sampling?
N/A - we do not dispense any category 3 compounds

5. What is the frequency for completing surface sampling? N/A - we do not dispense any category 3 compounds	
6. What is the frequency for using sporicidal agents? N/A - we do not dispense any category 3 compounds	
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes ■ No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes ■ No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dulari Patel

Name of Person who Completed the Form

Pharmacist in Charge

Title

Dulari K. Patel

Signature (copies or stamps not accepted)

11 / 12 / 2025

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

Document Ref: KIBK8-SHAAH-53VH6-TBRWW

CERTIFICATE *of* SIGNATURE

REF. NUMBER
KIBK8-SHAAH-53VH6-TBRWW

DOCUMENT COMPLETED BY ALL PARTIES ON
12 NOV 2025 15:59:04
UTC

SIGNER	TIMESTAMP	SIGNATURE
TIFFANY SCHEPPERS EMAIL TSCHEPPERS@INFUCARERX.COM	SENT 11 NOV 2025 16:56:54 VIEWED 11 NOV 2025 21:11:50 SIGNED 11 NOV 2025 21:12:20	Tiffany Scheppers, Corporate Secretary IP ADDRESS [redacted] LOCATION WAXHAW, UNITED STATES
RECIPIENT VERIFICATION	EMAIL VERIFIED 11 NOV 2025 21:11:50	
DULARI PATEL EMAIL DKPATEL@INFUCARERX.COM	SENT 11 NOV 2025 16:56:54 VIEWED 12 NOV 2025 15:58:03 SIGNED 12 NOV 2025 15:59:04	Dulari K. Patel IP ADDRESS [redacted] LOCATION LOS ANGELES, UNITED STATES
RECIPIENT VERIFICATION	EMAIL VERIFIED 12 NOV 2025 15:58:03	

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy Clinic Exempt Hospital Wholesaler Hypodermic

Date: 10/31/2024 Inspector: Joshua Lee

Firm: Infucare Rx Phone: (877) 469-6053

Address: 6108 San Fernando RD, Clean Room City: Glendale Zip: 91201

Ownership: CORPORATION

Permit #: LSC101747 PHY58562 Permit Exp: 1/1/2025 DEA#: [redacted] DEA Exp: 6/30/2025

Date of Self Assessment Form: 5/25/2023 Other Permit #: N/A Date of DEA Inventory: 7/30/2024

Hours M-F: 9AM-5PM Hours Saturday: CLOSED Hours Sunday: CLOSED

PIC DULARI K PATEL CPD RPH55546 Administrator

RPH Consultant

Staff RPH Name:	License #:	Staff Name:	License #:
JOSEPH F SCHUETZ	RPH72984	KATELINE D PARAS	TCH148538
		KIMBERLY A PERALTA	TCH146330
		LESLIE D TORRES	TCH139660
		STELLE ADORABLE	CLERK

Inspector Remarks:

Onsite Renewal Annual sterile compounding inspection: Home infusion retail pharmacy located in a business park. Pharmacy has no controlled substances. Parking is in the back, front door secured from public. Public entrance is in the front.

PIC Dulari Patel
[redacted] Cell
Dkpatel@infucarerx.com

- 2023 Community pharmacy and Compounding self-assessments reviewed
- Updated list of CSPs: reviewed.
-Cat 2 compounding.
- FDA, DEA and/or accreditation inspections with applicable reports issued within the past 12 months: July 2024 URAC inspection report not available for review during inspection.

Previous BOP Inspection Report:
- Reviewed previous inspection report for previous corrections or written notice of noncompliance. No issues from previous report.

Pharmacy Law Waivers: None used

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Sterile Compounding Area
- Certification completed by: Clean room services 9/9/24
- Dynamic testing, Non-viable air sampling, HEPA filter leak testing, air changes, smoke study, and viable air and surface sampling: Reviewed
- Description of PECs and SECs:
ISO 8 ante/ISO 7 IV room with ISO 5 laminar flow hood. Baxa repeater pump and Pinnacle TPN compounder.
- Sporicidal, cleaning, and disinfecting agents: Preempt, Sterile Peridox, sIPA. See discussion.
- Cleaning logs reviewed.

Policies and Procedures
- Updated and new sterile compounding policy and procedures reviewed.

Record Keeping
-Compounding records/master formula/labeling: reviewed. See discussion.
- Sterile compounding equipment calibration and maintenance logs: in place.
- Pressure differential monitoring logs: reviewed.
- Refrigerator/humidity/room temperature logs: reviewed.

Employee training/competencies: Reviewed.
- Didactic training, pharmaceutical calculations, gloved fingertip sampling, media fill testing, practical skills training in aseptic area practices, cleaning etc.

Quality Assurance
- End product sterility/potency testing: ARL Labs

ADRS
- All ADRS within 12 months have been reported as required: None to report.

Discussion:

Education:

See the following link for proposed compounding regulation status:
https://www.pharmacy.ca.gov/laws_regs/1735_pt_24.pdf
45-Day Comment Period: **April 19, 2024 to June 3, 2024**
Regulation Hearing: June 18, 2024 at 9:00 a.m.
Department of Consumer Affairs, Board of Pharmacy
First Floor Hearing Room
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833
WebEx Link: Pending
November 1, 2023, is the compendial date for several USP General Chapters, including General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations, <797> Pharmaceutical Compounding—Sterile Preparations, <800> Hazardous Drugs—Handling in Healthcare Settings, and <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging. Consistent with the policy statement the Board released on September 12, 2023, it is the Board's expectation that licensees are moving forward with all necessary implementation activities to comply with the updated

USP compounding standards.

The Board has undertaken a review of its compounding regulations and identified changes necessary to clarify or make more specific requirements of federal law and USP General Chapters.

During this transition period, licensees are encouraged to monitor the regulation process for updates, including signing up for the Board's subscriber alert system and by checking the Board's website.

Licensees are reminded to also ensure continuing compliance with other laws, regulations, and requirements that may apply to their activities, including, without limitation: the Federal Food, Drug, and Cosmetic Act (21 USC §§ 321–399i), including Section 503A thereof (21 USC § 353a); provisions of California's Sherman Food, Drug, and Cosmetic Law (Health and Safety Code §§ 109875–111929.4); and laws, regulations, and requirements related to radiopharmaceuticals and/or the handling of hazardous drugs, including requirements established by Cal/OSHA.

1. Revisions to USP Compounding General Chapters <795> and <797> https://go.usp.org/2022_Revisions_795_797
   BUD Scientific Rationale for the 2021 Proposed Revisions to <795>
   BUD Reference for the 2021 Proposed Revisions to <795>
   BUD Scientific Rationale for the 2021 Proposed Revisions to <797>
   BUD Reference for the 2021 Proposed Revisions to <797>
2. 9/29/23, Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act.
   https://www.fda.gov/media/94155/download
3. FDA Drug Establishments Current Registration Site:
   https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm
4. FDA to Compounders: Know Your Bulks and Excipients Suppliers:
   https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipients-suppliers

Discussion: Send all requested items to compounding.pharmacy@dca.ca.gov in one or consecutive emails by 11/7/24.

1. No temperature log for the two incubators. Send 7 days of daily readings.
2. Send URAC July 2024 inspection report for review.
3. No sterile germicidal detergent used to clean the inside of the hood daily. Send picture of new product used with new cleaning policy and procedures and training of staff documented.
4. Annual replacement of humidity and temperature monitoring equipment in clean room required since no calibration is done. Send plan of correction.
5. Send compliant compounding record and master formula for TPN 3:1 for review.

Licensee Remarks:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) Dulari Patel

Pharmacist (print) Dulari Patel

Inspector (sign) _____

Inspector (print) Joshua Lax

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

BOARD OF PHARMACY

LICENSING DETAILS FOR: LSC 102064

NAME: DM CLINICAL COLLABORATIONS DBA INFUCARE RX OF CA

LICENSE TYPE: STERILE COMPOUNDING PHARMACY

LICENSE STATUS: CLEAR

ADDRESS

6108 SAN FERNANDO RD
GLENDALE CA 91021
LOS ANGELES COUNTY

ISSUANCE DATE

NOVEMBER 5, 2025

EXPIRATION DATE

MARCH 15, 2026

CURRENT DATE / TIME

JANUARY 14, 2026
2:31:51 PM

LICENSE RELATIONSHIPS

NAME: DM CLINICAL COLLABORATIONS DBA INFUCARE RX OF CA
LICENSE/REGISTRATION TYPE: PHARMACY (COMMUNITY)
LICENSE NUMBER: 61378 **PRIMARY STATUS:** CLEAR

ADDRESS :
6108 SAN FERNANDO RD
GLENDALE CA 91201
LOS ANGELES COUNTY

NAME: PATEL, DULARI KETANKUMAR
LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST
LICENSE NUMBER: 55546 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 61378

NAME: DM CLINICAL COLLABORATIONS DBA INFUCARE RX OF CA

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

6108 SAN FERNANDO RD
GLENDALE CA 91201
LOS ANGELES COUNTY

ISSUANCE DATE

NOVEMBER 5, 2025

EXPIRATION DATE

MARCH 15, 2026

CURRENT DATE / TIME

JANUARY 14, 2026
2:32:11 PM

LICENSE RELATIONSHIPS

NAME: DM CLINICAL COLLABORATIONS DBA INFUCARE RX OF CA
LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY
LICENSE NUMBER: 102064 **PRIMARY STATUS:** CLEAR

ADDRESS :
6108 SAN FERNANDO RD
GLENDALE CA 91021
LOS ANGELES COUNTY

NAME: PATEL, DULARI KETANKUMAR
LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST
LICENSE NUMBER: 55546 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

CALIFORNIA STATE BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

License No. PHY 58562
Receipt No. 00195894

Valid Until: 1/1/2026

DM CLINICAL COLLABORATIONS DBA INFUCARE RX
6108 SAN FERNANDO RD
GLENDALE, CA 91201-2240

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.

This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

NON-TRANSFERABLE ---- POST IN PUBLIC VIEW ----

FORM WPHPHY (09/30/19) PHY

CALIC100,RENWALR,11182024,44165,6EQID4174

DM CLINICAL COLLABORATIONS DBA INFUCARE RX
6108 SAN FERNANDO RD
GLENDALE, CA 91201-2240 4174

BOARD OF PHARMACY
2720 GATEWAY OAKS DR, SUITE 100
SACRAMENTO, CA 95833

2003

BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal Certificate

Sterile Compounding License

License No. LSC 101747
Receipt No. 00195885

Valid Until: 1/1/2026

DM CLINICAL COLLABORATIONS DBA INFUCARE RX
6108 SAN FERNANDO RD
CLEAN ROOM
GLENDALE, CA 91201-2240

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.

This permit is valid only at the address shown.

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----- NON-TRANSFERABLE ----- POST IN PUBLIC VIEW -----

WPHLSC 09/30/19

CALIC100,RENWALR,12022024,27402,SEQID6970

DM CLINICAL COLLABORATIONS DBA INFUCARE RX
6108 SAN FERNANDO RD
CLEAN ROOM
GLENDALE, CA 91201-2240 6970

BOARD OF PHARMACY
2720 GATEWAY OAKS DR, SUITE 100
SACRAMENTO, CA 95833

2004

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 58562

NAME: DM CLINICAL COLLABORATIONS DBA INFUCARE RX

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

6108 SAN FERNANDO RD
GLENDALE CA 91201
LOS ANGELES COUNTY

ISSUANCE DATE

JANUARY 4, 2022

EXPIRATION DATE

JANUARY 1, 2026

CURRENT DATE / TIME

OCTOBER 14, 2025
11:56:0 AM

LICENSE RELATIONSHIPS

NAME: DM CLINICAL COLLABORATIONS DBA INFUCARE RX
LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY
LICENSE NUMBER: 101747 **PRIMARY STATUS:** CLEAR

ADDRESS :
6108 SAN FERNANDO RD
CLEAN ROOM
GLENDALE CA 91021
LOS ANGELES COUNTY

NAME: PATEL, DULARI KETANKUMAR
LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST
LICENSE NUMBER: 55548 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

4QQ

2006

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

y

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 03995	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Fast Access Specialty Therapeutics, LLC dba InfuCare Rx of LA

Physical Address: 2400 Veterans Memorial Boulevard, Suite 480

City: Kenner State: LA Zip: 70062

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-327-8881 Toll Free # (NAC 639.708, NRS 639.23286): 877-327-8881

Fax: 844-504-3278 Contact Email: licensing@infucarerx.com

Website: www.infucarerx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Spencer Sanson

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24440

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Spencer Sanson	NV Pharmacist Registration #: 24440
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: LA

Parent Company (if any): Factor One Source Pharmacy, LLC

Corporation/Organization Name: Fast Access Specialty Therapeutics, LLC dba InfuCare Rx of LA

Mailing Address: 2400 Veterans Memorial Boulevard, Suite 480

City: Kenner State: LA Zip: 70092

Telephone: 877-828-3940 Email: Licensing@infucarerx.com

Contact Person Name: Jessica Seefried

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Corporate Secretary and General Counsel (title) for Fast Access Specialty Therapeutics, LLC dba InfuCare Rx of LA (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Tiffany Scheppers

Print Name of Authorized Person

Tiffany Scheppers, Corporate Secretary

Original signature of Authorized Person (copies or stamps not accepted)

11 / 11 / 2025

Date

Document Ref: H84O7-6PMNU-EPTNM-8AC55

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tiffany Scheppers

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Tiffany Scheppers, Corporate Secretary

Original signature of Authorized Person (copies or stamps not accepted)

11 / 11 / 2025

Date

Board Use Only	Date Received: 12/8/25	Amount: $500CK 1000002408

Alabama State Board of Pharmacy Action
Re: Case No: 21-L-0071
Fast Access Specialty Pharmacy LLC dba InfuCare Rx of LA

On or about January 18, 2021, Sajal Roy, PharmD ("Roy"), the Alabama Supervising Pharmacist ("PIC") at Fast Access Specialty Pharmacy LLC dba InfuCare Rx of LA ("Pharmacy"), submitted his resignation as AL PIC of the Pharmacy to the Alabama Board of Pharmacy ("Board"). His employment resignation was submitted to the Pharmacy on or about January 18, and his last day of employment was March 4, 2021. Roy was asked by the Pharmacy to rescind his resignation as PIC until a replacement could be found, as his employment with the Pharmacy continued through March 4. The Pharmacy believed that Roy had rescinded his resignation, and as a result, it mistakenly did not notify the Board within 10 days with an action plan to designate another PIC. A new PIC was designated on March 3, 2021. The Board cited the Pharmacy for being unable to maintain a PIC and failing to notify the Board within 10 days with an action plan. The Pharmacy's license was not affected and remains in good standing.

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IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
FAST ACCESS SPECIALTY THERAPEUTICS LLC dba INFUCARE RX OF LA	)	
	)	
Non-Resident Pharmacy Permit Number: 113920	)	**CASE NO: 21-L-0071**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA has violated the provisions of law based upon the conduct set out in Count One of the Statement. Counts Two and Three shall be dismissed.

2. Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA shall pay an administrative fine in the amount of One Thousand Dollars ($1,000.00) within thirty (30) days of the effective date of this Consent Order, that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA attempt to discharge

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the same.

3. Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA's permit, including, but not limited to revocation.

6. That Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and is signing this Consent Order on the advice of its attorney.

DONE this the 6th of October, 2021.

FAST ACCESS SPECIALTY THERAPEUTICS LLC DBA INFUCARE RX OF LA

DocuSigned by:

BY: Dhara Patel

91403FB14F2340E...

ITS: President

Jerry Moore, Attorney for Fast Access Specialty Therapeutics LLC dba Infucare Rx of LA

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DONE this the_____ of_____, 2021.

ALABAMA STATE BOARD OF PHARMACY

By: _____
Brenda Denson, PharmD, President

By:_____
James S. Ward,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
WARD & COOPER, LLC
2100A Southbridge Parkway
Suite 645
Birmingham, AL 35209
(205) 871-5404

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EXHIBIT "A"

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
FAST ACCESS SPECIALTY THERAPEUTICS LLC dba INFUCARE RX OF LA	)	
	)	
Non-Resident Pharmacy Permit Number: 113920	)	**CASE NO: 21-L-0071**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Fast Access Specialty Therapeutics LLC
dba Infucare Rx of La
2400 Veterans Memorial Boulevard
Suite 480
Kenner, Louisiana 70062

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12), Code of Alabama (1975), §20-2-213(e) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on November 16, 2021 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Fast Access Specialty Therapuetics LLC dba Infucare Rx of LA should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that Fast Access Specialty Therapuetics LLC dba Infucare Rx of LA has been guilty of the following, to-wit:

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COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(12) in that you violated Board Rule 680-X-2.12(8) by you being unable to maintain a designated Supervising Pharmacist and failing to notify the Board within ten (10) days with an action plan to designate another pharmacist as Supervising Pharmacist to-wit: Sajal Kumar Roy ceased to be your Supervising Pharmacist on or about January 18, 2021 and you, as of the date hereof, have not submitted the referenced action plan to the Board.

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of the preceding Count.

Further, pursuant to the provisions of Code of Alabama, (1975), §20-2-53 and §41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), §20-2-1, et. seq., issued pursuant to Code of Alabama (1975), §20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT THREE

Violating Code of Alabama (1975), §20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), §34-23-1 et seq., said violation being based upon any or all of the allegations contained in the preceding Counts of this Statement of Charges and

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Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 31st day of March, 2021.

ALABAMA STATE BOARD OF PHARMACY

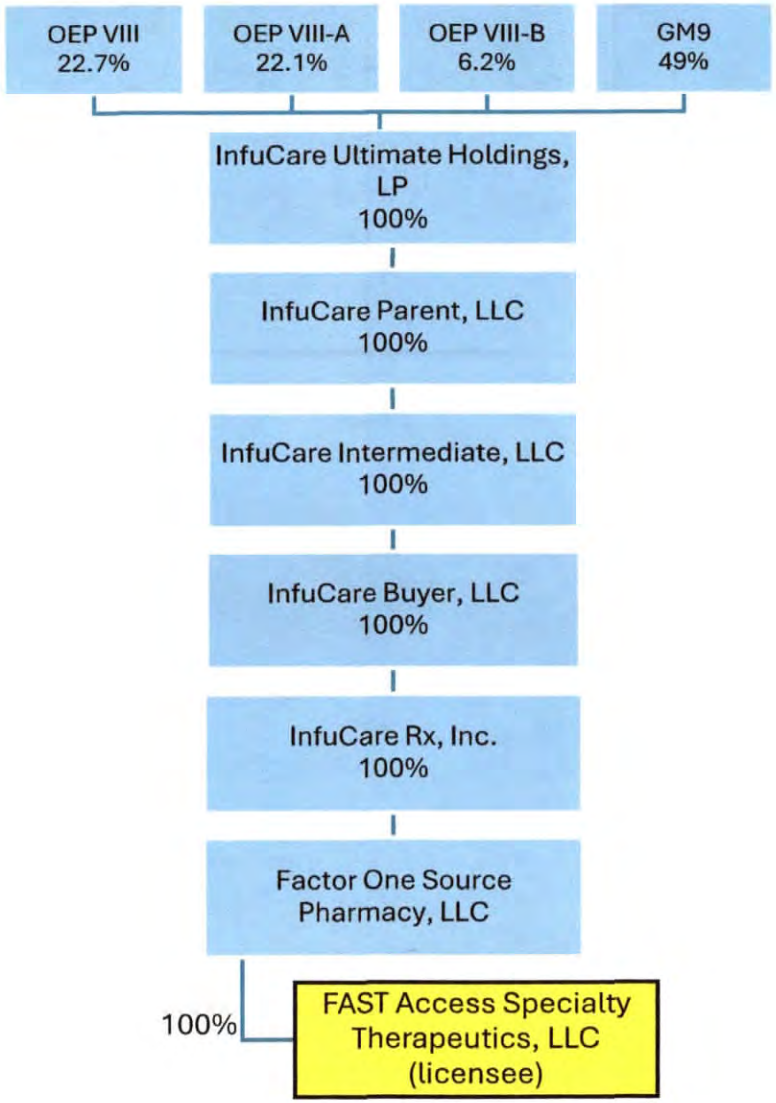
By: Donna C. Yeatman
Executive Secretary

Corporate Officers			
Name	**Title**	**Address**	**Phone**
Dhara Patel	President, Director, and Treasurer	695 US Hwy 46, STE 100, Fairfield, NJ 07004	877-828-3940
Tiffany Scheppers	Secretary and General Counsel	695 US Hwy 46, STE 100, Fairfield, NJ 07004	877-828-3940

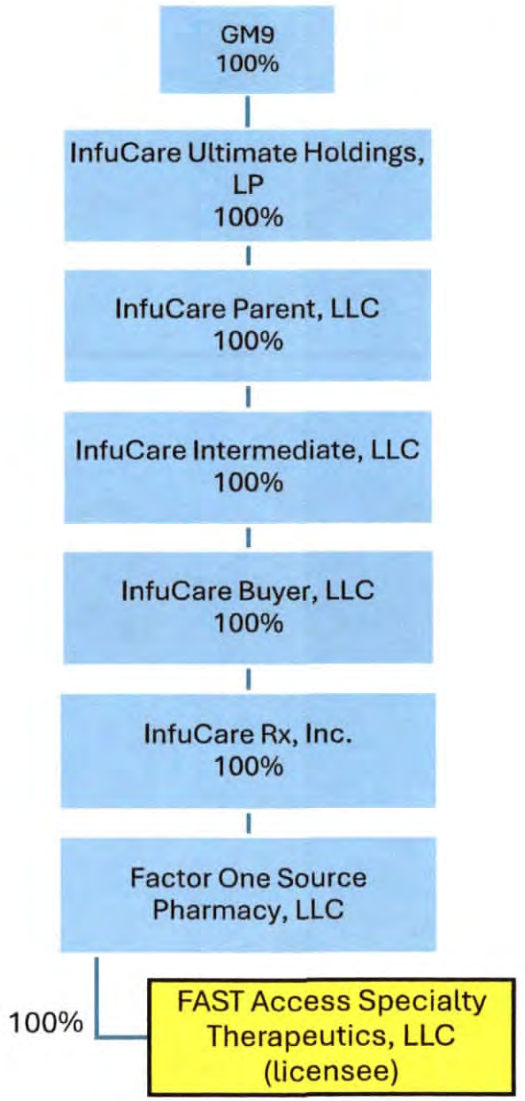
Fast Access Specialty Therapeutics, LLC DBA InfuCare Rx of LA			
2400 Veterans Memorial Boulevard, Suite 480, Kenner, LA 70062			
List of Shareholders			
Name	**Address**	**Phone**	**Percent Ownership**
Factor One Source Pharmacy, LLC	217 Glenn Street 3rd Floor, Suite 300, Cumberland, MD 21502	877-828-3940	100%

Pre- and Post- Sale for FAST Access Specialty Therapeutics, LLC

Pre-Close Structure



Post-Close Structure



2022

UNITED STATES OF AMERICA

State of Louisiana

Nancy Landry

SECRETARY OF STATE

As Secretary of State of the State of Louisiana, I do hereby Certify that

FAST ACCESS SPECIALTY THERAPEUTICS, L.L.C.

A limited liability company domiciled in METAIRIE, LOUISIANA,

Filed charter and qualified to do business in this State on September 17, 2009,

I further certify that the records of this Office indicate the company has paid all fees due the Secretary of State, and so far as the Office of the Secretary of State is concerned, is in good standing and is authorized to do business in this State.

I further certify that this certificate is not intended to reflect the financial condition of this company since this information is not available from the records of this Office.

In testimony whereof, I have hereunto set my hand and caused the Seal of my Office to be affixed at the City of Baton Rouge on,

October 17, 2025

Nancy Landry

Secretary of State

Web 40011784K

STATE OF LOUISIANA · UNION · JUSTICE · CONFIDENCE · SECRETARY OF STATE

Certificate ID: 12103096#TXM73

To validate this certificate, visit the following web site, go to **Business Services, Search for Louisiana Business Filings, Validate a Certificate**, then follow the instructions displayed.
www.sos.la.gov

2023

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Fast Access Specialty Therapeutics, LLC dba InfuCare Rx of LA

Pharmacy/Wholesaler License # (if applicable) PH03995

Physical Address 2400 Veterans Memorial Boulevard, Suite 480

City Kenner State LA Zip 70062

Mailing Address (if different from physical address) P.O. Box 2578

City Secaucus State NJ Zip 07096

Telephone 877-327-8881 Website www.infucarerx.com

Licensing Company Email licensing@infucarerx.com

Section 2: Personal Information

First Spencer Middle _____ Last Sanson

Alias(es, nicknames, name changes, etc.) N/A

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Arkansas for Medical Sciences		2016-2020	
Address: 4301 W. Markham St.	City: Little Rock	State: AR	Zip: 72205
Diploma/Degree obtained, if any: PharmD			

School Name		From - To (MM/YY – MM/YY)	
Hendrix College		2010-2013	
Address: 1600 Washington Ave	City: Conway	State: AR	Zip: 72032
Diploma/Degree obtained, if any: N/A			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2022-present	[redacted]			
2020-2022				
2014-2020				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Fast Access Specialty Therapeutics, LLC dba InfuCare Rx of LA			12/2023 to Present	
Business Address	**City**		**State**	**Zip**
2400 Veterans Memorial Boulevard, Suite 480	Kenner		LA	70062
Phone	**Title**		**Number of Employed Hours**	
877-327-8881	Pharmacist		5488	
Description of Duties				
Supervise pharmacy staff to ensure accurate and safe job performance. Directs, coordinates and supervises pharmacy activities. Ensure Pharmacy is adhering to rules and regulations.				

Business Name			From - To (MM/YY – MM/YY)	
Cardinal Health			10/2020 to 06/2022	
Business Address	**City**		**State**	**Zip**
1933 County Rd C2 W	St. Paul		MN	55113
Phone	**Title**		**Number of Employed Hours**	
651-636-3075	Nuclear Pharmacist		4864	
Description of Duties				
Nuclear pharmacy				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
9/2/2018	10/26/2018	TX	Arlington, TX	Tarrant
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2018-02450514		Arlington Police Department		
Reason/Charge				
Public Intoxication				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

I attended the LSU vs. Miami opening college football game in Arlington. It had been awhile since I drank alcohol and I learned that day the importance of drinking in moderation and not to drink on an empty stomach. Childhood friends had flown in along with my parents for the game. I began drinking that morning during the tailgate for the big opener. And due to weight-loss initiatives at the time I decided not to eat breakfast while everyone else did. I drank close to the same amount as everyone else that day. However, I believe due to the heat(dehydration), lack of food, and lower tolerance I became inebriated more so than others I was with. Once it was time to enter the game we separated: my family went to one section and my friends and I went to another. Upon getting rejected when trying to enter the game I attempted to re-enter. At the time I believed that I was denied access due to a misunderstanding of how intoxicated I was and was contributed to by our over-hyped cheering for the LSU Tigers. This is why I believed I should try to re-enter. Due to me attempting to re-enter after being denied. It was deemed that I was being disobedient and deserved a public intoxication. I then was escorted to a room for 4 hours until the game concluded upon which my friends picked me up. I then pleaded no-contendere and paid a $300 fee for the public intoxication.

I have had no arrests/ issues since this arrest and have been licensed and employed since summer of 2020. I currently work in a specialty pharmacy that ships to multiple states which is why I am applying for this license.

This occurred while in pharmacy school in Arkansas. Included is a recent attestation that I have completed all obligations for the Arkansas Board of Pharmacy, and I have been in good standing since.

Spencer Sanson
Original Signature (electronic, copies or stamps not accepted)

11/11/25
Date

I, Spencer Sanson, **certify that as the designated representative for**

Fast Access Specialty Therapeutics, LLC dba InfuCare Rx of LA,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SS I am at least 21 years of age;
3. SS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Spencer Sanson

Print Name (First, Last)

Spencer Sanson

Original Signature (electronic, copies or stamps not accepted)

11/11/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Spencer Sanson

Print Name (First, Last)

Spencer Sanson — 11/11/2025

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of LOUISIANA, ss. County of PARISH JEFFERSON

I, Spencer Sanson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Spencer Sanson — 11/11/2025

Original Signature — **Date**

Subscribed and Sworn to before me this 11 day of November.

Notary Public Signature

CARL A. BUTLER NOTARY PUBLIC ID NO 42025 MY COMMISSION IS FOR LIFE STATE OF LOUISIANA (Seal)

Detailed Statement 09/02/2018:

I attended the LSU vs. Miami opening college football game in Arlington. It had been awhile since I drank alcohol and I learned that day the importance of drinking in moderation and not to drink on an empty stomach. Childhood friends had flown in along with my parents for the game. I began drinking that morning during the tailgate for the big opener. And due to weight-loss initiatives at the time I decided not to eat breakfast while everyone else did. I drank close to the same amount as everyone else that day. However, I believe due to the heat(dehydration), lack of food, and lower tolerance I became inebriated more so than others I was with. Once it was time to enter the game we separated: my family went to one section and my friends and I went to another. Upon getting rejected when trying to enter the game I attempted to re-enter. At the time I believed that I was denied access due to a misunderstanding of how intoxicated I was and was contributed to by our over-hyped cheering for the LSU Tigers. This is why I believed I should try to re-enter. Due to me attempting to re-enter after being denied. It was deemed that I was being disobedient and deserved a public intoxication. I then was escorted to a room for 4 hours until the game concluded upon which my friends picked me up. I then pleaded no-contendere and paid a $300 fee for the public intoxication.

I have had no arrests/ issues since this arrest and have been licensed and employed since summer of 2020. I currently work in a specialty pharmacy that ships to multiple states which is why I am applying for this license.

This occurred while in pharmacy school in Arkansas. Included is a recent attestation that I have completed all obligations for the Arkansas Board of Pharmacy, and I have been in good standings since.

Arkansas State Board of Pharmacy

322 South Main Street, Suite 600 Little Rock, AR 72201
P: 501.682.0190 F: 501.682.0195
asbp@arkansas.gov • www.pharmacyboard.arkansas.gov
John Clay Kirtley, Pharm.D., Executive Director

November 14, 2024

Spencer Willliam Sanson
[redacted]
Metairie LA [redacted]

Via email: [redacted]@gmail.com

Dear Dr. Sanson,

I am writing to confirm that your license with the Arkansas State Board of Pharmacy is in good standing. You have completed all previous ordered obligations and currently have no pending matters with the Board.

If you have any questions, you may contact me at (501) 68-0190.

Sincerely,

Ashley Vailes

Ashley Vailes
General Counsel

ARLINGTON
THE AMERICAN DREAM CITY

Municipal Court

RECORD CHECK
Spencer Sanson
For date of birth-see request form

Citation #	Offense Date	Charge	Plea/Judgment	Final Disposition	Paid/Outstanding
NO RECORDS					

Effective September 1st, 2017-Texas Code of Criminal Procedures, Article 44.2812 does not allow the release of municipal court records on final conviction or deferred dismissal cases, after a period of five years, following final disposition.

Municipal Court retains Class C misdemeanor records for a period of 5 years following final disposition of the case.

This should not be taken as a comment on the retention of records maintained by anybody other than the Arlington Municipal Court.

Any charges greater than a Class C misdemeanor should be directed to Tarrant County.

Date 8/15/2024

Deborah Hill
Deputy Court Clerk
Arlington Municipal Court

MUNICIPAL COURT OF ARLINGTON TEXAS

Arlington Police Department
Compact

Print Date/Time: 10/26/2018 07:25
Login ID:
Case Number: [redacted]

ORI Number: Arlington Police Department TX2200100

Case Details:

Case Number: 2018-02450514
Location: 900 E RANDOL MILL RD Arlington,TX 76011
Incident Type: Public Intoxication
Occured From: 09/02/2018 17:47
Occured Thru: 09/02/2018 17:47
Reported Date: 09/02/2018 17:47 Sunday
Reporting Officer ID: 2799-Ritchie Status: Closed Status Date: 09/02/2018
Assigned Bureau: Vice Disposition: Arrest - Adult Disposition Date: 09/25/2018

Offenses

No.	Group/ORI	Crime Code	Statute	Description	Counts
1	TX2200100	90E	49.02	PUBLIC INTOXICATION	1

Offense # 1
Group/ORI: TX2200100 Crime Code: 90E Statute: 49.02 Counts: 1 Attempt/ Commit Code: Commit
Description: PUBLIC INTOXICATION Offense Date: 09/02/2018
Scene Code: Arena/Stadium/etc Bias/Motivation: No Bias
Gang Related: No
IBR Seq. No: 1

Offender Suspected of Using
Alcohol: No
Drugs: No
Computer: No

Subjects

Type	No.	Name	Address	Phone	Race	Sex	DOB/Age
Suspect	1	Sanson, Spencer William	[redacted]	[redacted]	W	M	[redacted] 25
Victim	1	State of Texas	620 W DIVISION ST Arlington,TX 76011	(817)459-5700			

Arlington Police Department
Compact

Print Date/Time: 10/26/2018 07:25
Login ID: [redacted]
Case Number: [redacted]

ORI Number: Arlington Police Department TX2200100

Subject # 1-Suspect

Primary: No
Name: Sanson, Spencer William
Address: [redacted]
Conway AK
Primary Phone: [redacted]

Suspect Type: Arrestee
Race: W
Sex: M
DOB: [redacted]
Height: [redacted]
Weight: [redacted]
Build: Medium
Eyes:
Hair:
Age: [redacted]
DVL #: [redacted]
State: AR

Related Offenses

Group/ORI	Crime Code	Statute	Description
TX2200100	90E	49.02	PUBLIC INTOXICATION

Subject # 1-Victim

Primary: No
Name: State of Texas
Address: 620 W DIVISION ST
Arlington TX 76011
Primary Phone: (817)459-5700

Victim Type: Society
State:

Related Offenses

Group/ORI	Crime Code	Statute	Description
TX2200100	90E	49.02	PUBLIC INTOXICATION

Arrests

Arrest No.	Name	Address	Date/Time	Type	Age
42685A	Sanson, Spencer William	[redacted] Arlington,TX [redacted]	09/02/2018 17:47	On-View	25

Arrest # 42685 A

Name: Sanson, Spencer William
Address: [redacted]
Conway, AK
Phone: [redacted]

Date/Time: 09/02/2018 17:47
Type: On-View
Race: W
Sex: M
DOB: [redacted]
Height: [redacted]
Weight: [redacted]
Build: Medium
Eyes:
Hair: [redacted]
Marital: Married
DVL#: [redacted]
State: AR

Location: 900 E RANDOL MILL RD
Arlington,TX 76011

Age at Arrest: 25 **Resident Status:** Unknown

Arresting Officers	Bureau	School Resource Officer	Weapon Codes
2799-Ritchie		No	*Unarmed

Arrest Charges

No.	Group/ORI	Crime Code	Statute	Description
1	TX2200100	90E	49.02	PUBLIC INTOXICATION

Counts: 1 **Attempt/Commit:** Commit
Other ORI: No

Property

Date	Code	Type	Make	Model	Description	Tag No.	Item No.

Vehicles

No.	Role	Vehicle Type	Year	Make	Model	Color	License Plate	State

Arlington Police Department
Compact

Print Date/Time: 10/28/2018 07:25
Login ID:
Case Number: [redacted]

ORI Number: Arlington Police Department TX2200100

Routing:

Case, Officer: hernandeze3173, Supervisor: Bryanta2613, Merged By: carmonas3163

ARLINGTON POLICE DEPARTMENT

FIELD CASE REPORT CASE# 2018-02450514

EVENT

REPORTED DATE/TIME	OCCURRED INCIDENT TYPE	LOCATION OF OCCURRENCE
9/2/2018 5:47 PM	Public Intoxication	900 E RANDOL MILL RD ARLINGTON, TX 76011
OCCURRED FROM DATE/TIME	OCCURRED THRU DATE/TIME	
09/02/2018 17:47	09/02/2018 17:47	

OFFENSES

	STATUTE/DESCRIPTION	COUNTS	ATTEMPT/COMMIT
	49.02 PUBLIC INTOXICATION		Commit

SUBJECT

JACKET/SUBJECT TYPE	NAME (LAST, FIRST, MIDDLE, SUFFIX)
Adult Suspect	Sanson, Spencer William
DOB / AGE or AGE RANGE	ADDRESS (STREET, CITY, STATE, ZIP)
[redacted]	[redacted] Conway , AK

RACE	SEX	HEIGHT or RANGE	WEIGHT or RANGE	HAIR	EYE
W	M	5'10	220	BRO	BLU

DL NUMBER/STATE	PRIMARY PHONE	PHONE #2	PHONE #3

SUBJECT

JACKET/SUBJECT TYPE	NAME (LAST, FIRST, MIDDLE, SUFFIX)
Business Victim	State of Texas ,
DOB / AGE or AGE RANGE	ADDRESS (STREET, CITY, STATE, ZIP)

RACE	SEX	HEIGHT or RANGE	WEIGHT or RANGE	HAIR	EYE

DL NUMBER/STATE	PRIMARY PHONE	PHONE #2	PHONE #3

SUBJECT

JACKET/SUBJECT TYPE	NAME (LAST, FIRST, MIDDLE, SUFFIX)
DOB / AGE or AGE RANGE	ADDRESS (STREET, CITY, STATE, ZIP)

RACE	SEX	HEIGHT or RANGE	WEIGHT or RANGE	HAIR	EYE

DL NUMBER/STATE	PRIMARY PHONE	PHONE #2	PHONE #3

Disclaimer: For Law Enforcement Use Only Not For Public Dissemination.

REPORTING OFFICER	DATE	REVIEWED BY
Ritchie #2799	9/2/2018	Bryant, Ann

ARLINGTON POLICE DEPARTMENT

FIELD CASE REPORT CASE# 2018-02450514

SUMMARY NARRATIVE

Contact was made with the subject after subject had attempted to make entry into the Cowboys Stadium and was being refused by Cowboy's security. Subject attempted once again after being told not to come in due to the security stated subject had been drinking, had slurred speech was stumbling whenever he walked and had the odor commonly associated with alcohol omitting from his breath. Subject was arrested for public intoxication.

NARRATIVE

On September 2nd, 2018 at approximately 1800 hours, I Officer Ritchie ID #2799 was working in an off duty capacity at the Cowboys stadium located at 900 E Randol Mill Rd in Arlington, TX. I was assigned to be the lot 4 parking lot, I heard over the radio a motor officer request Arlington PD assistance due to an intoxicated subject. Once I arrived on scene I made contact with Sergeant Brown with Southlake Police Department who advised that he had made contact with the subject later identified to me as Spencer Sanson W/M DOB [redacted] Sergeant Brown advised that Mr. Sanson had initially tried to make entry into the LSU side student level entry and had been turned away by Cowboy's security who stated they believed he might have been intoxicated and could not allow him entry into the stadium. The subject then left with his friends who stated they would take possession of him. Subject then went back to entrance where again he attempted to make entry. Cowboy's security advised once again that he could not make entry into the stadium due to his level of intoxication. That is whenever they called APD. I did notice Mr. Sanson who was already seated due to Sergeant Brown. He had the strong order of alcohol omitting from his breath as well as he was slurring his words as he was speaking with me. His friends were near by but due to the fact that they did not have the availability to keep him from the entrance the first time he was a danger to himself his friends were not able to keep him safe. In order to keep Mr. Sanson safe I advised that he was going to be placed under arrest for public intoxication and asked him to stand up. I did assist Mr. Sanson in standing up while I was doing so and walking over to the mule to be transported I noticed that Mr. Sanson seemed to be having a hard time walking in a straight line, he did seem to stumbling quite a bit while I was escorting home to the mule. Mr. Sanson was searched incident to arrest no contra bound was found He was then transported to the holding facility located underneath Cowboy's stadium. I then released him to the booking staff at the Cowboys stadium. subject was released without incident citation #000800270 was filled out for public intoxication and left with the jail staff as an arrest.

Nothing further at this time Officer Ritchie ID #2799, beat 270.

REPORTING OFFICER	DATE	REVIEWED BY
2799 Ritchie	9/2/2018	Bryant, Ann 09/03/2018

ARLINGTON POLICE DEPARTMENT

ARREST INFORMATION CASE# 2018-02450514

DETAILS

ARREST DATE/TIME	ARREST TYPE	ARRESTING OFFICER
9/2/2018 5:47 PM	On-View	2799 Ritchie

LOCATION OF ARREST: 900 E RANDOL MILL RD ARLINGTON, TX

ARRESTEE

SUBJECT

SUBJECT TYPE	NAME (LAST FIRST MIDDLE SUFFIX)
	Sanson, Spencer William

DOB	AGE	ADDRESS (STREET, CITY, STATE, ZIP)
[redacted]	25	[redacted] Conway, AK

RACE	SEX	HEIGHT	WEIGHT	HAIR COLOR	EYE COLOR
W	M	[redacted]			

DL NUMBER/STATE	PRIMARY PHONE	PHONE #2	PHONE #3

CHARGES

CHARGES

STATUTE / DESCRIPTION / DISPOSITION	COUNTS	ATTEMP/CONSPT
49.02 PUBLIC INTOXICATION	1	Commit

NARRATIVE

Contact was made with the subject after subject had attempted to make entry into the Cowboys Stadium and was being refused by Cowboy's security. Subject attempted once again after being told not to come in due to the security stated subject had been drinking, had slurred speech was stumbling whenever he walked and had the odor commonly associated with alcohol omitting from his breath. Subject was arrested for public intoxication.

REPORTING OFFICER	DATE	REVIEWED BY
2799 Ritchie	9/2/2018	

OF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: FAST Access Specialty Therapeutics, LLC dba InfuCare Rx Of LA

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH03995

Physical Address: 2400 Veterans Memorial Blvd., Ste 480

City: Kenner State: LA Zip: 70062

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-327-8881 Website: www.infucarerx.com

Licensing Company Email: licensing@infucarerx.com

Section 2: Personal Information

First: Dhara Middle: Devendra Last: Patel

Alias(es, nicknames, name changes, etc.): N/A

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Armstrong Atlantic State University		Unknown	
Address	**City**	**State**	**Zip**
11935 Abercorn St.	Savannah	GA	31419
Diploma/Degree obtained, if any			
Bachelors Degree in Liberal Arts			

School Name		From - To (MM/YY – MM/YY)	
Richmond Hill High School		Unknown	
Address	**City**	**State**	**Zip**
Unknown			
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
Unknown-Present	[redacted]			
Unknown-Present				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
InfuCare Rx, Inc.			2015 - Present
Business Address	**City**	**State**	**Zip**
695 Us Hwy 46, STE 100	Fairfield	NJ	07004
Phone	**Title**		
877-828-3940	President		
Description of Duties			
President of InfuCare Rx, Inc.			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dhara Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 12/2/2025

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Passaic

I, Dhara Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature — **Date:** 12/2/2025

Subscribed and Sworn to before me this 2nd day of December 2025.

Notary Public Signature

DANIEL ALBARRAN
Notary Public, State of New Jersey
My Commission Expires Dec 15, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: FAST Access Specialty Therapeutics, LLC dba InfuCare Rx Of LA

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH03995

Physical Address: 2400 Veterans Memorial Blvd

City: Kenner State: LA Zip: 70062

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-327-8881 Website: www.infucarerx.com

Licensing Company Email: licensing@infucarerx.com

Section 2: Personal Information

First: Tiffany Middle: Samantha Last: Scheppers

Alias(es, nicknames, name changes, etc.): N/A

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Missouri St Louis		Unknown	
Address	City	State	Zip
1 University Blvd.	St. Louis	MO	63121-4400
Diploma/Degree obtained, if any			
MBA not completed			

School Name		From - To (MM/YY – MM/YY)	
St. Louis University School of Law		8/1996-5/1999	
Address	City	State	Zip
100 N Tucker Blvd	St. Louis	MO	63101
Diploma/Degree obtained, if any			
Juris Doctor			

School Name		From - To (MM/YY – MM/YY)	
St. Louis University		8/1993-5/1999	
Address	City	State	Zip
1 N Grand Blvd	St. Louis	MO	63101
Diploma/Degree obtained, if any			
Nursing			

School Name		From - To (MM/YY – MM/YY)	
Cornelia Connelly School of the Holy Child Jesus		1984-1988	
Address	City	State	Zip
2323 W Broadway	Anaheim	CA	92804
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/2015-present	[redacted]			
3/2013-8/2015				
1/2000-3/2013				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Infucare Rx Inc.			03/2021 - Present
Business Address	**City**	**State**	**Zip**
695 US Hwy 46, STE 100	Fairfield	NJ	07004
Phone	**Title**		
877-828-3940	General Counsel and Corporate Secretary		
Description of Duties			
Oversee all corporate, regulatory, employment, litigation, and compliance legal matters.			

Business Name			From - To (MM/YY – MM/YY)
Asembia, LLC			07/2019 - 12/2020
Business Address	**City**	**State**	**Zip**
200 Park Ave #300	Florham Park	NJ	07932
Phone	**Title**		
973-564-8004	Senior Vice President, General Counsel and Chief Compliance Officer; Corporate Secretary		
Description of Duties			
Oversee all corporate, regulatory, employment, litigation, and compliance legal matters; Current Officer acting as Corporate Secretary; Advised executive leadership and Board of Directors on complex regulatory compliance matters.			

Business Name			From - To (MM/YY – MM/YY)
Outside General Counsel			03/2019 - 07/2019
Business Address	**City**	**State**	**Zip**
N/A	Charlotte	NC	N/A
Phone	**Title**		
314-808-3974	Outside General Counsel		
Description of Duties			
Delivered outsourced general counsel and compliance services to, and temporary coverage for, in-house general counsel and chief compliance officer clients, re: health care, pharma, biotech and CRO/CSO companies on legal and regulatory.			

Business Name			From - To (MM/YY – MM/YY)
SYNEOS HEALTH, INC			08/2012 - 03/2019
Business Address	**City**	**State**	**Zip**
1030 Sync Street	Morrisville	NC	27560
Phone	**Title**		
919-876-9300	Senior Associate General Counsel & Chief Compliance Officer; Commercial Division		
Description of Duties			
Supervised legal and compliance teams across US, Canada, Europe and APAC, reporting directly to the General Counsel.			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tiffany Scheppers

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/2025

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Mecklenburg

I, Tiffany Scheppers, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/19/2025

Date

Subscribed and Sworn to before me this 19 day of NOV 2025.

Notary Public Signature

My Commission Expires
Nov 7, 2029

NIMESH R. PATEL NOTARY PUBLIC MECKLENBURG COUNTY, N.C.

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: FAST Access Specialty Therapeutics, LLC dba InfuCare Rx Of LA

NV Pharmacy or Outsourcing facility license # (if applicable): PH03995

Physical Address: 2400 Veterans Memorial Boulevard, Suite 480

City: Kenner State: LA Zip: 70062

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-327-8881 Toll Free # (NAC 639.708, NRS 639.23286): 877-327-8881

Fax: 844-504-3278 Contact Email: licensing@infucarerx.com

Website: www.infucarerx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Spencer Sanson

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24440

Name of Designated Person(s) as defined by revised USP-797 guidelines: Phillip Andrews, Ian Spinney

Email of Designated Person(s): pandrews@infucarerx.com and ispinney@infucarerx.com

Telephone of Designated Person(s): 877-327-8881

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

   ■ Category 1 ■ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ■ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? **No** ☐ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 10/28/2025

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? **N/A** ☐ Yes ■ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Monthly

10. Will you be performing sterile hazardous drug compounding? ☐ Yes ■ No

If you marked "**Yes**", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Amikacin Sulfate, Ampicillin Sodium, Avycaz, Azithromycin, Aztreonam, ceFAZolin Sodium, Cefepime HCl, cefOXitin, Sodium, cefTAZidime, cefTRIAXone , DAPTOmycin, Ertapenem, Gentamicin Sulfate, IMIPENEM/CILASTATIN, Meropenem, Micafungin Sodium, MYCAMINE, Nafcillin, Oxacillin Sodium, Penicillin G Potassium, PENICILLIN G, POTASSIUM, PFIZERPEN, PIPERACILLIN SODIUM/TAZOB, TEFLARO, Tigecycline, Unasyn, Vancomycin HCl, Zerbaxa, TPN, Hydration

12. What laboratory performs your sterility or endotoxin testing?

Name: N/A

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

Document Ref: H84O7-6PMNU-EPTNM-6AC55

13. What is your procedure for visual inspection of compounded sterile products?
We visually inspect each compounded sterile product under a black and white light. The visual inspection is done once the compounded sterile product is prepared (and again prior to shipping if stored in the refrigerator immediately after compounding).

14. How often do you perform glove fingertip and medial fill testing?
Every 6 months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
Initially, staff members are trained to ensure qualification in compounded sterile preparations. The knowledge check is done via SoleSource training and the competency is completed via hands on visual observations. Ongoing training is done annually for knowledge check via SoleSource, and visual observation competencies via Simplifi. Additionally, gloved fingertip and thumb sampling and media fill is done every 6 months.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
A daily cleaning is done using a germicidal disinfectant (sterile TB1-3300) at all ISO 5 and ISO7 area, high tough areas, interior surfaces, pass through, work surfaces, floors,and sink. All the listed areas are then wiped using sterile Isopropyl Alcohol 70%. A monthly cleaning is done using a sproficidal agent (Peridox RTU) in all the areas for daily cleaning, ceilings, walls, doors, equipment outside PEC, storage bin, and furniture surfaces.

17. Who performs the sterile compounding process at your facility?
Compounding staff includes anyone that has completed all parts of the initial and onboarding training.

18. Who is responsible and accountable for the sterile compounding process at your facility?
Designated Person

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
The products are shipped in packaging to maintain the refrigerated temperature requirements. Ice bricks and bubble wrapping is also used to maintain the product efficacy.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A - we do not dispense any hazardous compounded medications		
2. Are you complying with all USP 800 guidelines?	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device: N/A - we do not dispense any hazardous compounded medications		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? N/A - we do not dispense any hazardous compounded medications

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?
N/A - we do not dispense any hazardous compounded medications

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:
N/A - we do not dispense any category 3 compounds

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?
N/A - we do not dispense any category 3 compounds

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? **N/A** Yes No

4. What is the frequency for completing volumetric active air sampling?
N/A - we do not dispense any category 3 compounds

Document Ref: H84O7-6PMNU-EPTNM-6AC55

5. What is the frequency for completing surface sampling? N/A - we do not dispense any category 3 compounds	
6. What is the frequency for using sporicidal agents? N/A - we do not dispense any category 3 compounds	
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes ■ No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes ■ No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Spencer Sanson

Name of Person who Completed the Form

Pharmacist in Charge

Title

Spencer Sanson

Signature (copies or stamps not accepted)

11 / 11 / 2025

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

Document Ref: H84O7-6PMNU-EPTNM-6AC55

CERTIFICATE *of* SIGNATURE

REF. NUMBER
H84O7-6PMNU-EPTNM-6AC55

DOCUMENT COMPLETED BY ALL PARTIES ON
11 NOV 2025 21:19:04
UTC

SIGNER	TIMESTAMP	SIGNATURE
SPENCER SANSON EMAIL SSANSON@INFUCARERX.COM	SENT 11 NOV 2025 16:23:14 VIEWED 11 NOV 2025 16:26:48 SIGNED 11 NOV 2025 16:27:16	Spencer Sanson IP ADDRESS [redacted] LOCATION NEW ORLEANS, UNITED STATES
RECIPIENT VERIFICATION	EMAIL VERIFIED 11 NOV 2025 16:26:48	
TIFFANY SCHEPPERS EMAIL TSCHEPPERS@INFUCARERX.COM	SENT 11 NOV 2025 16:23:14 VIEWED 11 NOV 2025 21:18:42 SIGNED 11 NOV 2025 21:19:04	Tiffany Scheppers, Corporate Secretary IP ADDRESS [redacted] LOCATION WAXHAW, UNITED STATES
RECIPIENT VERIFICATION	EMAIL VERIFIED 11 NOV 2025 21:18:42	

Louisiana Board of Pharmacy

3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov ~ Telephone: 225.925.6496 ~ E-Mail: info@pharmacy.la.gov

Pharmacy Inspection Report

Permit Data	Report No. 005	Inspected by: Dennis	Territory: Dennis	Date: 1/16/2025

Reason for Visit: ☐ Initial Survey ☒ Service Review ☐ Follow-Up Survey ☐ Compliance Check

1. Pharmacy Name	2. Permit No.	3. CDS License	4. Classification	5. Renewal Yr.
Infucare Rx of LA	7442	49472	IR	2025

6. Physical Address	7. City, State, Zip	8. CSP License
2400 Veterans Memorial Blvd. Ste. 480	Kenner, La. 70062	50 N/A ☐

9. Phone No.	10. Authorized email address for report:	11. Rx Software	12. DEA No.	DEA Expiration
504-885-3378	pandrews@infucarerx.com	CPR+	[redacted]	9/30/2025

13. Store Hours	14. Pharmacy Hours
N/A ☒	9a-5p Mon-Fri; Closed Sat and Sun

15. Pharmacist-In-Charge Name	16. PIC License No.	17. Renewal Year	18. PIC Present During Inspection?
Phillip P. Andrews	15873	2025	Yes ☒ No ☐

	Professional and Occupational Standards		
19	Are permit credentials current and active? LA R.S. 37:1201	Yes ☒ No ☐ N/A ☐	
20	Does permit staff administer immunizations? LA R.S. 37:1218, 1218.1; LAC 46:LIII.521	No	
21	Does permit mail or deliver prescriptions to patients?	Yes	Mail
	If yes, are prescriptions delivered or mailed to other states?	Yes	Mail
22	Is permit licensed in any state other than Louisiana? If yes, list.	Yes	multiple states
23	Does permit provide "office use" medication to providers?	No	
24	Does the permit participate in a drug take-back program?	No	
	If yes, is it properly registered with the DEA? 21 CFR Part 1317	Yes ☐ No ☐ N/A ☒	
25	Does the prescription department provide sufficient space, fixtures, supplies and equipment commensurate with the nature and scope of the pharmacy's practice? LAC 46:LIII.1103.A	Yes ☒ No ☐ N/A ☐	
26	Is temperature in drug storage area within USP standards? LAC 46:LIII.1103.A, E	Yes ☒ No ☐ N/A ☐	
27	Is permit clean and orderly? Are medications and supplies stored appropriately? LAC 46:LIII.1103.A	Yes ☒ No ☐ N/A ☐	
28	Is permit well-lit? LAC 46:LIII.1103.A	Yes ☒ No ☐ N/A ☐	
29	Is a sink providing hot and cold running water located within the prescription department? LAC 46:LIII.1103.C	Yes ☒ No ☐ N/A ☐	
30	Is refrigerator and/or freezer temperature within USP standards? (Document temperature) LAC 46:LIII.1103.E	Yes ☒ No ☐ N/A ☐	37, 39, 43, 41-refrigerators
31	Does the permit have a working security system? LAC 46:LIII.1103.F	Yes ☒ No ☐ N/A ☐	
32	Does the permit have general security measures in place? LAC 46:LIII.1103.F	Yes ☒ No ☐ N/A ☐	
33	Does the permit have access to required references? LAC 46:LIII.1103.H	Yes ☒ No ☐ N/A ☐	
34	Are misbranded, non-labeled, or expired medications removed from active inventory? LAC 46:LIII.2501	Yes ☒ No ☐ N/A ☐	
35	Does the permit maintain any off-site inventory, such as an EDK or AMS? If yes, list.	No	
36	Does the permit maintain a Policy & Procedure manual? LAC 46:LIII.1105.D	Yes ☒ No ☐ N/A ☐	
37	Are credentials of licensed personnel current and active? LA R.S.37:1201	Yes ☒ No ☐ N/A ☐	
38	Is PST:PNT/CPT/PTC ratio compliant with regulations? (Document ratio) LAC 46:LIII.709, 907	Yes ☒ No ☐ N/A ☐	4 PST; 5 CPT
39	Does permit provide patient counseling? LAC 46:LIII.517	Yes ☒ No ☐ N/A ☐	
40	Does the permit utilize a method for the positive identification of a pharmacist as defined in LAC Title 46:1119?	Yes ☒ No ☐ N/A ☐	Compliant Software
41	Are required permit records retained on site?	Yes	
42	Does permit utilize CSOS or paper DEA Form 222?	N/A	
	Are DEA Forms 222 properly executed? 21 CFR Part 1305	Yes ☐ No ☐ N/A ☒	
	List wholesalers and reverse distributors used:		
43	Are CDS invoices retrievable and dated? 21 CFR 1304.21, 1304.22, LAC 46:LIII.2735	Yes ☐ No ☐ N/A ☒	
44	Are CDS inventories conducted as required? (Annual, PIC Change, Theft/Loss) List dates LAC 46:LIII.2733	Yes ☒ No ☐ N/A ☐	1/3/25-annual (zero inv.)
45	Are CDS medications stored in a manner compliant with LAC Title 46:2717?	Yes ☐ No ☐ N/A ☒	
46	Is required information present on CDS prescriptions? LAC 46:LIII.2745	Yes ☐ No ☐ N/A ☒	
47	Pharmacist on-duty confirms an understanding of the Pharmacist's Corresponding Responsibility. LAC 46:LIII.2745.B,C	Yes	
48	Are prescriptions filed in a manner compliant with laws and regulations? LAC 46:LIII.1123	Yes ☐ No ☐ N/A ☒	
49	Does the permit perform non-sterile compounding? LAC 46:LIII.2535	No	N/A
50	Does the permit perform sterile compounding? LAC 46:LIII.2535	Yes	See Universal form for USP <797> compliance

Louisiana Board of Pharmacy

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Pharmacy Inspection Report

Permit Data	Report No. 005	Inspected by: Dennis	Territory: Dennis	Date: 1/16/2025

Pharmacy Name	Permit No.	CDS License	Classification	Renewal Yr.
Infucare Rx of LA	**7442**	**49472**	**IR**	**2025**

51. Pharmacy Staff Present During Inspection	License No.	Renewal Year
Spencer Sanson, PST	24258	2025
Ian Spinney, PST	22249	2025
Tiffany Lawson, PST	19662	2025
Naiomi Arroyo, CPT	13212	2024-2025
Kierra Downing, CPT	15278	2024-2025
Casey Rooney, CPT	9678	2024-2025
Tiffany Mcgee, CPT	7693	2024-2025
Kelly Williams, CPT	8709	2024-2025

52. Prior Inspection Date:	53. Deficiencies/Non-Compliance on Prior Inspection	54. Correction(s) Observed
7/11/2023	None	None

55. Comments: NOTE: A finding of satisfactory compliance is not indicative of a detailed inspection/investigation and does not exclude the permit and/or staff from possible future violations of compliance.
-Permit has non-resident permits.
42-46-Permit does not procure or stock CDS medications.
-Reminder to obtain annual CE hours and ensure they are uploaded into NABP CE monitor prior to renewing credential.
-Reminder to update with Board office any changes of address/employment for licensees.

Sterile compounding- Permit has an ISO 5 certified LAFW located in an ISO 7 buffer room that opens to an ISO 8 anteroom. Hood and rooms were certified by ENV Services on 6/3/2024 and 12/17/2024 with passing results on all tests. Environmental sampling has also been completed with no growth reported. All employee competencies have been completed per USP 797. Daily and monthly cleaning records reviewed. Permit compounds low risk sterile products. Sample of compounding records viewed. No high risk or hazardous.

Inspection report emailed to pandrews@infucarerx.com

Authorized Signature & Title

Daniel M. Dennis, R.Ph.
Compliance Officer, Louisiana Board of Pharmacy

Louisiana Board of Pharmacy Online eLicense Website

The Louisiana Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, and further, performs daily updates to the website. Therefore, the website is a secure and primary source for credential verification, as authentic as a direct inquiry to the Board.

Lookup Detail View

Name and Address

Name	PublicAddress
Infucare Rx of LA	2400 Veterans Memorial Blvd Ste 480 Kenner, LA 70062-8728

Credential Information with supervision

License	License Type	Issue Date	Expiration Date	Status	Pharmacist In Charge
PHY.007442-IR	Pharmacy - Community ~ Independent	03/07/2017	12/31/2025	Current, without restriction or limitation	Phillip P. Andrews

List of Current Employees

Name	License	License Type	Expiration Date	Status
Aris M. Christophe	CPT.008500	Certified Pharmacy Technician	06/30/2026	ACTIVE
Charleetha Denise Lewis	CPT.017086	Certified Pharmacy Technician	06/30/2026	ACTIVE
Kelly M. Williams	CPT.008709	Certified Pharmacy Technician	06/30/2026	ACTIVE
Phillip P. Andrews	PST.015873	Pharmacist	12/31/2025	ACTIVE
Tiffany J. Lawson	PST.019662	Pharmacist	12/31/2025	ACTIVE
Tiffany S. McGee	CPT.007693	Certified Pharmacy Technician	06/30/2026	ACTIVE

CDS Schedules and Restrictions

I	II	II-N	III	III-N	IV	V	Restrictions	Alternative Privileges

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Louisiana Board of Pharmacy Online eLicense Website

The Louisiana Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, and further, performs daily updates to the website. Therefore, the website is a secure and primary source for credential verification, as authentic as a direct inquiry to the Board.

Lookup Detail View

Name

Name
Infucare Rx of LA

Credential Information

License	License Type	Issue Date	Expiration Date	Status
CSP.000050-PHY	Compounded Sterile Preparation Pharmacy	09/19/2022	12/31/2025	Current, without restriction or limitation

CDS Schedules and Restrictions

I	II	II-N	III	III-N	IV	V	Restrictions	Alternative Privileges

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Louisiana Board of Pharmacy Online eLicense Website

The Louisiana Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, and further, performs daily updates to the website. Therefore, the website is a secure and primary source for credential verification, as authentic as a direct inquiry to the Board.

Lookup Detail View

Name and Address

Name	PublicAddress
Infucare Rx of LA	2400 Veterans Memorial Blvd Ste 480 Kenner, LA 70062-8728

Credential Information

License	License Type	Issue Date	Expiration Date	Status
CDS.049472-PHY	CDS License - Pharmacy	03/07/2017	12/31/2025	Current, without restriction or limitation

CDS Schedules and Restrictions

I	II	II-N	III	III-N	IV	V	Restrictions	Alternative Privileges
No	Yes	Yes	Yes	Yes	Yes	Yes		

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Universal Inspection Form

			Inspection Information
Business e-Profile ID:			
Legal Business Name:	Infucare Rx of LA	**Conference Call Date:**	
Doing Business As (DBA):	Infucare Rx of LA	**Start Time: 24-hour format (13:00)**	
Address:	2400 Veterans Memorial Blvd. Ste. 480	**End Time: 24-hour format (13:00)**	
City:	Kenner	**Onsite Inspection Date(s):**	1/16/2025
State:	La.	**Start Time(s): 24-hour format (13:00)**	12p
Zip Code:	70062	**End Time(s): 24-hour format (13:00)**	230p
Telephone number:	504-885-3378	**Inspector Name:**	Daniel Dennis
Toll free number:		**Inspection Performed by (NABP, State, etc):**	Louisiana Board of Pharmacy
Fax number:	504-844-3278	**Observer Name/Affiliation (if applicable):**	
Website:		**Observer Name/Affiliation (if applicable):**	

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.
General Pharmacy-
Nonsterile -
Sterile-
Hazardous-

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed (X)
	Start Time: (24-hour format)	End Time: (24-hour format)	
Sunday			x
Monday	9a	5p	
Tuesday	9a	5p	
Wednesday	9a	5p	
Thursday	9a	5p	
Friday	9a	5p	
Saturday			x

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Phillip P. Andrews	pandrews@infucarerx.com	
Nonsterile Compounding Supervisor			
Sterile Compounding Supervisor	Phillip P. Andrews	pandrews@infucarerx.com	
Hazardous Compounding Supervisor			

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Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Spencer Sanson	Pharmacist	Y
2	Ian Spinney	Pharmacist	Y
3	Tiffany Lawson	Pharmacist	Y
4	Naiomi Arroyo	Pharmacy Technician	Y
5	Kierra Downing	Pharmacy Technician	Y
6	Casey Rooney	Pharmacy Technician	Y
7	Tiffany Mcgee	Pharmacy Technician	Y
8	Kelly Williams	Pharmacy Technician	Y
9			
10			

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Louisiana Board of Pharmacy	Infucare Rx of LA	7442-IR	12/31/2025
Louisiana Board of Pharmacy	Infucare Rx of LA	49472-CDS	12/31/2025
DEA	Infucare Rx of LA	FF6607280	9/30/2025

Inspector Notes: List states in which Non-Resident licenses are held

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Attachments	
Document Name	**Description**
See attached sheet	

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	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Telepharmacy	
Open to the Public		Central Fill/Processing/Shared Services	
Closed Door	x	Specialty Pharmacy	x
Drive-through window		Handles Medical Marijuana	
Mail/Deliver (in state)		Nuclear Pharmacy	
Mail/Deliver (out-of-state list below)		Manufacturer	
Veterinary Pharmacy		Wholesale Distributor	
Investigational Drugs, Clinical Trials/Research		Provide prescription drugs for "Office Use"	
Institutional		Outsourcing Facility	
Long-Term Care		Nonsterile Compounding	
HMO/PBM only		Nonsterile Hazardous Drug Compounding	
Internet Pharmacy (New Rx)		Sterile Compounding	x
Internet Pharmacy (Refill Rx)		Sterile Hazardous Drug Compounding	

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		**Compounded Sterile Preparations (CSPs) Type "X" for all that apply**	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements	
CNSPs for INDs		CSPs for INDs	
CNSPs which are essential copies of a commerically available drug product on the Drug Shortage List or justified by a documented medical need for an individual patient - If so, list		CSPs which are essential copies of a commercially available drug product on the Drug Shortage List or justified by a documented medical need for an individual patient - If so, list	
CNSPs sold OTC		CSPs sold OTC	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific:		Patient specific:	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	x
Distributed (eg non patient-specific):		Distributed (eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	
Types of CNSPs:		Categories of CSPs:	
Aqueous		Category 1 CSPs	
Nonaqueous		Category 2 CSPs	x

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Specific types:		Category 3 CSPs	
Solid oral preparations		Types of CSPs:	
Liquid oral preparations		Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	
Topical preparations:		Blood-derived or other biological material (eg autologous serum)	
Creams		Injections including infusions	x
Gels		Irrigations for internal body cavities (eg bladder or peritoneal cavity)	
Ointments		Ophthalmic dosage forms	
Lotions		Aqueous preparations for pulmonary inhalation	
Nasal and sinus preparations:		Baths and soaks for live organs and tissues	
Nasal sprays		Implants/ Pellets	
Nasal irrigations		Other (please list):	
Other (please list):			

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Facility Size in Square Feet and Number of PECs		Personnel	
Total Pharmacy size:		Total Pharmacists:	
Nonsterile Compounding Room size:		Number of Compounding Pharmacists	
Nonsterile Compounding powder hoods number:		Total Graduate Students or Residents:	
Nonsterile Hazardous Drugs (HD) Compounding Room size:		Total Student Interns:	
Nonsterile HD Compounding CVE/BSC/CACI hoods number:		Total Technicians:	
Sterile Compounding Ante Room size:		Number of Compounding Technicians	
Sterile Compounding Clean/Buffer Room size:		Of technicians, how many are certified?	
Sterile Compounding Number LAFW hoods/areas:		Of technicians, how many are techs-in-training?	
Sterile Compounding Number BSC hoods:		Total Other Licensed Personnel:	
Sterile Compounding Number CAI/CACI hoods:		Total Other Unlicensed Personnel:	
Negative Pressure Sterile HD Room size:		Ratio #Tech:#RPh present at time of inspection:	
Sterile HD Compounding Number of BSC hoods:		Total Pharmacist Hours Per Week:	
Sterile HD Compounding Number of CACI hoods:		Total Technician Hours Per Week:	

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	

	Volume Dispensed		Volume Distributed
Total Prescriptions Dispensed/day:	47	Total Orders Distributed/day:	
% Veterinary Prescriptions		% Veterinary Orders	
% Controlled Substance Prescriptions		% Controlled Substance Orders	
% Nonsterile Compounded Prescriptions		% Nonsterile Compounded Orders	
% Sterile Compounded Prescriptions	1%	% Sterile Compounded Orders	
% Hazardous Drugs (HD) Prescriptions		% Hazardous Drugs (HD) Orders	

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Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)	17		month
Alaska (AK)			
Arizona (AZ)	3		month
Arkansas (AR)	14		month
California (CA)	5		month
Colorado (CO)	6		month
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)	11		month
Georgia (GA)	1		month
Hawaii (HI)			
Idaho (ID)			
Illinois (IL)			
Indiana (IN)			
Iowa (IA)			
Kansas (KS)			
Kentucky (KY)	2		month
Louisiana (LA)	1148		month
Maine (ME)			
Maryland (MD)	7		month
Massachusetts (MA)			
Michigan (MI)	3		month
Minnesota (MN)	2		month
Mississippi (MS)	20		month
Missouri (MO)			
Montana (MT)			

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States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)			
Nevada (NV)	6		month
New Hampshire (NH)			
New Jersey (NJ)			
New Mexico (NM)			
New York (NY)	1		month
North Carolina (NC)			
North Dakota (ND)	4		month
Ohio (OH)			
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)			
Rhode Island (RI)			
South Carolina (SC)			
South Dakota (SD)			
Tennessee (TN)	6		month
Texas (TX)	10		month
Utah (UT)	3		month
Vermont (VT)			
Virginia (VA)			
Washington (WA)			
West Virginia (WV)			
Wisconsin (WI)			
Wyoming (WY)			
Other:			

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Infucare Rx of LA dba Infucare Rx of LA
e-Profile ID: 0
Inspection Date: 01/00/1900 - 01/16/2025

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)			
1.0	Does the pharmacy have a designated person(s) who meets the requirements in compliance with USP <797> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals (ie, the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions."*** ***If no, go to compliance statements.***	Yes		1.1.3, 2
1.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		18
1.2	The designated person(s) is responsible and accountable for the performance and operation of the facility. ***Per USP, "The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality."***	Yes		2, 4.2, 4.5
1.3	The designated person(s) is responsible for personnel performing sterile compounding or other related functions (eg, quality checks and prescription dispensing of compounded preparations).	Yes		2, 17

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e-Profile ID: 0
Inspection Date: 01/00/1900 - 01/16/2025

		Observation	Inspector Notes	USP Reference(s)
1.4	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented.	Yes		2, 17
1.5	The designated person(s) ensures that SOP revisions are implemented.	Yes		2, 17
1.6	The designated person(s) communicates all SOP revisions to all impacted personnel. ***Inspector note: USP <797> recommends that personnel should also document acknowledgment and communication of SOP changes and revisions.***	Yes		2, 17
1.7	The designated person(s) ensures that personnel demonstrate competency in performing every procedure that relates to their job function.	Yes		2, 17
1.8	The designated person(s) ensures that corrective actions are taken if problems, deviations, out-of-range results, failures, or errors are identified. ***Inspector note: Per USP, "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective."***	Yes		2, 5, 12
2.0	Has the pharmacy developed and implemented SOPs that describe sterile compounding processes and other support activities in compliance with USP <797> standards? ***Inspector note: In order for this to be answered yes, all topics must be addressed if applicable to their business practices.*** ***If no, go to compliance statements.***	Yes		17

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		Observation	Inspector Notes	USP Reference(s)
2.1	**Scope of Practice:** Types of CSPs that are prepared (eg, immediate use, allergenic extracts, Category 1, Category 2, Category 3). Roles and responsibilities of the designated person(s).	Yes		1.5
2.2	**Personnel Training and Evaluation:** Description of initial and ongoing training and competency for the designated person(s), compounding personnel, personnel with direct oversight of compounding personnel, and personnel who only perform restocking or cleaning, and disinfecting duties outside of the primary engineering control (PEC). Description of media-fill testing procedures, hand hygiene and garbing competency, and aseptic manipulation competency. Training and competency assessment of personnel on all sterilization methods and equipment used by the facility. Frequency of training is defined.	Yes		2, 2.2, 10 Box 1, Box 2, Table 2, Table 3
2.3	**Personal Hygiene and Garbing:** Description of the required garb, manner of storage, and order of garbing, including disinfection procedures for reusing goggles, respirators, and other reusable equipment. ***Inspector note: Per USP, the RABS (or pharmaceutical isolator) sleeve and glove changes should (not required) be changed per the manufacturer's recommendations and defined in the facility's SOPs.***	Yes		3, 3.3
2.4	**Facility Design and Engineering Controls:** Description of design requirements to maintain air quality standards and procedures for evaluating, maintaining, and certifying the areas used for compounding.	Yes		4, 4.2
2.5	**Certification and Recertification:** Description of sampling sites and procedures.	Yes		5, 5.1

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		Observation	Inspector Notes	USP Reference(s)
2.6	**Microbiological Air and Surface Monitoring:** Description of the pharmacy's microbiological air and surface monitoring program which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (eg, surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective actions and documentation requirements.	Yes		6, 6.1, 6.2, 6.3
2.7	**Cleaning, Disinfection, and Application of Sporicidal Disinfectants and Sterile 70% IPA:** Description of procedures for cleaning, disinfecting, and applying sporicidal disinfectants and include the frequency, methods, locations of cleaning, and documentation requirements.	Yes		7, 7.2 Box 7, Box 8
2.8	**Equipment:** Description of procedures for the calibration, maintenance, cleaning, use of the equipment, and documentation requirements.	Yes		9.1, 10, 20
2.9	**Components:** Description of procedures that address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and container closures.	Yes		9.3
2.10	**Master Formulation and Compounding Records:** Description of procedures for developing and maintaining MFRs and required information, documentation, and record-keeping requirements for MFRs and CRs.	Yes		11.1, 11.2, 20

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		Observation	Inspector Notes	USP Reference(s)
2.11	**Release Inspections and Testing:** Description of release testing procedures (eg, visual inspections and/or sterility and endotoxin testing), out-of-specification procedures, corrective action procedures, and documentation requirements.	Yes		12, 18, 20
2.12	**Labeling:** Procedures for labeling and label verification (confirming against the prescription or medication order, the MFR, and the CR) in order to prevent errors, CSP mix-ups, and required displayed information.	Yes		13
2.13	**CSP handling, storage, packaging, shipping, and transport:** Processes and techniques for handling, storing, packaging, and transporting CSPs that include temperature monitoring, excursions, shipping containers, packaging requirements, and selected transportation modes.	Yes		19
2.14	**Documentation:** Record keeping requirements and procedures for documentation maintenance and storage. ***Inspector note: USP requires readily retrievable records for two years; however, it is acknowledged that state or accreditation organizations may require records for a longer period of time.***	Yes		20

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Sterile Compounding Inspection for USP <797>

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		Observation	Inspector Notes	USP Reference(s)
2.15	**Sterilization and Depyrogenation:** Description of methods used for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment. ***If not applicable to their business practices, inspector should answer statement as N/A.***	Yes		10
2.16	**Immediate Use CSPs:** Description of processes followed to meet all conditions of exemption from the requirements for Category 1, Category 2, and Category 3 CSPs. ***If not applicable to their business practices, inspector should answer statement as N/A.***	Yes		1.3
2.17	**Blood/Biological Handling:** Description of processes used to avoid cross-contamination and meet applicable regulatory requirements. ***If not applicable to their business practices, inspector should answer statement as N/A.***	Yes		1.1.2
2.18	**Allergenic Extracts:** Description of procedures for training, competency assessments, personnel hygiene and garbing, facility requirements, cleaning and disinfecting, beyond use dates (BUDs), labeling, storage, shipping and transporting, and documentation. ***If applicable to their business practices, please complete the Allergenic Extracts module.*** ***If not applicable to their business practices, inspector should answer statement as N/A.***	Yes		21

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Inspection Date: 01/00/1900 - 01/16/2025

		Observation	Inspector Notes	USP Reference(s)
	CSPs - Immediate Use, Proprietary Vial/Bag Systems, and Blood-Derived			1
3.0	Does the pharmacy prepare and dispense compounded sterile preparations for direct and immediate use?	N/A		1.3
4.0	Does the pharmacy meet all conditions specified in USP <797> for CSPs compounded for direct and immediate use? ***Inspector note: Per USP <797>, all conditions must be met to qualify for exemptions of the requirements for Category 1, Category 2, and Category 3 CSPs.*** ***If no, go to compliance statements.***	N/A		1.3
4.1	Aseptic techniques, processes, and procedures are followed. ***Inspector note: Per USP <797>, facility SOPs must describe procedures followed "to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs."***	N/A		1.3
4.2	Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. ***Review personnel records to verify.***	N/A		1.3

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		Observation	Inspector Notes	USP Reference(s)
4.3	Preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs. ***Inspector note: Examples of this include approved labeling and/or published or unpublished stability and compatibility studies.***	N/A		1.3
4.4	Preparation involves not more than three (3) different sterile products (eg, ingredients and/or components in a single container).	N/A		1.3
4.5	Unused components from a single-use container are discarded after the preparation for one individual patient is complete (ie, single-dose containers are not used for more than one patient).	N/A		1.3
4.6	Administration begins within four hours of the start of the preparation, and if not, the preparation is discarded. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3
4.7	Unless the person preparing the preparation is administering or witnessing administration, the preparation is labeled with names and amounts of all active ingredients, name or initials of preparer, and exact four-hour time period in which administration must begin. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Infucare Rx of LA dba Infucare Rx of LA
e-Profile ID: 0
Inspection Date: 01/00/1900 - 01/16/2025

		Observation	Inspector Notes	USP Reference(s)
5.0	Does the pharmacy prepare proprietary bag and vial systems (ex. addEASE, ADD-Vantage, Mini Bag Plus, Vial2Bag) in compliance with USP <797> standards? ***Inspector note: Docking and activation of proprietary bag and vial systems for immediate administration to an individual patient is out of scope of USP <797> and may be performed outside of an ISO Class 5 environment.*** ***If no, go to the compliance statements.*** ***If the pharmacy does not stock, prepare, and/or dispense any proprietary vial and bag systems, inspector should answer statement as N/A.***	N/A		1.4
5.1	Docking for *future activation* and administration is performed in an ISO Class 5 environment and in accordance with requirements of USP <797>, with the exception of BUD assignment.	N/A		1.4
5.2	BUD assignment is not longer than specified in the manufacturer's labeling.	N/A		1.4
6.0	Does the pharmacy meet the conditions specified in USP <797> for CSPs to be prepared per approved labeling? ***Inspector note: Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is considered outside the scope of the USP chapter.*** ***If no, go to compliance statements.*** ***If the pharmacy only <u>compounds</u> sterile preparations (eg, does <u>not</u> prepare sterile preparations that strictly adheres to the conventionally manufactured approved labeling for preparation), inspector should answer statement as N/A.***	Yes		1.4

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		Observation	Inspector Notes	USP Reference(s)
6.1	The product is prepared as a single dose for an individual patient.	Yes		1.4
6.2	The approved labeling includes information for the diluent, the resultant strength, the container closure system, and the storage time.	Yes		1.4
7.0	Does the pharmacy perform compounding activities that require the manipulation of a patient's blood-derived or other biological material (eg, autologous serum)?	No		1.1.2
8.0	For compounding activities that require the manipulation of a patient's blood-derived or other biological material, does the pharmacy perform manipulations that are clearly separated from other compounding activities and equipment used in CSP preparation activities and are controlled by specific SOPs to avoid any cross-contamination? ***Inspector note: Per USP, a separate cart could be used for blood-derived or other biological materials (a separate area is not required by the chapter). Pharmacy should change garb. Pharmacy to have cleaning processes as part of SOPs to avoid cross-contamination.*** ***If the pharmacy does not compound with blood products or other biological materials, inspector should answer statement as N/A. If the inspector answers the compliance question as "no", please describe your observations.***	N/A		1.1.2
	Facility Design and Engineering Controls			4

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		Observation	Inspector Notes	USP Reference(s)
9.0	**Segregated Compounding Area (SCA):** Does the pharmacy use an SCA as an SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP, only Category 1 CSPs may be compounded in a SCA. If no, go to compliance statements. If pharmacy only uses a cleanroom suite for sterile compounding preparations, inspector should answer question as N/A.***	N/A		4.1, 4.1.1, 4.1.2, 4.2.1 Table 5
9.1	The facility is designed to afford a well-lighted and comfortable working environment.	N/A		4.2, 4.2.1
9.2	Only Category 1 CSPS are prepared in a SCA. ***If pharmacy is compounding Category 2 or Category 3 CSPs in a SCA, inspector should answer this statement as no and collect photographs and copies of the MFR, CR, and provide a description of their observations in the Inspector Notes.***	N/A		4.2.1, 4.2.3 Table 5
9.3	The SCA is located away from unsealed windows, doors that connect to outdoors, and traffic flow. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	N/A		4.2.1
9.4	The SCA is located away from environmental control challenges and separate from areas not related to compounding (ie, restrooms, warehouses, food preparation areas).	N/A		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
9.5	A visible perimeter establishes the boundaries of the SCA. ***Inspector note: Per USP, the SCA is defined as "a designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only." USP further defines a perimeter as "a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA." The perimeter will be defined in the pharmacy's SOPs. Tape or an alternative method may be used to define this visible perimeter, since this is not a classified space.***	N/A		4.2.1 Glossary
9.6	Access to the SCA is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning.***	N/A		4.2.1
9.7	Free-standing humidifiers/dehumidifiers and air conditioners are not located within the perimeter of the SCA.	N/A		4.2
9.8	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the compounding area. ***Inspector note: Per USP, these items should be low-shedding, easily cleaned, and disinfected. This applies to items within the perimeter around the Primary Engineering Control (PEC).***	N/A		4.5
9.9	Shipping cartons or other corrugated or uncoated cardboard are not allowed in the SCA.	N/A		4.5

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9.10	The SCA and all surfaces (walls, floors, counters, equipment) are clean, uncluttered, and dedicated to compounding.	N/A		4.2.1, 4.3.2
9.11	The sink is located inside the SCA or in close proximity and is located at least one meter away from the PEC.	N/A		4.4
9.12	The area within one meter of the PEC is dedicated only for sterile compounding (eg, not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities, such as patient care).	N/A		4, 4.2.1
9.13	If overhangs or ledges are present in the SCA, are they easily cleanable? *If no, describe observations in Inspector Notes.*	N/A		4.2.1, 4.3.2
10.0	Are surfaces smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected? *Inspector note: this is a recommendation by USP.* *If no, describe in comments Inspector Notes (eg, peeling of Formica countertops).*	Yes		4.3.2
11.0	Are surfaces resistant to damage from cleaning, sanitizing, and sporicidal agents used? *Inspector note: this is a recommendation by USP.* *If no, describe in comments inspector observations (ie observed rust on preparation cart or flaking of particle board on shelving).*	Yes		4.2.1, 4.3.2

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		Observation	Inspector Notes	USP Reference(s)
12.0	**Cleanroom Suite:** Does the pharmacy use a Cleanroom Suite (ISO-classified anteroom and buffer room) as a SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP <797>, a cleanroom suite is required if compounding any Category 2 and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If pharmacy only uses an SCA for Category 1 CSPs, inspector should answer question as N/A.***	Yes		4.1, 4.1.1, 4.1.2, 4.2.1, 4.3.1 Table 5
12.1	Access to the cleanroom suite is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning. Some examples pharmacies may use to demonstrate compliance with this statement (but are not specifically required by the chapter) include posting a sign or creating a badge access point for authorized personnel to enter the cleanroom suite.***	Yes		4.2.1
12.2	The facility is designed to afford a well-lit environment.	Yes		4.2, 4.2.1
12.3	The facility provides a comfortable working environment (eg, temperature and humidity settings so appropriate garb can be donned).	Yes		4.2.1
12.4	The anteroom and buffer room are separated from surrounding unclassified areas by fixed walls and doors.	Yes		4, 4.2.1

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12.5	Controls are in place to minimize the flow of lower-quality air into the more-controlled areas. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	Yes		4.2.1
12.6	Anterooms providing access to only positive pressure buffer rooms meet at least ISO Class 8 specifications. ***If the pharmacy has a negative pressure room, inspector should answer statement as N/A.***	Yes		4.1.2, 4.2.1
12.7	The anteroom provides access to a negative pressure room and meets at least ISO Class 7 specifications. ***If the pharmacy does not compound hazardous drugs, inspector should answer statement as N/A.***	Yes		4.1.2, 4.2.1
12.8	The buffer room, where the PEC is placed, meets ISO Class 7 or better air quality specifications. ***Inspector note: If the PEC is a pharmaceutical isolator, the buffer room must be at least ISO Class 8 air quality or better and an anteroom is not required.*** ***Per USP <797>, a pharmaceutical isolator is defined as an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. A CAI or CACI is not a pharmaceutical isolator.***	Yes		4.1.2, 4.2.1, 4.2.3

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		Observation	Inspector Notes	USP Reference(s)
12.9	Air supply to the anteroom and buffer room is introduced through HEPA filters in the ceiling.	Yes		4.2.1
12.10	Air returns are located low on the wall. ***If the pharmacy has a visual smoke study (as described in the USP chapter and compliance statement below), inspector should answer statement as N/A.***	Yes		4.2.1
12.11	A visual smoke study demonstrates an absence of stagnant air where particles can accumulate and is repeated if any equipment/placement changes when air returns are not located low on the wall. ***Inspector note: Per USP, "the smoke study, along with environmental monitoring, must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (eg, HVAC alterations, chapter of HEPA filter units)."*** ***If air returns are low on the wall, inspector should answer statement as N/A.***	Yes		4.2.1
12.12	The anteroom has a line of demarcation to separate the dirty side from the clean side or has two separate anterooms, a dirty anteroom and a clean anteroom. ***Describe observations for the type of line of demarcation in the Inspector Notes.***	Yes		4.2.1
12.13	Personnel enter the dirty side/room first from the unclassified area and the clean side/room is located closest to the buffer room.	Yes		4.2.1
12.14	All surfaces (ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets) are smooth, impervious, free from cracks and crevices, and non-shedding.	Yes		4.2.1, 4.3.1

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		Observation	Inspector Notes	USP Reference(s)
12.15	Junctures between ceilings and walls and between the walls and floors are sealed.	Yes		4.2.1, 4.3.1
12.16	If the ceiling consists of inlaid panels, the panels are caulked to seal them to the support frame. ***If the ceiling does not consist of inlaid panels, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.17	Walls are constructed of, or covered with, a durable material (eg, epoxy paint, heavy gauge polymer) and integrity of surface maintained.	Yes		4.2.1, 4.3.1
12.18	Walls, if paneled, are joined together and sealed to the support structure. ***If walls are not paneled, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.19	Floors include coving to the sidewall or the juncture between floor and wall is caulked.	Yes		4.2.1, 4.3.1
12.20	If overhangs or ledges are present, they are easily cleanable. ***If there are no overhangs, ledges, utility pipes, windowsills, etc, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.21	Exterior lens surfaces of the ceiling light fixtures are smooth, mounted flush, and sealed.	Yes		4.2.1, 4.3.1
12.22	All other penetrations through the ceiling or walls (eg, camera domes) are sealed.	Yes		4.2.1, 4.3.1

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		Observation	Inspector Notes	USP Reference(s)
12.23	The buffer room does not contain plumbed water sources (eg, sinks, eyewashes, showers, or floor drains).	Yes		4.4
12.24	The anteroom does not contain floor drains.	Yes		4.4
13.0	Are **PECs** used to prepare CSPs located in the appropriate space (eg, buffer room or SCA) for category types prepared in compliance with USP <797> standards? ***Inspector to review certification reports and observe compounding area(s) to evaluate.*** ***If no, go to compliance statements.***	Yes		4.2.1, 4.2.2, 4.2.3 Table 4, Table 5
13.1	All compounded sterile preparations (that are not for immediate use) are compounded in a PEC.	Yes		1.3, 4, 4.1.2
13.2	PEC is certified to maintain ISO 5 classification or better conditions during dynamic operating conditions. ***The inspector should only answer yes if the PEC has been certified within the past six months.***	Yes		4.2.2, 4.2.3, 5
13.3	The PEC is located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC. ***Review certification report.***	Yes		4, 4.2.2, 4.2.3

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		Observation	Inspector Notes	USP Reference(s)
13.4	Placement of the PEC allows for cleaning around the PEC.	Yes		4.2.3
13.5	**Category 2 and Category 3**: PEC(s) are located in a cleanroom suite. ***If pharmacy only compounds Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.2.3 Table 5

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		Observation	Inspector Notes	USP Reference(s)
14.0	Does the pharmacy have any CAIs/CACIs used for sterile compounded preparations? ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3 Table 5
15.0	Are **CAIs/CACIs** (RABS) used for compounding sterile preparations operated in compliance with manufacturer specifications **and** USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3
15.1	The documented recovery time is followed after opening the CAI/CACI transfer chamber to maintain ISO Class 5 air quality. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.2	Staff ensures that adequate recovery time is allowed after closing the CAI/CACI during compounding operations. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.3	Sterile gloves are worn over the gloves attached to the CAI/CACI sleeve. ***Inspector note: Per USP, if using a RABS (ie, a CAI or CACI), disposable gloves should be (not required) worn inside the gloves attached to the RABS sleeves.***	N/A		3.3

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		Observation	Inspector Notes	USP Reference(s)
16.0	Are there controls in place to minimize the influx of contaminants from materials (supplies and equipment) and personnel as they move from areas of lower quality to those of higher quality in compliance with USP <797> standards? ***Inspector note: An example of material movement from lower quality air to higher quality air includes movement from a non-classified area to an ISO Class 8 anteroom, ISO Class 8 anteroom to an ISO Class 7 buffer room, or from an ISO Class 7 buffer room to an ISO Class 5 PEC.*** ***If no, go to compliance statements.***	Yes		4.5
16.1	Before any item is introduced into the SEC, placed into the pass-through chamber, or brought into the SCA (providing that packaging integrity will not be compromised), it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (IPA) using low-lint wipers by personnel wearing gloves.	Yes		4.5
16.2	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.	Yes		4.5
17.0	Does the pharmacy have the appropriate facility design and controls (including the fixtures, types of equipment, materials, and supplies that are stored) in the classified areas in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		4, 9.1, 19.1

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		Observation	Inspector Notes	USP Reference(s)
17.1	The sink used for hand hygiene, located outside of the anteroom, is placed in an appropriate area and clean space to minimize the risk of bringing contaminants into the anteroom. ***Inspector note: Inspector should evaluate the sink location in relation to the activities that occur where the sink is located as well as the distance between the sink and the entrance to the compounding suite/SCA. Examples that may not be considered appropriate include but are not limited to: sink is located in the bathroom, an adjacent suite or property, or in an employee breakroom where food is prepared.*** ***If the sink is located in the anteroom, inspector should answer statement as N/A.***	Yes		4.4
17.2	The sink used for hand hygiene, located inside of the anteroom, is placed in an appropriate area to minimize the risk of bringing contaminants into the buffer room. ***Inspector note: Inspector should evaluate the sink location in relation to the doors and compounding activities. For example, the sink is where compounders perform hand hygiene close to where garb is stored (where it can easily get wet/splashed).*** ***If the sink is located outside the anteroom, inspector should answer statement as N/A.***	Yes		4.4

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17.3	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes		4.2.1
17.4	The inside and outside doors of a pass-through are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes		4.2.1
17.5	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. ***Inspector note: Per USP, items necessary for performing compounding activities are low-shedding and can be easily cleaned and disinfected.*** ***If no, describe the types of items that are observed. If appropriate, submit a photograph with inspection report.***	Yes		4.5, 9.1
17.6	Tacky mats are not used in the classified areas. ***Inspector note: Per USP <797>, "Tacky mats must not be placed within ISO-classified areas."***	Yes		4.2.1
17.7	Shipping cartons or other corrugated or uncoated cardboard are not permitted in the classified areas.	Yes		4.5
17.8	Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels.	Yes		4.5
17.9	Carts (including casters) are cleaned and disinfected prior to moving from the dirty side to the clean side of the anteroom.	Yes		4.5

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Infucare Rx of LA dba Infucare Rx of LA
e-Profile ID: 0
Inspection Date: 01/00/1900 - 01/16/2025

		Observation	Inspector Notes	USP Reference(s)
18.0	Does the pharmacy's facility design for maintaining (eg, recording, monitoring, and controlling) temperature and humidity (eg, HVAC) comply with USP <797> standards? ***Inspector note: Compounded preparations that are finished and stored will be addressed in the general pharmacy module. Inspector should be aware that USP cleanroom temperature recommendations may not be harmonized with USP, FDA, or manufacturer/supplier temperature requirements for drug storage.*** ***If no, go to compliance statements.***	Yes		4.2, 19.1 USP <659>
18.1	The compounding area temperature and humidity is maintained by a heating, ventilation, and air conditioning (HVAC) system. ***If inspector finds a free-standing air conditioner, humidifier, or dehumidifier within the classified area or the SCA, the inspector should answer statement as "No." Additionally, inspector should describe what they observed, where the equipment was located, and collect/submit photographs.***	Yes		4.2, 9.3.4, 19.1
18.2	The pharmacy records the temperature of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes		4.2, 9.3.4, 19.1
18.3	The pharmacy records the humidity of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of humidity recording in the notes.***	Yes		4.2, 9.3.4, 19.1

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18.4	The pharmacy maintains records of temperature and humidity that are specific to the cleanroom suite. ***Temperature and humidity for drug storage areas will be documented in the general pharmacy module.*** ***If the pharmacy only uses an SCA, inspector should answer statement as N/A.***	Yes		4.2, 9.3.4, 19.1
18.5	The pharmacy can readily retrieve temperature and humidity records. ***If the electronic monitoring system is only capable of providing text message alerts for excursions alone (eg, a report cannot be generated for ongoing temperature conditions), inspector should answer statement as "No."***	Yes		4.2, 9.3.4, 19.1
18.6	The pharmacy controls temperature and humidity to maintain appropriate working conditions if no overnight drug storage occurs and/or is following the most restrictive drug label. ***Inspector note: Per USP <797>, the cleanroom suite should be maintained at a temperature of 20°C or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb.*** ***CRT is defined as 20°C-25°C per USP <659>.***	Yes		4.2, 9.3.4, 19.1
18.7	The placement of the HVAC unit does not cause cross contamination or interfere with the functioning of the classified area. ***Inspector note: Air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open faced PEC such as a laminar airflow workbench (LAFW).***	Yes		4, 4.2

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		Observation	Inspector Notes	USP Reference(s)
18.8	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes		4.2, 9.3.4
18.9	Humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes		4.2, 9.3.4
19.0	Does the pharmacy store drugs in the cleanroom suite overnight and/or for long periods of time? ***Inspector note: Long periods of time is not defined as pre-compounding preparation right before compounding activities are commenced.***	N/A		4.2, 9.3.4, 19.1
20.0	If the pharmacy is storing drugs inside the cleanroom suite overnight and/or long periods of time, are any of the drugs stored unable to tolerate temperature excursions?	N/A		4.2, 9.3.4, 19.1
21.0	What is the current temperature of the cleanroom suite/SCA? ***Record in the Inspector Notes.***	[redacted]		4.2, 9.3.4, 19.1
22.0	What is the current relative humidity percentage of the cleanroom suite/SCA? ***Record in the Inspector Notes.***			4.2, 9.3.4, 19.1
23.0	Is the humidity maintained at less than 60% relative humidity (RH) in the compounding area to minimize risk of microbial proliferation?	N/A		4.2, 9.3.4, 19.1

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		Observation	Inspector Notes	USP Reference(s)
24.0	Is differential positive pressure maintained in compliance with USP <797> standards? *Inspector note: Per USP <797>, no pressure differential is required between the SCA and the surrounding area.* *If no, go to compliance statements.* *Inspector should view logs and current status (while observing compounding) to verify.* *If the pharmacy uses an SCA for sterile compounding environment, inspector should answer statement as N/A.*	Yes		4.2.1, 4.2.5, 5
24.1	The facility design creates room separation to allow positive pressure differentials between spaces (rooms) for movement of air from higher quality air to lower quality air. *Inspector should review a graphic of the airflow contained in the certification report.*	Yes		4.2.1, 4.2.5, 5
24.2	The facility has a system in place to continuously monitor pressure differentials (eg, magnehelic gauge). *Per USP, pressure differentials need to be monitored continuously, but personnel are not specifically required to visually monitor pressure during compounding activities.*	Yes		4.2.1, 4.2.5, 5
24.3	The facility has a record system to record pressure differentials on days when compounding occurs. *Inspector note: Per USP, the quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurs.*	Yes		4.2.1, 4.2.5, 5

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		Observation	Inspector Notes	USP Reference(s)
24.4	The differential positive pressure between unclassified and the first space in the compounding suite is at least 0.020 inch water column. ***Inspector note: Per USP, certifiers should confirm (this is a USP recommendation) positive pressure around doorways, pass-throughs and any opening in the cleanroom suite with smoke testing (to confirm positive pressure is maintained) with initial certification of the cleanroom suite.*** ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the general pharmacy area).***	Yes		4.2.1, 4.2.5, 5
24.5	The differential positive pressure between adjacent classified areas is at least 0.020 inch water column. ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the ISO Class 7 buffer room).***	Yes		4.2.1, 4.2.5, 5
24.6	Pressure differential monitoring and quantitative results are reviewed and documented at least daily on days when compounding occurs.	Yes		4.2.1, 4.2.5, 5
25.0	Does the pharmacy have a policy in place to cease compounding when the pharmacy is unable to maintain positive pressure differentials (outside of anticipated variations due to opening and closing of doors)?	Yes		4.2.1, 4.2.5, 5
26.0	Are pressure differential monitoring procedures in place that include an alarm or alert when there is an excursion? ***Inspector note: USP <797> does not require there to be an alarm or an alert.***	N/A		4.2.5

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27.0	Does the facility perform both sterile and nonsterile compounding?	N/A		4.2.1
28.0	If the pharmacy performs nonsterile compounding and sterile compounding, are the designated areas separate and distinct from each other?	N/A		4.2.1
29.0	If PECs are placed into the same room that are used for both sterile and nonsterile compounding, is the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP <797>, PECs used for both sterile and nonsterile compounding may be placed in the same room only if the PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification.*** ***If no, go to compliance statements.*** ***If the pharmacy does not perform nonsterile compounding in the same room as sterile compounding, inspector should answer this question as N/A.***	N/A		4.2.1, 4.2.6
29.1	PECs used for nonsterile compounding are placed at least one meter away from PECs used for sterile compounding.			4.2.1
29.2	Particle-generating activity must not be performed while sterile compounding is in process.			4.2.1
29.3	PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification air quality during nonsterile compounding.			4.2.1

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		Observation	Inspector Notes	USP Reference(s)
30.0	Does the pharmacy prepare Category 2 and Category 3 CSPs from nonsterile components? ***Inspector note: Category 1 CSPs can be made from nonsterile components. If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	N/A		4.2.1, 4.2.6
31.0	Does the pharmacy's presterilization procedures comply with USP <797> standards? ***If no, go to compliance statements.***	N/A		4.2.6
31.1	Presterilization procedures, such as weighing and mixing, are completed in an ISO Class 8 or better environment (eg, anteroom or buffer room). ***Inspector note: This statement only applies for Category 2 and Category 3.***	N/A		4.2.6
31.2	Presterilization procedures, such as weighing and mixing, are performed in a single-use containment glove bag, CVE, BSC, or CACI to minimize the risk of airborne contamination. ***Inspector note: This statement only applies for Category 2 and Category 3. CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every six months.***	N/A		4.2.6
	Certification and Environmental Monitoring Inspector to review past two (2) Certification reports for the SEC and all PECs.			5

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		Observation	Inspector Notes	USP Reference(s)
32.0	Does the pharmacy ensure that each area related to CSP preparation is certified to meet the classified air quality standard appropriate for the activities conducted in that area in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***Inspector is to review current certification reports.***	Yes		5
32.1	The most recent PEC and SEC certification reports are available for review.	Yes		4.2, 5, 20
32.2	Certification of all classified areas, including PECs, is performed at least every six months.	Yes		4.2.3, 5
32.3	Certification of all classified areas, including PECs, is performed whenever a device is relocated or a major service to the facility is performed. ***Inspector note: Classified areas must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.***	Yes		5
32.4	Certification reports are reviewed by the designated person(s). ***Inspector note: If the designated person(s) review is not documented, describe how it is ensured that the review occurred.***	Yes		4.2, 5
32.5	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, pharmaceutical isolators, IVLFZ, and robotic enclosures) have been certified within the last six months. ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.2.3, 5

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		Observation	Inspector Notes	USP Reference(s)
32.6	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. ***Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.*** ***If no, describe what occurred and the pharmacy's response to total airborne particle sampling results, data evaluation, and action level (eg, pharmacy took PEC out of service, pharmacy ordered new HEPA filter, PEC was repaired and re-certified).***	Yes		4.1.1, 5.1 Table 4
32.7	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last six months. ***Inspector note: Per ISO definition, ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air under dynamic operating conditions and ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air under dynamic operating conditions.*** ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.1.1, 4.1.2, 5.1 Table 4
32.8	All SECs meet ISO Class 7 air quality requirements and ISO Class 8 air quality requirements where permitted, with particle counts documented within the report. ***If no, describe what occurred and the pharmacy's response (eg, pharmacy reduced BUD, pharmacy used an alternative facility, pharmacy followed mitigation strategies, and/or disaster planning processes).***	Yes		4.1.1, 5.1 Table 4

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		Observation	Inspector Notes	USP Reference(s)
33.0	Does the certification report received by the pharmacy have all required elements documented for the pharmacy's designated person(s) to make an informed decision related to functionality of PEC and SEC environments in compliance with USP <797> standards? ***Inspector note: It is recommended that the designated person review the certification report in its entirety.*** ***If no, go to compliance statements.***	Yes		5, 20
33.1	The certification report includes information about the equipment used for performing each test including last calibration date (or date when next calibration is due). ***Inspector note: Per USP, "total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment" and "all impaction air samplers must be serviced and calibrated as recommended by the manufacturer."***	Yes		5.1, 6.1, 20
33.2	The certification report includes the name of the certifier. ***Inspector note: Per USP <797>, a qualified certifier may have received training and education from professional organizations such as the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) and Controlled Environment Testing Association (CETA). Both organizations provide certification (Registered Certification Professional – Sterile Compounding Facilities), education, and resources.***	Yes		5

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33.3	The certification report describes the "dynamic conditions" including the number of personnel in the cleanroom suite. ***Inspector note: Compounders can perform mock compounding activities and/or performing media-fill while the certifier is conducting testing. Number of personnel present in the SEC must be documented.***	Yes		5, 20
33.4	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **air volume and room air exchange rate (ACPH)**. ***Inspector note: Per USP <797>, unclassified SCAs have no ACPH requirement. If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5 Table 6
33.5	**SEC:** All of the following ACPH required elements were documented on the certification report: the ACPH from HVAC, the ACPH contributed from the PEC, and the total ACPH. ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5
33.6	**The ISO Class 8 anteroom** is certified and documented as having a minimum of 20 ACPH with at least 15 ACPH of the total air change rate coming from HVAC through HEPA filters located in the ceiling. ***If the pharmacy has an ISO Class 7 anteroom, inspector should mark as N/A.***	Yes		4.2.4, 5 Table 6

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		Observation	Inspector Notes	USP Reference(s)
33.7	**The ISO Class 7 buffer room and ISO Class 7 anteroom (if required)** is certified and documented as having a minimum of 30 ACPH with at least 15 ACPH of the total air change rate in a room coming from the HVAC through HEPA filters located in the ceiling. ***Inspector note: If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off, except for maintenance.***	Yes		4.2.4, 5 Table 6
33.8	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **room pressure differential** in doorways between adjacent rooms.	Yes		4.2.5, 5
33.9	**SEC:** The differential pressure measured was at least 0.020 inch water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed. ***Inspector note: No pressure differential is required between the SCA and the surrounding area.***	Yes		4.2.1, 4.2.5, 5
33.10	**SEC:** All SEC HEPA filters were leak tested (to confirm **HEPA filter integrity**).	Yes		5
33.11	**SEC:** All SEC HEPA filters with leaks were repaired. ***If leaks were not repaired, describe what actions pharmacy took (eg, pharmacy implemented mitigation strategies such as reduced BUD or used alternative pharmacy location).*** ***If no repairs were needed, inspector should answer statement as N/A.***	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
33.12	**PEC: (Dynamic airflow) Smoke pattern tests** are performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the CSPs. ***Inspector note: Per USP, "HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design, control, and use minimizes turbulence and creation of eddies or stagnant air in the PEC."*** ***Describe if smoke pattern testing of PEC was documented thoroughly in the report or through video.***	Yes		4.2.2, 4.2.3, 5
33.13	**PEC: Dynamic airflow smoke pattern** confirms equipment and supplies necessary for performing compounding activities in the PEC do not disrupt unidirectional airflow. ***Inspector note: Per USP, "Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location."***	Yes		4.2.2, 4.2.3, 4.5, 5, 9.1

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33.14	**PEC: Total (nonviable) particle count** testing was performed under dynamic operating conditions using calibrated electronic equipment. ***Inspector note: Per USP, "Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures...Measurements of total airborne particles in other classified areas, including the buffer room(s) and anteroom(s), should be taken at representative locations that reflect the quality of air in the room(s)."***	Yes		5, 5.1
33.15	**PEC:** All PEC HEPA filters were leak tested (to confirm **HEPA filter integrity**). ***Inspector note: The certification report for each PEC should show air velocities within the PEC.***	Yes		5
33.16	**PEC:** All PEC HEPA filters with leaks identified were repaired. ***If leaks were not repaired, describe what actions pharmacy took (example: PEC taken out of service until HEPA filter could be replaced).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A		5

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33.17	**PEC-IVLFZ**: Pharmacy's integrated vertical laminar flow zone (IVLFZ) meets design, functional requirements, and certification requirements under USP <797>. ***Inspector note: Per USP <797>, "Strategic location of air returns in addition to full coverage of HEPA-filters above the work surface is required. Both static and dynamic smoke studies of air returns in addition to full coverage of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (eg, with video)."*** ***If pharmacy does not use an IVLFZ, inspector should answer statement as N/A.***	Yes		4.2.3
33.18	If a **robotic enclosure is used as the PEC**, or placed within the PEC, a dynamic airflow smoke pattern test must be performed initially and at least every 6 months thereafter to ensure that: 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the direct compounding area(s). ***If pharmacy does not use a robotic enclosure, inspector should answer statement as N/A.***	N/A		4.2.3

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		Observation	Inspector Notes	USP Reference(s)
34.0	Was smoke testing performed in SEC to confirm all particle generating equipment (eg, computers, printers, refrigerators, PECs) do not disrupt airflow? ***Inspector note: This question will be N/A unless the pharmacy is new, has recently completed construction, or equipment has been moved within SEC since last certification.***	Yes		5
35.0	Does the pharmacy have an established environmental monitoring (eg, microbiological air and surface monitoring) program in compliance with USP <797> standards? ***Inspector note: Per USP, "The goals of a microbiological air and surface monitoring program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained."*** ***If no, go to compliance statements.***	Yes		6, 6.1, 6.2
35.1	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed initially in the selected sampling sites to establish a baseline level of environmental quality for each classified area, ie, each ISO Class 5 PEC, each ISO Class 7, and ISO Class 8 room.	Yes		6, 6.1, 6.2
35.2	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in conjunction with the certification of new facilities and equipment.	Yes		6, 6.1, 6.2

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Sterile Compounding Inspection for USP <797>

Facility Name: Infucare Rx of LA dba Infucare Rx of LA
e-Profile ID: 0
Inspection Date: 01/00/1900 - 01/16/2025

		Observation	Inspector Notes	USP Reference(s)
35.3	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed after any servicing of facilities or equipment.	Yes		6, 6.1, 6.2
35.4	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified problems (eg, positive growth in sterility tests of sterile compounded preparation).	Yes		6, 6.1, 6.2
35.5	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified trends (eg, repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination).	Yes		6, 6.1, 6.2
35.6	Results from the environmental monitoring program (eg, viable air and/or surface monitoring) are reviewed in response to changes that could impact the sterile compounding environment (eg, change in cleaning agents) and in conjunction with personnel data (ie, training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination. ***Inspector note: Per USP, the program is reviewed to "assess risks for contamination, potential routes of contamination, and the adequacy of cleaning and disinfecting agents and procedures. Regular review of the sampling data must be performed to detect trends and the results of the review must be documented."***	Yes		6, 6.1, 6.2, 20 Table 4, Table 7, Table 8

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		Observation	Inspector Notes	USP Reference(s)
35.7	The pharmacy ensures that viable air and surface sampling is performed by a trained and competent individual who is familiar with the methods and procedures for air sampling and surface testing. ***If sampling is conducted by internal personnel, inspector should verify that documented training and competencies are located in the employee file.***	Yes		6, 6.1, 6.2
35.8	Environmental monitoring program (eg, viable air and/or surface monitoring) describes/identifies corrective actions to minimize the risk of CSP contamination and that these corrective actions are documented.	Yes		6, 20
36.0	Is surface sampling performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected (to obtain a sample that is representative of the typical compounding conditions at the pharmacy)? ***Inspector note: this is a USP recommendation.***	Yes		6.1, 6.3
37.0	Does the pharmacy send out all air quality for viable airborne samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	N/A		6.2.2
38.0	Does the pharmacy send out all surfaces for viable particle samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	N/A		6.3

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		Observation	Inspector Notes	USP Reference(s)
39.0	For any samples that are sent to an external lab (third party), does the pharmacy receive a report from the third party confirming incubation parameters meet USP <797> requirements (eg, the correct temperature and the correct length of incubation time are documented in the report)? ***Inspector note: Incubation parameters are the same as seen in statements 40.6-40.7 and 41.4-41.5.*** ***This question applies for any air or surface sample sent to an external lab.*** ***If no, describe observations.***	Yes		6.2.2
40.0	Are processes for sampling and monitoring **air quality for viable airborne** particles in compliance with USP <797> standards? ***Inspector note: Per USP <797>, facilities performing any Category 3 compounding must adhere to the increased environmental monitoring requirements for all classified areas where Category 3 CSPs are compounded and increased environmental monitoring requirements apply at all times regardless of whether Category 3 CSPs are being compounded on a given day.*** ***Review six months of air sampling data to verify. If no, go to the compliance statements.***	Yes		6.2, 6.2.1, 6.2.2, 6.2.3, 14.4.2 Box 5, Table 7
40.1	All classified areas are sampled using a volumetric active air sampling device (impaction air sampler). ***Inspector note: This sampling must be performed during dynamic operating conditions (to obtain a sample that is representative of the typical compounding conditions at the pharmacy).***	Yes		6.1, 6.2.1

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		Observation	Inspector Notes	USP Reference(s)
40.2	All classified areas are sampled at the **frequencies** specified by USP for volumetric active air sampling. ***Inspector note: Per USP <797>, Category 1 and Category 2 compounding frequency is every six months and Category 3 compounding frequency is monthly.*** ***For facilities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.***	Yes		6.2.1, 14.4.2
40.3	At least one cubic meter (1000 L) of air is tested using the volumetric active air sampling device from each sample location.	Yes		6.2.2 Box 5
40.4	All impaction air samplers are serviced and calibrated as recommended by the manufacturer.	Yes		6.1
40.5	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a media that supports the growth of bacteria and fungi (eg, TSA), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements.***	Yes		6.2.2 Box 5

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		Observation	Inspector Notes	USP Reference(s)
40.6	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797> (Box 5), when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C–35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C–25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.2.2 Box 5
40.7	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797> (Box 5), two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, malt extract agar [MEA] or sabouraud dextrose agar [SDA]). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.2.2 Box 6

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		Observation	Inspector Notes	USP Reference(s)
40.8	Results for all plates are recorded for each sample and did not exceed USP <797> Table 7 action levels (or internal action levels if more restrictive). **ISO Class 5: >1 cfu/m^3/device** **ISO Class 7: >10 cfu/m^3/device** **ISO Class 8: > 100 cfu/m^3/device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media separately.***	Yes		6.2.3 Table 7
40.9	For any air sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes		6.2.3
40.10	For any areas that exceed action levels, an investigation is conducted to attempt to determine cause and a corrective action plan is implemented.	Yes		6.2.3
41.0	Are processes for sampling and monitoring **surfaces for viable particles** in compliance with USP <797> standards? ***Review six months of surface sampling data to verify. If no, go to the compliance statements.***	Yes		6.3

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		Observation	Inspector Notes	USP Reference(s)
41.1	**Surfaces** and pass-through chambers in the cleanroom suite and SCA are sampled for microbial contamination for each classified area. ***Inspector note: Sampling locations must include work surfaces in each classified room, the interior of each ISO Class 5 PEC, and all pass-through chambers connecting to classified areas. USP recommends samples be taken from: equipment contained within the PEC, staging or working area near the PEC, and frequently touched surfaces.***	Yes		6.3, 6.3.1
41.2	**Surfaces** within the cleanroom suite and SCA are sampled at the **frequencies** specified by USP for viable particle surface sampling. ***Inspector note: Category 1 and Category 2 CSP surface sampling frequency is monthly and Category 3 compounding is weekly, regardless of the frequency of compounding Category 3 CSPs.*** ***Additionally, surface sampling is to be performed within the PEC used to prepare Category 3 CSPs, at the end of each batch, before cleaning and disinfection occurs unless a self-enclosed robot is used. If a self-enclosed robot is used, frequency is at least once daily at the end of compounding operations.*** ***For facilities compounding any Category 3 CSPs, a surface sampling must be completed prior to assigning BUDs longer than the limits established in Table 13.***	Yes		6.3, 6.3.1, 14.4.2

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		Observation	Inspector Notes	USP Reference(s)
41.3	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a surface sampling device with a raised convex surface for sampling flat surfaces is used that contain general microbial growth media that supports the growth of bacteria and fungi (eg, TSA supplemented with additives that neutralize effects of any disinfecting agent, eg, lecithin and polysorbate 80), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements. Per USP, "sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations such as crevices, corners, and spaces between surfaces."***	Yes		6.3.2 Box 6
41.4	The pharmacy incubates all surface samples in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797>, when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C-35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C-25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.3.2 Box 6

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		Observation	Inspector Notes	USP Reference(s)
41.5	The pharmacy incubates all surface samples in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797>, two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, MEA or SDA). Media must be supplemented with neutralizing additives (eg, lecithin and polysorbate 80). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.3.2 Box 7
41.6	Results for all plates are recorded for each sample and did not exceed USP <797> Table 8 action levels (or internal action levels if more restrictive). **ISO Class 5: >3 cfu/media device** **ISO Class 7: >5 cfu/media device** **ISO Class 8: > 50 cfu/media device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately.***	Yes		6.3.3 Table 8
41.7	For any surface sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes		6.3.3

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		Observation	Inspector Notes	USP Reference(s)
41.8	For any areas that exceed action levels, an investigation is conducted to determine cause, and a corrective action plan is implemented.	Yes		6.3.3
	Compounding Personal Hygiene and Garbing			
42.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		3.1
42.1	Compounding personnel are required to report conditions that may contaminate the sterile preparation and environment to the designated person(s). *Inspector note: Per USP <797>, examples of conditions that have a higher risk of contaminating the CSP and sterile environment includes: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.*	Yes		3, 3.1
42.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in compounding areas before their conditions have been resolved. *Inspector note: Per USP <797>, the designated person(s) may permit accommodations as long as the quality of the CSP and environment will not be affected.*	Yes		3, 3.1

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42.3	Any accommodations permitted by the designated person(s) are documented.	Yes		3.1
42.4	Food (including mints, gum, etc) and drinks are not permitted in anterooms, buffer rooms, or segregated compounding areas.	Yes		3.1
43.0	Does the pharmacy stock the necessary garb to ensure minimum garbing requirements are continuously met in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		3.3
43.1	The pharmacy stocks gowns and/or coveralls that are low-lint with sleeves that fit snugly around the wrists and an enclosed neck.	Yes		3.3
43.2	The pharmacy stocks shoe covers that are low lint.	Yes		3.3
43.3	The pharmacy stocks head covers that are low lint and cover the hair and ears.	Yes		3.3
43.4	The pharmacy stocks facial hair covers (not masks) that are low-lint. *If the pharmacy does not have personnel with beards, inspector should answer this statement as N/A.*	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
43.5	The pharmacy stocks masks that are low lint.	Yes		3.3
43.6	The pharmacy stocks sterile, powder-free gloves.	Yes		3.3
43.7	**Category 1 and Category 2:** All non-disposable garb used to prepare Category 1 and Category 2 CSPs is laundered before reuse. ***If only disposable items are used, inspector should mark as N/A.***	N/A		3.3
43.8	**Category 3 only:** The pharmacy stocks low lint face and neck coverings that ensure no skin is exposed. ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2

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43.9	**Category 3 only:** The pharmacy stocks sterile, low lint outer garb (including sterile sleeves over gauntlet sleeves when a RABS is used). ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3
43.10	**Category 3 only:** All non-disposable garb used to prepare Category 3 CSPs is **laundered and resterilized** with a validated cycle before each use. ***Document whether laundering and sterilization is performed in-house or by an outside vendor.*** ***If only disposable items are used, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2

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		Observation	Inspector Notes	USP Reference(s)
	Media-Fill			
44.0	Is the media-fill testing simulation performed by the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP, "When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean-casein digest media. The simulation must capture elements that could potentially affect the sterility of the CSP."*** ***If no, go to compliance statements.***	Yes		2.3
44.1	The simulation captures factors associated with the length of the process that can pose contamination risk (eg, operator fatigue, quality of equipment).	Yes		2.3
44.2	The simulation captures number of aseptic additions or transfers.	Yes		2.3
44.3	The simulation captures number, type, and complexity of manipulations.	Yes		2.3
44.4	The simulation captures number of personnel in the buffer room or SCA.	Yes		2.3

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44.5	Does the facility define "the most difficult and challenging procedures" and the rationale for how they are the most challenging? ***Inspector note: Best practice is for this to be documented in an SOP. Inspectors may also find this information documented on a training/competency assessment checklist. For complex/variety of compounding practices, inspectors may find additional media fills are completed (more than what is required by the USP chapters).***	Yes		2.3, 20
45.0	Are the pharmacy's media-fill storage, review, and preparation processes in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		2.3
45.1	If pharmacy uses commercial sterile microbial growth media, a COA was obtained. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.2	The COA for the commercial sterile microbial growth media includes statements from the supplier that the lot of the growth media will support the growth of microorganisms. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3

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		Observation	Inspector Notes	USP Reference(s)
45.3	Storage of commercial sterile microbial growth media is in accordance with manufacturer instructions. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.4	Commercial sterile microbial growth media is stored and used before its expiration date. ***Inspector note: Media is to be inoculated by the expiration date, meaning that the test needs to be started (not that incubation needs to be completed before the expiration date).*** ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.5	Sterile-to-sterile media-fill testing microbial growth media (non-commercial) was prepared and growth promotion capability was demonstrated prior to use, following USP <71>. ***If pharmacy only uses commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.6	Nonsterile starting components (commercially available nonsterile soybean-casein digest powder) are dissolved to make a 3% nonsterile solution, manipulated in a manner that simulates nonsterile-to-sterile compounding activities, with a minimum of one positive control container. ***If pharmacy does not perform sterile compounding using nonsterile ingredients, inspector should answer statement as N/A.***	N/A		Box 2
	Cleaning and Disinfection			7

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Inspection Date: 01/00/1900 - 01/16/2025

		Observation	Inspector Notes	USP Reference(s)
46.0	Is the pharmacy equipped with the necessary cleaning and disinfecting equipment and supplies that comply with USP <797> standards? ***If no, go to compliance statements.***	Yes		7, 7.1.1, 7.1.2 <1072>
46.1	All cleaning and disinfecting supplies (eg, wipers, sponges, pads, and mop heads), with the exception of tool handles and holders, are low lint.	Yes		7.1.2
46.2	Reusable cleaning tools are made of cleanable materials (no wood handles or any other porous material).	Yes		7.1.2
46.3	Reusable cleaning tools are dedicated for use in the classified areas or SCA and are not removed from these areas except for disposal.	Yes		7.1.2
46.4	The pharmacy has the appropriate cleaners **EPA-registered disinfecting agent(s)** to adequately perform cleaning and disinfection. ***Inspector note: Examples of EPA-registered disinfectants include, but are not limited to: phenolics; oxidizers, such as peroxyacetic acid and sodium hypochlorite; quaternary ammonium; and hydrogen peroxide. If the agent is EPA-registered, a registration number will be on the label. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 7, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.***	Yes		7.1.1 Box 7 <1072>

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Sterile Compounding Inspection for USP <797>

Facility Name: Infucare Rx of LA dba Infucare Rx of LA
e-Profile ID: 0
Inspection Date: 01/00/1900 - 01/16/2025

		Observation	Inspector Notes	USP Reference(s)
46.5	The pharmacy has the appropriate **EPA-registered sporicidal agent(s)** to adequately perform sporicidal disinfection. ***Inspector notes: Examples of EPA-registered agents include but are not limited to: oxidizers such as peroxyacetic acid, sodium hypochlorite, and hydrogen peroxide. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 8, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.*** ***Per USP, Inspector should check to see if agent is effective against Clostridium difficile.***	Yes		7.1.1 Box 7 <1072>
46.6	All cleaning and disinfectant agents are appropriately labeled including expiration dates. ***Inspector should verify that no expired agents are present.***	Yes		7.1.1
46.7	When used in the PEC, any cleaning and disinfecting agents that are not "ready-to-use" formulations are diluted using sterile water. ***If only ready-to-use formulations are used, inspector should answer statement as N/A.***	N/A		7.1.1
47.0	Does the pharmacy's documented **cleaning and disinfection** activities for surfaces in the classified areas and/or SCA comply with the **frequencies** specified in USP <797> Table 10? ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2 Table 10

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Sterile Compounding Inspection for USP <797>

Facility Name: Infucare Rx of LA dba Infucare Rx of LA
e-Profile ID: 0
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		Observation	Inspector Notes	USP Reference(s)
47.1	All interior surfaces of the PEC are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.2	All interior surfaces of the PEC are cleaned and disinfected when surface contamination is known or suspected.	Yes		7.2 Table 10
47.3	The removable work tray inside the PEC is cleaned and disinfected on days when compounding occurs. ***If the PEC is not equipped with a removeable work tray, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.4	All equipment inside the PEC is cleaned and disinfected on days when compounding occurs.	Yes		7.2, 9.1 Table 10
47.5	All work surfaces outside of the PEC (eg, counters, work tables) are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.6	All pass-through chambers are cleaned and disinfected on days when compounding occurs. ***If the pharmacy is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.7	Floors in the buffer room, anteroom, and/or SCA are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.8	Sinks used for hand hygiene are cleaned and disinfected on each day of use.	Yes		4.4, 7.2, Table 10
47.9	Walls, doors, and door frames are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.10	Storage and shelving bins are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.11	All equipment outside the PEC are cleaned and disinfected monthly. ***Inspector note: Equipment in the SEC/SCA may include, but is not limited to: carts, refrigerators, computers, barcode readers, and label printers.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.12	Ceilings in the buffer room and anteroom are cleaned and disinfected monthly. ***If the pharmacy performs compounding only in a SCA, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.13	Ceilings in the SCA are required to be cleaned and disinfected only when visibly soiled and when surface contamination is suspected. ***If the pharmacy performs compounding only in a cleanroom suite, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.14	The surface of the removable work tray and the area underneath the removable work tray of the PEC is cleaned and disinfected monthly. ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	Yes		7.2 Table 10
48.0	Does the pharmacy's documented application of **sporicidal disinfectant** on surfaces comply with the **frequencies** specified for each CSP category in USP <797> Table 10? ***Inspector note: Per USP <797>, if the pharmacy prepares any Category 3 CSPs, the cleaning requirements for Category 3 must be followed at all times regardless of whether a Category 3 CSPs is prepared on any given day.*** ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2, 14.4.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.1	**Sporicidal disinfectant** is applied to all interior surfaces of the **PEC** at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2, Table 10
48.2	Sporicidal disinfectant is applied to equipment inside the PEC at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10
48.3	Sporicidal disinfectant is applied to work surfaces outside the PEC (eg, counters, work tables) at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, application frequency is monthly. For any Category 3 compounding, application frequency is weekly.***	Yes		7.2 Table 10
48.4	Sporicidal disinfectant is applied to surfaces in the pass-through chambers at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.*** ***If the facility is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.5	Sporicidal disinfectant is applied to the floors in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10
48.6	Sporicidal disinfectant is applied to walls, doors, and door frames at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.7	Sporicidal disinfectant is applied to storage shelving and bins at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.8	Sporicidal disinfectant is applied to equipment stored outside the PEC at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.9	Sporicidal disinfectant is applied to ceilings in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: Per USP <797>, Table 10, the application frequency is monthly for all category types. Per USP, ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is suspected. The SCA may not have an accessible ceiling.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.10	Sporicidal disinfectant is applied to sinks used for hand hygiene at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		4.4, 7.2 Table 10
48.11	Sporicidal disinfectant is applied to the work surface of the removable tray in the PEC and area underneath the removable work tray at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*** ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
	Components			9
49.0	Does the pharmacy compound CSPs using active pharmaceutical ingredients (APIs) and non-API components? ***Inspector note: Per USP <797>, non-API components may include pharmaceutical excipients, sterile containers, and container closure systems.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	N/A		9.3
50.0	Is the pharmacy's selection of active API and non-API components in compliance with USP <797> standards? ***Verify by selecting products from the shelf of different suppliers and ask to see the COAs for those products. If no, go to compliance statements.***	N/A		9.3
50.1	**APIs**: APIs used are compliant with the criteria in the USP–NF monograph, if one exists. ***If pharmacy does not compound CSPs that have a USP monograph, inspector should answer this statement as N/A.***	N/A		9.3.1
50.2	**APIs:** All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that test results for the component show that the API meets expected quality.	N/A		9.3.1

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		Observation	Inspector Notes	USP Reference(s)
50.3	**APIs:** All APIs used are manufactured by an FDA-registered facility. *Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.*	N/A		9.3.1
50.4	All **non-API components** comply with the criteria in the USP–NF monograph, if one exists.	N/A		9.3.1
50.5	All **non-API components** are accompanied by documentation (eg, COA, labeling) that include the specifications and test results and shows that the component meets the specifications.	N/A		9.3.1
50.6	All **non-API components** used are manufactured by an FDA-registered facility. *Inspector note: Per USP <797>, "If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see USP <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications."*	N/A		9.3.1

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		Observation	Inspector Notes	USP Reference(s)
51.0	Does the pharmacy have processes in place to evaluate API and non-API components upon receipt and before use in compliance with USP <797> standards? ***Inspector note: Non-API components may be defined as excipients, containers, and container closure systems.*** ***If no, go to compliance statements.*** ***If the pharmacy does not compound with API or other non-API components, inspector should answer question as N/A.***	N/A		9.3.2, 9.3.3
51.1	APIs or other components have been evaluated for use in sterile drug preparation. ***Inspector note: Per USP <797>, "Components labeled with 'not for pharmaceutical use,' 'not for injectable use,' 'not for human use' or an equivalent statement must not be used to compound for these purposes."*** ***If no, photograph and describe in the notes column. Request copies of the invoices for products with these types of labels.***	N/A		9.3.2, 9.3.3
51.2	Upon receipt of each lot of a component, personnel verify the labeling and condition of each component and examine the external packaging for evidence of deterioration and other aspects of unacceptable quality (eg, outer packaging is damaged, temperature-sensing indicators show that the component has been exposed to excessive temperatures).	N/A		9.3.2, 9.3.3
51.3	Each lot of commercially available sterile, depyrogenated containers and container-closure systems are accompanied by a COA or other documentation showing conformance with established specifications for sterility and depyrogenation requirements.	N/A		9.3.1, 9.3.2, 9.3.3

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		Observation	Inspector Notes	USP Reference(s)
51.4	The date of receipt by the pharmacy is clearly marked on each API or component package that lacks a vendor expiration date and are assigned and labeled with an expiration date not to exceed one year after receipt by the pharmacy.	N/A		9.3.2, 9.3.3
51.5	All components are reinspected before use. ***Inspector note: Per USP <797>, all packages must be inspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures are visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use.***	N/A		9.3.2, 9.3.3
51.6	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	N/A		9.3.2, 9.3.3
51.7	Any other lots of that component from that vendor are examined to determine whether other lots have the same defect.	N/A		9.3.2, 9.3.3
	Equipment and Supplies			9

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		Observation	Inspector Notes	USP Reference(s)
52.0	Is the pharmacy equipped with the appropriate supplies and equipment used for compounding in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		9, 9.1, 9.2
52.1	Supplies (eg, beakers, utensils, needles, syringes, filters, and tubing sets) that contact components are not reactive, additive, sorptive, and do not alter the quality of sterile compounded preparation. *Inspector note: The appropriate supplies are available as applicable to the type of CSPs prepared (eg, non-PVC, silicone-free, able to withstand high heat, able to be sterilized).*	Yes		9.2
52.2	Any supplies that are in direct contact with CSPs are sterile and/or depyrogenated.	Yes		9.2
52.3	The equipment must be able to be cleaned using the required agents and tools without damaging the equipment and/or contaminating the compounded preparation. *Inspector note: Equipment used in compounding are of suitable composition and the surfaces that contact components are not reactive or sorptive.*	Yes		9.1

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		Observation	Inspector Notes	USP Reference(s)
52.4	When nonsterile ingredients, products, components, or devices (eg, non-sterile APIs and nonsterile vials and closures) are used for compounding, the pharmacy has the appropriate equipment to sterilize the finished product. Per USP, "Injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure must be sterilized within 6 hours after completing the preparation to minimize the generation of bacterial endotoxins in CSPs." ***If the pharmacy does not perform compounding that requires sterilization, inspector should answer statement as N/A.***	Yes		9.1, 9.3.1, 10
53.0	Does the pharmacy operate and maintain records for all equipment used for compounding in accordance with manufacturer specifications and USP <797> standards? ***If no, go to compliance statements.***	Yes		9.1, 20
53.1	Automated, mechanical, or electronic equipment (monitoring equipment, autoclaves, ovens, etc) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines.	Yes		9.1, 9.3.4

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		Observation	Inspector Notes	USP Reference(s)
53.2	Automated compounding devices (ACDs) and other similar equipment (single channel or multi-channel) are assessed for accuracy and calibrated daily, prior to initial use, and a daily record is maintained. ***Inspector note: Per USP, "The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification."***	Yes		9.1
53.3	Incubators used for environmental and personnel monitoring are placed in a location outside of the sterile compounding area and calibrated in accordance with manufacturer's instructions. ***If the pharmacy does not incubate samples and or/media-fills in-house, inspector should answer statement as N/A.***	Yes		6.1, 6.2.2, 6.3.2
53.4	Incubators used for environmental and personnel monitoring are monitored for temperature during incubation periods either manually or by use of a continuous recording device. ***Inspector note: Incubators store media at 20˚C-25˚C and 30˚C-35˚C. If the pharmacy has more than one incubator, review records for both incubators.*** ***View incubator temperature records to verify. Evaluate the size of the incubator and volume of media it can store. If the pharmacy does not incubate samples and/or media-fills in-house, inspector should answer statement as N/A.***	Yes		6.2.2, 6.3.2 Box 5

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		Observation	Inspector Notes	USP Reference(s)
	Compounding Personnel Observation - Inspector ***must*** observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. If the inspector is unable to view activities from a window or other observation area, it is expected they will gown/garb into compounding area. It is acceptable for pharmacy staff to perform mock compounding activities (with sterile saline or other drug) as long as all observations can be viewed.			
54.0	**Personnel Preparation Observation:** Before entering the compounding area, do compounding personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		3.1
54.1	All outer garments such as hats, scarves, sweaters, bandanas, vests, coats, and jackets are removed.	Yes		3.1
54.2	Makeup and/or cosmetics are removed.	Yes		3.1
54.3	All hand, wrist, and other exposed jewelry, including piercings such as earrings, lip or eyebrow piercings, etc, are removed and any jewelry that cannot be removed is covered.	Yes		3.1
54.4	Earbuds or headphones are removed.	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
54.5	Electronic devices that are not necessary for compounding or other required tasks are prohibited from entering the compounding areas.	Yes		3.1
54.6	Nails are kept clean and neatly trimmed.	Yes		3.1
54.7	Any nail polish, artificial nails, or extenders are removed.	Yes		3.1
54.8	If worn, eyeglasses are wiped. ***If none of the pharmacy staff wear glasses, inspector should answer statement as N/A.***	Yes		3.1
54.9	Any accommodations permitted by the designated person(s) have been documented. ***Inspector note: Per USP <797>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	Yes		3.1
55.0	**Hand Hygiene Observation:** Were compounding personnel entering the compounding area observed performing the appropriate hand washing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.2 Box 3
55.1	All personnel entering the compounding area performed hand hygiene.	Yes		3.2 Box 3

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National Association of Boards of Pharmacy®
Universal Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Infucare Rx of LA dba Infucare Rx of LA
e-Profile ID: 0
Inspection Date: 01/00/1900 - 01/16/2025

		Observation	Inspector Notes	USP Reference(s)
55.2	The order of hand washing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2 Box 3
55.3	Fingernails are cleaned under warm running water using a disposable nail cleaner (eg, nail pick). ***Inspector note: During observations, inspect whether nail picks are available for use when performing hand hygiene.***	Yes		3.2 Box 3
55.4	Brushes are not used for hand hygiene.	Yes		3.2 Box 3
55.5	Hands and forearms are washed up to the elbows with soap and warm water for at least 30 seconds. ***Inspector note: Compounding personnel describe method for ensuring they have washed for 30 seconds (example: clock or timer is available near the sink).***	Yes		3.2 Box 3
55.6	Soap containers are not refilled or topped off.	Yes		3.2
55.7	Hands and forearms are completely dried up to the elbows with low-lint disposable towels or wipers.	Yes		3.2 Box 3
55.8	Hand dryers are not used for hand hygiene.	Yes		3.2 Box 3

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56.0	**Garbing Observation:** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3
56.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3
56.2	Compounding personnel entering the cleanroom suite and/or SCA adhere to the minimum garbing requirements in USP <797>. ***Inspector note: Per USP <797>, additional garbing requirements must be continuously met in the buffer room where Category 3 CSPs are prepared, regardless of whether Category 3 CSPs are compounded on a given day.***	Yes		3.3
56.3	Donning procedures are performed in an order that reduces the risk of contamination. ***Inspector note: USP recommends (not requires) the donning procedure to be performed in the anteroom.*** ***If no, inspector must describe in the notes column why a risk of contamination is a concern.***	Yes		3.3
56.4	Doffing procedures are performed in an order that reduces the risk of contamination.	Yes		3.3
56.5	The order of garbing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2, 3.3

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		Observation	Inspector Notes	USP Reference(s)
56.6	Sterile gloves are donned in a classified room or SCA.	Yes		3.2
56.7	Skin is not exposed inside the ISO Class 5 PEC.	Yes		3.3
56.8	Garb is replaced immediately if it becomes visibly soiled or if its integrity is compromised.	Yes		3.3
56.9	**Category 1 and Category 2 only:** Upon exit of the compounding area, all garb (except for gowns) is discarded or laundered prior to reuse. ***Inspector note: Gowns (disposable and non-disposable) may be reused within the same shift by the same person only if stored appropriately.*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused, inspector should answer statement as N/A.***	Yes		3.3
56.10	**Category 1 and Category 2 only:** Gowns reused within the same shift and by the same person are maintained in a manner that prevents contamination. ***Inspector note: Per USP <797>, gowns stored for reuse must be maintained in a classified area or adjacent to or within the SCA in a manner that prevents contamination (eg, away from sinks to avoid splashing).*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused; inspector should answer statement as N/A.***	Yes		3.3
57.0	List the name(s) of the CSPs observed by the inspector as part of live compounding demonstration.			

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		Observation	Inspector Notes	USP Reference(s)
58.0	**Compounding Observation:** Are compounding personnel observed using the appropriate aseptic technique that ensures the quality of the CSP and the environment is maintained in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		1, 2.1, 2.3
58.1	All sterile compounding is performed in a PEC with ISO Class 5 conditions or better. ***If the pharmacy only performs immediate use compounding, inspector should answer this statement as N/A.***	Yes		4.1.2
58.2	**Category 2 and Category 3 only:** All PECs are placed in a cleanroom suite. ***Inspector note: Per USP, "If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA."*** ***If the pharmacy only prepares Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.1.2
58.3	Compounding personnel ascertain before use that components are of the correct identity, appropriate quality, within the expiration date, and have been stored under the proper conditions.	Yes		9.3.3

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		Observation	Inspector Notes	USP Reference(s)
58.4	All items are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA prior to being introduced into the clean side of the anteroom, placed into a pass-through chamber, and/or brought into the SCA. ***Inspector note: The wiping procedure or agents used should not compromise the packaging integrity or render the product label unreadable. Disinfectant dwell time minimums, as specified by the manufacturer, are to be followed.***	Yes		8.1
58.5	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. ***Inspector note: Per USP, "When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable."***	Yes		8.2
58.6	Aseptic processes and manipulations are performed in a manner intended to minimize the risk of contamination. ***Inspector note: Observe the compounder's technique to ensure proper aseptic technique is utilized such as: preparation occurs in the direct compounding area (DCA); the compounder does not interrupt first air during the compounding process; proper set up of equipment, supplies, and components that ensure first air is not interrupted; the compounder handles the syringe in a manner that does not introduce contaminates (touch contamination on the plunger rod); proper entry and exit of materials in ISO Class 5 PEC; and frequent sanitization of gloves.***	Yes		2.3

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		Observation	Inspector Notes	USP Reference(s)
58.7	All critical sites (eg, vial stoppers, ampule necks, and IV bag septums) are wiped with sterile 70% IPA in the PEC and allowed to dry before puncturing.	Yes		7, 8.3
58.8	Gloves are disinfected with sterile 70% IPA immediately before compounding and regularly throughout the compounding process. ***Inspector note: Per USP, best practice is to re-sanitize each time hands re-enter the PEC. This may not occur when compounder is staging the next batch.***	Yes		3.3
58.9	Gloves are regularly inspected for holes, punctures, or tears, and are replaced immediately if such defects are detected.	Yes		3.3
59.0	Do compounding personnel adhere to the USP established time limits for components after initial puncture or entry in compliance with USP <797> standards? ***Look at punctured, stored containers and confirm if puncture time or BUD is noted on the container and stored within time limits. If no, go to compliance statements.***	Yes		15
59.1	Single dose containers (entered or punctured only in an ISO Class 5 air or cleaner air) are not used beyond 12 hours after initial puncture or entry or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured single-dose vials, compounded single-dose CSPs used as components, and CSP stock solutions. The labeled storage requirements during that 12-hour period must be maintained. Additionally, per USP, "This time limit for entering or puncturing (a single-dose CSP or CSP stock solution) is not intended to restrict the BUD of the final CSP."***	Yes		15.1, 16.2

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		Observation	Inspector Notes	USP Reference(s)
59.2	Multiple-use containers are not used for more than 28 days after initial puncture or entry, manufacturer specifications, or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured multiple-dose vials and compounded multiple-dose CSPs used as components. Multiple-dose CSPs are required to meet the criteria for antimicrobial effectiveness testing (USP <51>) and must be stored under the conditions upon which its BUD is based (eg, refrigerator or controlled room temperature).***	Yes		14.5, 15.2, 16.1
59.3	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. ***Inspector note: Ampules or vials where the container closure system has been removed must not be stored for any time period.***	Yes		15.1
59.4	Pharmacy bulk package containers of sterile drugs for parenteral use are only entered or punctured in an ISO Class 5 PEC. ***Inspector note: Per USP, the pharmacy bulk package system must be used according to the manufacturer's labeling.***	Yes		15.3

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		Observation	Inspector Notes	USP Reference(s)
60.0	**Inspect several different finished compounded sterile preparations.** Are all the finished compounded sterile preparations free from any evidence of particulates, filaments, floaters, or signs of contamination? ***Inspector note: Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, filament or floater); number of preparations affected (eg, two of the five vials on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12
61.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes or high risk drugs or high risk populations (eg, neonates). These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage. Some checks may be done retrospectively and with the assistance of technology.***	Yes		2 Table 2, Table 3

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		Observation	Inspector Notes	USP Reference(s)
62.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and disinfection activities in compliance with USP <797> standards? ***If inspector is unable to observe cleaning activities (due to timing of compounding activities observed), inspector should interview compounder(s) to have them walk through their normal process. If this occurs, inspector should record in notes column "process only."*** ***If no, go to compliance statements.***	Yes		7
62.1	All cleaning and disinfection activities are performed by appropriately garbed personnel.	Yes		7
62.2	Cleaning and disinfection are performed on all surfaces in the classified area and SCA.	Yes		7
62.3	Cleaning is performed in the direction of clean to dirty areas.	Yes		7
62.4	Reusable cleaning tools are disinfected prior to and after each use.	Yes		7.1.2
62.5	Only sterile cleaning, disinfecting, and sporicidal agents are permitted for use in the PEC. ***Inspector note: If pharmacy utilizes non-ready to use (RTU) agents, they must be diluted with sterile water. Per USP, "Once opened, sterile cleaning and disinfecting agents and supplies (eg, closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs."***	Yes		7.1.1, 7.1.2
62.6	Only sterile supplies and equipment are permitted for use in the PEC. ***Inspector notes: Non-disposable cleaning tools or handles must be properly disinfected prior to entering the PEC and prior to use.***	Yes		7.1.1, 7.1.2

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		Observation	Inspector Notes	USP Reference(s)
62.7	Compounding personnel are using the appropriate sterile cleaning, disinfecting, and sporicidal agents within the PEC.	Yes		7.1.1
62.8	Compounding personnel are using the appropriate cleaning and disinfecting procedures and techniques within the PEC. ***Inspector note: Per USP, "All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs"; "Cleaning must be performed in the direction of clean to dirty areas"; and when 70% sterile IPA is used, it is used last and allowed to dry. There are differing opinions on the best order of cleaning.*** ***Procedure includes using a sterile low-lint wiper to all surfaces. Allow surfaces to dry completely before beginning compounding.***	Yes		7.1.2 Box 7, Box 8
62.9	The manufacturer's directions or published data for the minimum contact time is followed for each of the cleaning, disinfecting, and sporicidal disinfectant used. ***Per USP, contact times should be included in the SOP based on the agent used.***	Yes		7.1.1 Box 7, Box 8
62.10	Sterile 70% IPA is applied to all surfaces in the ISO Class 5 PEC at the frequencies specified by USP during active compounding. ***Inspector note: Per USP <797>, sterile 70% IPA must be applied: immediately before initiating compounding procedures, to the work surface of the PEC at least every 30 minutes (if the compounding process takes 30 minutes or less), to the work surface of the PEC immediately after compounding (when the compounding process takes more than 30 minutes), after each batch or lot is completed, and after cleaning and disinfecting.***	Yes		7

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		Observation	Inspector Notes	USP Reference(s)
	Sterilization and Depyrogenation			**10**
63.0	Does the pharmacy compound preparations with any nonsterile starting components?	No		10
64.0	Are injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure, sterilized within six hours after completing the preparation? ***If no, describe observations and collect a copy of the master formulation record, a copy of the compounding record, and a copy of the process for sterilization.*** ***If the pharmacy does not compound with nonsterile components or devices, or they only compound sterile ophthalmic and/or sterile drugs administered by inhalation, inspector should answer question as N/A.***	N/A		10
65.0	**Filter Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***View compounding records for CSPs sterilized by filtration to verify.*** ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.2 USP <1229.4>

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65.1	Sterilization by filtration is performed in an ISO 5 environment.	N/A		4.1.2, 10.2
65.2	Filters used have enough capacity to filter the required volumes. ***Inspector note: Per USP, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process."***	N/A		10.2
65.3	The 0.2 micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP. ***Inspector note: Per USP <797>, sterilizing filters must be appropriate for pharmaceutical use. Sterilizing filters labeled "for laboratory use" or equivalent must not be used. "Sterilizing filters must be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (ie, pressure, flow rate, and volume filtered)."***	N/A		10.2
65.4	Confirmation of filter integrity (bubble testing) is performed and documented for each filter used with each batch sterilized by filtration. ***Inspector note: If multiple filters are required for the compounding process, each of the filters must be tested.*** ***If no, collect a copy of the master formulation record and compounding record.***	N/A		10.2

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65.5	A prefiltration step is performed for any CSPs that are known to contain excessive particulate matter. ***Inspector note: The prefiltration step consists of using a filter with a larger nominal pore size (eg, 1.2 micron) or a separate filter of larger nominal pore size should be placed upstream of (ie, prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter.***	N/A		10.2
65.6	CSPs that are prepared using a filter that failed integrity tests are either discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time. ***If no, collect a copy of the master formulation record and compounding record.***	N/A		10.2
65.7	Single-use filters are only used once.	N/A		4.1.2, 10.2

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66.0	**Steam Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment (autoclave), documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***View documentation on compounding records for CSPs sterilized by steam to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.3 USP <1229.1>
66.1	The pharmacy has evaluated if steam sterilization would cause degradation of the drug. ***Inspector note: Per USP, compounded preparations that are degraded by moisture, pressure, or temperatures used may not be sterilized by steam heat.***	N/A		10.3
66.2	Steam supplied is free of contaminants and generated using water per manufacturer's specifications.	N/A		10.3
66.3	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.3

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66.4	Items are placed in the autoclave in a manner that allows steam to reach them without entrapment of air. ***Inspector note: The pharmacy should have the autoclave cycle validated for the size of the batch, sterilization temperature, and sterilization time to ensure the load will be sterile.***	N/A		10.3 USP <1229.1>
66.5	Sealed containers used are able to generate steam internally (eg, small amount of water in empty crimped vials).	N/A		10.3
66.6	The appropriate biological indicators (USP <1229>) are used to verify the effectiveness of each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent; see Biological Indicators for Sterilization USP <1229.5>), and other confirmation methods such as physicochemical indicators (see Physicochemical Integrators and Indicators for Sterilization USP <1229.9>). The date, run, and load numbers of the steam sterilizer used to sterilize a CSP is documented in the compounding record."***	N/A		10.3 USP <1229.5> USP <1229.9>

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66.7	All items are directly exposed to steam under adequate pressure for the length of time necessary as determined by use of appropriate biological indicators to render the items sterile. ***Inspector note: Per USP <797>, the duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period (an example provided in the chapter is 20-60 minutes at 121°C saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized).*** ***Any parameters for the autoclave must be set through validation.***	N/A		10.3 USP <1229.1>
66.8	A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (eg, deviations in temperature or pressure) and results documented on the CR.	N/A		10.3, 20

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Sterile Compounding Inspection for USP <797>

Facility Name: Infucare Rx of LA dba Infucare Rx of LA
e-Profile ID: 0
Inspection Date: 01/00/1900 - 01/16/2025

		Observation	Inspector Notes	USP Reference(s)
67.0	**Dry Heat Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity. USP <1229.8> also applies.*** ***View documentation on compounding records for CSPs sterilized by dry heat to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.4 USP <1229.8>
67.1	The pharmacy has the appropriate dry heat sterilization equipment. ***Inspector note: Dry heat sterilization is usually performed in an oven designed for sterilization at 160°C or higher. The dry heat oven should be able to get to the appropriate temperature and pressure, for example, not be a toaster oven.***	N/A		10.4
67.2	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.4
67.3	During sterilization, sufficient space is left between materials to allow for circulation of hot air.	N/A		10.4

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		Observation	Inspector Notes	USP Reference(s)
67.4	CSPs and other items are exposed to dry heat for the length of time necessary for all items to reach sterilizing temperature of 160°C or higher. ***Inspector note: Per USP <797>, if lower temperatures are used, they are validated by biological indicators (see USP <1229.8>, Validation of Dry Heat Sterilization, Biological Indicators). The calibrated oven must be equipped with temperature controls and a timer.***	N/A		10.4
67.5	The appropriate biological indicators are used to verify the effectiveness each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of dry heat sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus atrophaeus (ATCC 9372; see Biological Indicators for Sterilization USP <1229.5>) and other confirmation methods (e.g., temperature-sensing devices). The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR."***	N/A		10.4 USP <1229.5>
67.6	A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (eg, deviations in temperature or exposure time) and results documented on the CR.	N/A		10.4, 20

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		Observation	Inspector Notes	USP Reference(s)
68.0	**Dry Heat Depyrogenation:** Is the appropriate depyrogenation method used and documented in compliance with USP <797> standards? *View documentation records of items depyrogenated to confirm.* *If the pharmacy does not use this method, inspector should answer question as N/A.*	N/A		10.1 USP <1228.1>
68.1	Glassware, metal, and other thermostable containers are exposed to dry heat for the length of time necessary for all items to be rendered pyrogen free.	N/A		10.1
68.2	The effectiveness of the dry heat depyrogenation cycle is established and documented. *Inspector note: Per USP <797>, this must be done initially, re-established any time there are changes made to the cycle (eg, load conditions, duration, temperature), and verified at least annually by using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥ 3-log reduction in endotoxins (see Bacterial Endotoxins Test USP <85>). The verification must be documented.*	N/A		10.1 USP <1228.1> USP <85>
68.3	Items that are not thermostable are depyrogenated by multiple rinses with sterile, nonpyrogenic water (eg, sterile water for injection or sterile water for irrigation) and then thoroughly drained or dried immediately before use in compounding. *Inspector note: USP <1228.4> Depyrogenation by Rinsing also applies.*	N/A		10.1 USP <1228.4>
	Master Formulation and Compounding Records **Inspector should review a minimum of five (5) master formulation records and five (5) compounding records.**			**11**

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		Observation	Inspector Notes	USP Reference(s)
69.0	Are **Master Formulation Records (MFRs)** created and maintained in compliance with USP <797> standards? *If no, go to A14compliance statements.*	Yes		11.1
69.1	The pharmacy creates and maintains MFRs for CSPs that are prepared for more than one patient.	Yes		11.1, 20
69.2	MFR changes and alterations are approved and documented according to the pharmacy's SOPs.	Yes		11.1
69.3	The pharmacy creates and maintains MFRs for CSPs that are prepared from nonsterile ingredients.	Yes		11.1, 20
69.4	The MFR includes the name, strength or activity, and dosage form of the sterile compounded preparation.	Yes		11.1, 20
69.5	The MFR includes the identities and amounts of all ingredients.	Yes		11.1, 20
69.6	The MFR includes the type and size of container closure.	Yes		11.1, 20

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		Observation	Inspector Notes	USP Reference(s)
69.7	The MFR includes complete instructions for preparing the sterile compounded preparation, including equipment, supplies, a description of the compounding steps, and any special precautions.	Yes		11.1, 20
69.8	The MFR includes a physical description of the final CSP.	Yes		11.1, 20
69.9	The MFR includes the BUD and storage requirements.	Yes		11.1, 14.2, 20
69.10	The MFR includes the reference source to support the stability of the CSP.	Yes		11.1, 20
69.11	The MFR includes quality control procedures (eg, pH testing, filter integrity testing).	N/A		11.1, 20
69.12	The MFR includes other information as needed to describe the compounding process and ensure repeatability (eg, adjusting pH and tonicity, sterilization method).	N/A		11.1, 20
69.13	The MFR includes all required release tests, and if applicable, sterility test methods, process, number and endotoxin test and limits.	N/A		11.1, 12, 20

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		Observation	Inspector Notes	USP Reference(s)
70.0	Are **Compounding Records (CR)** created and maintained in compliance with USP <797> standards? ***Inspector note: Per USP, a prescription or medication order or label may serve as the CR. Also, a copy of the MFR can be made that contains spaces for recording the information needed to complete the CR (eg, both the MFR and CR are on the same document/form). A CR may be kept electronically, if readily retrievable, as long as it contains all required information.*** ***If no, go to compliance statements.***	Yes		11.2 Box 10
70.1	The pharmacy creates and maintains CRs for all for immediate-use CSPs prepared for more than one patient. ***Inspector note: if pharmacy does not prepare any CSPs for immediate-use, inspector should answer compliance statement as N/A.***	Yes		11.2 Box 10
70.2	The pharmacy creates and maintains CRs for all Category 1, Category 2, and Category 3 CSPs.	Yes		11.2 Box 10
70.3	The CR includes the name, strength or activity, dosage form of the CSP, and (if applicable) the MFR reference.	Yes		11.2 Box 10
70.4	The CR includes the date and time of preparation.	Yes		11.2 Box 10
70.5	The CR includes an assigned internal identification number (eg, prescription, order, or lot number).	Yes		11.2 Box 10
70.6	The CR includes the identity of the individual(s) involved in the compounding process.	Yes		11.2 Box 10

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		Observation	Inspector Notes	USP Reference(s)
70.7	The CR includes identity of the individual(s) verifying the final CSP.	Yes		11.2 Box 10
70.8	The CR includes the name of each component.	Yes		11.2 Box 10
70.9	The CR includes the vendor/manufacturer, lot number, and expiration date for each component. ***Inspector note: this is required for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).***	Yes		11.2 Box 10
70.10	The CR includes the weight or volume of each component.	Yes		11.2 Box 10
70.11	The CR includes the strength or activity of each component.	Yes		11.2 Box 10
70.12	The CR includes the total quantity compounded.	Yes		11.2 Box 10
70.13	The CR includes the final yield (eg, quantity, containers, number of units).	Yes		11.2 Box 10
70.14	The CR includes the assigned BUD and storage requirements.	Yes		11.2 Box 10
70.15	The CR includes results of quality-control procedures (eg, visual inspection, filter integrity testing, pH testing).	Yes		11.2, 12 Box 10

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		Observation	Inspector Notes	USP Reference(s)
70.16	The CR includes calculations made to determine and verify quantities and/or concentrations of components. ***Inspector note: Per USP, "If applicable, the CR must also include...Calculations."***	Yes		11.2 Box 10
70.17	The CR is verified by the pharmacist for appropriateness and accuracy with in-process and final checks. ***Inspector note: "Documentation must comply with all laws and regulations of the applicable regulatory jurisdiction."***	Yes		2, 11.2, 12.1, 13, 20 Box 10
71.0	Are the pharmacy's labels for CSPs in compliance with USP <797> standards and display all required information? ***If no, go to compliance statements.***	Yes		13 USP <7>
71.1	Information on the label is prominently and legibly displayed. ***Inspector note: Definition of labeling includes other accompanying materials with the CSP, which includes, "written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed." The shipping container is not included in the definition of the "label."***	Yes		13
71.2	Labeling meets any state or federal regulatory requirements.	Yes		13

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		Observation	Inspector Notes	USP Reference(s)
71.3	Labeling on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		13
71.4	Labeling on the immediate container includes the active ingredients and their amounts, activity, or concentration.	Yes		13
71.5	Labeling on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		13
71.6	Labeling on the immediate container includes the BUD. Per USP, "Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded (ie, the BUD)."	Yes		13, 14.1
71.7	The compounded CSP label does not use the term "expiration date" or equivalent.	Yes		13, 14.1 USP <7>
71.8	Labeling on the immediate container includes the dosage form.	Yes		13
71.9	Labeling on the immediate container includes the total amount or volume when not obvious from the container.	Yes		13

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71.10	Labeling on the immediate container states that the CSP is a single-dose container (when space permits).	Yes		13
71.11	Labeling on the immediate container states that the CSP is a multiple-dose container.	Yes		13
71.12	Labeling includes the route of administration, as applicable.	Yes		13

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71.13	Labeling includes any special handling instructions and/or warning statements, as applicable.	Yes		13
71.14	Labeling includes the compounding facility name and contact information if the CSP is to be sent outside of the facility or health care system in which it was compounded.	Yes		13
72.0	Does the label contain information identifying the CSP is a compounded preparation? ***Inspector note: Per USP, this is a recommendation/should.***	N/A		13 USP <7>
	Establishing BUDs			**14**
73.0	**Category 1 and Category 2 CSPs:** Does the pharmacy assign BUDs for Category 1 and Category 2 CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		14, 14.1, 14.2
73.1	The assigned BUD does not exceed the shortest expiration date of any of the individual commercially available starting components.	Yes		14.3

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73.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and that its packaging maintains its integrity for the duration of the assigned BUD.	Yes		14.3
73.3	**Category 1 CSPs:** BUDs for **Category 1 CSPs** prepared in an SCA do not exceed the limits established in Table 12. ***Inspector note: Per USP <797> Table 12, BUD maximum limits for Category 1 CSPs are defined as 12 hours at controlled room temperature (CRT 20°C-25°C) or 24 hours refrigerated (2°C-8°C).*** ***If no Category 1 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, Table 12
73.4	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs using one or more nonsterile starting components are defined as: one day CRT; four days refrigerator; and 45 days freezer. Aseptically processed Category 2 CSPs using only sterile starting components are defined as: four days CRT; 10 days refrigerator; and 45 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, Table 13

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		Observation	Inspector Notes	USP Reference(s)
73.5	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs, that were sterility tested and passed, regardless of starting components being sterile or nonsterile, are defined as: 30 days CRT; 45 days refrigerator; and 60 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, 14.2.1, 14.2.3, Table 13
73.6	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to probability of nonsterile unit (PNSU) of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 14 days CRT; 28 days refrigerator; and 45 days freezer.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, 14.2.1, Table 13

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		Observation	Inspector Notes	USP Reference(s)
73.7	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to PNSU of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 45 days CRT; 60 days refrigerator; and 90 days freezer. Endotoxin testing is required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing.*** ***USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components are also endotoxin tested.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, 14.2.1, 14.2.3, Table 13

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		Observation	Inspector Notes	USP Reference(s)
74.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest beyond use date of any individual compounded components? ***Inspector note: Per USP, "the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (eg, pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted." Other examples where this may occur: formula within a formula, preservative-free compounded component used in a preserved final CSP, "in-use" times for pharmacy bulk packages, and cyclosporine ophthalmic stock solution.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		14.3

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		Observation	Inspector Notes	USP Reference(s)
75.0	Are BUDs for **Category 3 CSPs** assigned in compliance with all conditions outlined in USP <797> standards and do not exceed the maximum limits established in Table 14? ***Inspector note: If all of the conditions described for Category 3 CSPs are not met, the applicable BUD must not exceed the established maximum limits in Table 13 for Category 2 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer question as N/A.***	N/A		14.3, 14.4., 14.4.1, 14.4.2, 14.4.3, 14.4.4, Table 14
75.1	The assigned BUD does not exceed the shortest expiration date of any of the individual starting components.	N/A		14.3 Table 14
75.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and its packaging maintains its integrity for the duration of the assigned BUD.	N/A		14.3 Table 15
75.3	BUDs for **Category 3 CSPs** do not exceed the maximum limits for aseptically processed (eg, filtered) established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits for aseptically processed Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 60 days CRT; 90 days refrigerator; and 120 days frozen.***	N/A		14.4.1 Table 14

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		Observation	Inspector Notes	USP Reference(s)
75.4	BUDs for **Category 3 CSPs** do not exceed the maximum limits for terminally sterilized established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits terminally sterilized Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 90 days CRT; 120 days refrigerator; and 180 days frozen.***	N/A		14.4.1 Table 14
75.5	**Category 3 CSPs** are supported by stability data obtained using methods described in USP <1225> or a validated noninferior stability-indicating analytical method. ***Inspector note: Per USP <797>, Category 3 CSPs must prepared according to the EXACT formulation (API and other ingredients of identical grade and procedures) from which the stability data is derived. Category 3 CSPs must be packaged and stored in container closure of the same materials of composition as used in study and the facility must have documentation of the stability study.*** ***View records to verify the preparation exactly matches the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.***	N/A		14.4.3 Table 14 USP <1225>
75.6	**Category 3 CSPs** undergo sterility testing. ***Inspector note: Sterility testing is performed on all Category 3 CSPs.***	N/A		14.4.4 Table 14 USP <71>
75.7	**Category 3 CSPs** undergo bacterial endotoxin testing. ***If all compounds prepared are ophthalmics and/or drug administered by inhalation, bacterial endotoxin is not required, inspector should answer statement as N/A.***	N/A		12.3, 14.4.4 Table 14 USP <85>

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Sterile Compounding Inspection for USP <797>

Facility Name: Infucare Rx of LA dba Infucare Rx of LA
e-Profile ID: 0
Inspection Date: 01/00/1900 - 01/16/2025

		Observation	Inspector Notes	USP Reference(s)
75.8	**Category 3 CSPs** undergo particulate matter testing. ***Inspector note: If the Category 3 CSP is an injection or an ophthalmic solution, particulate matter testing is also conducted once per formulation with acceptable results (See USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions).***	N/A		14.4.3 Table 14 USP <788>, <789>
75.9	**Category 3 CSPs** undergo an evaluation for the container closure system. ***Inspector note: The container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD (see USP <1207> Package Integrity Evaluation— Sterile Products). Evaluation must be done once for each formulation and for each container closure system in which it will be packaged.***	N/A		14.4.3 Table 14 USP <1207>
76.0	Are **multiple-dose CSPs prepared** in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not prepare multiple-dose CSPs, inspector should answer question as N/A.***	Yes		14.5
76.1	Multiple-dose CSPs are prepared as a Category 2 or Category 3 CSP only.	Yes		14.5

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		Observation	Inspector Notes	USP Reference(s)
76.2	When preservatives are used, they are appropriate for the CSP formulation and the route of administration. Inspector note: Per USP <797>, "The preservative must not be inactivated by any ingredients in the CSP, and some preservatives are not always appropriate for the patient (eg, neonates) or route of administration (eg, intrathecal or ophthalmic injection)."	Yes		14.5
76.3	Aqueous multiple-dose CSPs pass antimicrobial effectiveness testing in accordance with USP <51>. ***Inspector note: Per USP <797>, a test can be one test done for each formulation in the particular container-closure system in which it will be packaged, or test results provided by an FDA-registered facility or in appropriate peer-reviewed literature,, provided the sterile compounded preparation formulation and container-closure system used are exactly the same as those tested, unless a bracketing study is performed. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.*** ***Additionally, multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs prepared as a Category 2 or Category 3 CSP are not required to pass antimicrobial effectiveness testing if the preparation is: For use by a single patient, labeled (in the label or labeling) to indicate that, once opened, it must be discarded after 24 hours when stored at controlled room temperature and/or that, once opened, it must be discarded after 72 hours when stored under refrigeration.***	Yes		14.5 USP <51>

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		Observation	Inspector Notes	USP Reference(s)
76.4	Multiple-dose CSPs are labeled to indicate the beyond use date of the CSP once it is opened or punctured. ***Inspector note: Labeling on the CSP should indicate that once the CSP container is entered or punctured, it must not be used for longer than the assigned BUD or 28 days (if supported by antimicrobial effectiveness testing results), whichever is shorter.*** ***Inspector should review the CR or final compounded preparation to verify the label contains this information.***	Yes		14.5
76.5	Container-closure systems used are evaluated for maintaining integrity (USP <1207>) for each formulation and fill volume. ***Inspector note: Per USP <797>, the container closure integrity test needs to be conducted only once on each formulation and on fill volume in the particular container closure system in which the multiple-dose CSP will be packaged.***	Yes		14.5 USP <1207>
	Finished Preparation Release Checks and Tests			**12**
77.0	Are all CSPs visually inspected for quality prior to release or dispensing in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		12.1
77.1	The CSP label is visually inspected to confirm that the CSP and its labeling match the prescription or medication order.	Yes		12.1

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		Observation	Inspector Notes	USP Reference(s)
77.2	CSPs are visually inspected for quality characteristics such as discoloration, visible particulates, or cloudiness.	Yes		12.1
77.3	CSPs are visually inspected to verify container closure integrity (eg, checking for leakage, cracks in the container, or improper seals).	Yes		12.1
77.4	A visual inspection is also repeated prior to release or dispense for CSPs that have been stored in the pharmacy and not released or dispensed on the day of preparation.	Yes		12.1
77.5	Any CSPs found to be of unacceptable quality (eg, observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		12.1
78.0	For any CSPs assigned beyond use dates that require sterility testing, does the pharmacy ensure that all testing is performed, evaluated, and documented in accordance with USP <71> or a validated alternative method that is noninferior to USP <71> testing and USP <797> standards? ***Inspector note: Alternative testing methods may not be accepted in all regulatory jurisdictions that the pharmacy conducts business.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare any CSPs that require sterility testing, inspector should mark as N/A.***	N/A		12.2

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		Observation	Inspector Notes	USP Reference(s)
78.1	The required number of sterile compounded preparation units, as described in USP <71> and USP <797>, are tested. ***Inspector note: Per USP <71> Table 3, the minimum number of items to be tested for each medium is:*** ***Parenterals*** ***Not more than 100 containers = 10% or four containers, whichever is greater*** ***More than 100, but not more than 250 containers = 10 containers*** ***Large volume parenterals*** ***2% or 10 containers, whichever is less*** ***Non-parenterals (eye drops, inhalation, pellets, etc.)*** ***Not more than 200 containers = 5% or two containers, whichever is greater*** ***More than 200, but not more than 250 containers = 10 containers*** ***Per USP <797>, if the number of CSPs compounded in a single batch is less than what is needed for testing as specified in USP <71> Table 3, additional units must be compounded to be able to perform testing as follows:*** ****If 1-39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number.*** ****If more than 40 CSPs are prepared in a single batch, the sample sizes specified in USP <71> Table 3 must be used.***			12.2, 14.2.3 USP <71>
78.2	Batch sizes of sterile CSPs do not exceed 250. ***Inspector Note: Per USP <797>, the maximum batch size for all sterile compounded preparation requiring sterility testing is limited to 250 final yield units.***	N/A		12.2, 14.2.3

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		Observation	Inspector Notes	USP Reference(s)
78.3	Pharmacy is utilizing an alternative method for sterility assurance testing (other than USP <71>). ***Inspector note: Per USP, "If an alternative method is used for sterility testing, the method must be validated (see USP <1223>) and demonstrated to be suitable for that CSP formulation."*** ***If an alternative method is used, describe the method used and how the pharmacy ensures they are compliant with state-specific regulations.***	N/A		12.2 USP <71>, <1223>
78.4	When sterility testing identifies a failure, the pharmacy has processes to investigate and identify any contributing factors. ***Inspector note: Per USP, "Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented." Additionally, some rapid sterility test methods do not allow for the identification of the recovered microorganisms. If one of these methods is used, the pharmacy is not in compliance with the chapter, as the investigation must include identification of the recovered microorganism.***	N/A		12.2

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		Observation	Inspector Notes	USP Reference(s)
79.0	For any CSPs assigned BUDs that require **bacterial endotoxin testing**, does the pharmacy ensure that all testing is performed and documented in compliance with USP <85> and USP <797> standards? ***Inspector note: Endotoxin limits reflect limits in an official monograph, or calculated as described in USP Chapter <85> for the route of administration for humans, and for animals based on weight.*** ***Although USP <797> refers to USP <85> Bacterial Endotoxins Test for calculating endotoxin limits for the appropriate route of administration, it does not address products administered epidurally or administered directly into the central nervous system. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare CSPs that require bacterial endotoxin testing, inspector should answer question as N/A.***	N/A		12.3 USP <85>
79.1	The pharmacy has an appropriate procedure for calculating/determining endotoxin limits. ***Per USP, there are endotoxin limits listed in USP product and compounded preparation monographs. The laboratory may be performing the calculation rather than the pharmacy; however, if done in house, this should be included in the pharmacy SOPs.*** ***If the dosage form does not require, inspector should answer statement as N/A.***	N/A		12.3

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		Observation	Inspector Notes	USP Reference(s)
79.2	The pharmacy collects patient weight to make bacterial endotoxin calculation for an animal patient. ***If the dosage form does not require or the pharmacy does not compound sterile preparations for animals, inspector should answer statement as N/A.***	N/A		12.3
79.3	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 2 CSPs** compounded from one or more nonsterile components that are assigned a BUD requiring sterility testing per Table 13. ***Inspector note: USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components is also endotoxin tested.***	N/A		12.3 Table 13 USP <85>
79.4	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 3 CSPs** compounded from one or more nonsterile components.	N/A		12.3 Table 13 USP <85>
79.5	Any CSPs with failed endotoxin testing are quarantined, not further released, and action is taken for any product released prior to receipt of failed test results. ***View testing records and note any products with failed results and actions taken.***	N/A		12.2, 12.3
	CSP Packaging, Shipping and Transport			**19**
80.0	Are processes and techniques for packaging and transporting CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		19.1, 19.2, 19.3

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		Observation	Inspector Notes	USP Reference(s)
80.1	The pharmacy uses the appropriate shipping containers and packaging materials (eg, coolers and light-resistant packaging) based on the product specifications.	Yes		19.2
80.2	CSPs are appropriately packaged to protect against damage, leakage, contamination, degradation, and adsorption during storage and transport. ***Inspector should look at packaging materials used to ensure cushioning to prevent breakage of glass vials and ensure that container is generally clean without non-microbial growth that would come in direct contact with CSPs.***	Yes		19.2
80.3	Specific handling instructions when applicable, are included on the exterior of the container.	Yes		19.3
80.4	The pharmacy selects transport modes that ensure CSPs are delivered properly in undamaged, sterile, and stable conditions (eg, no undue exposure to heat, cold, or light). ***Inspector note: Transport modes include pneumatic tube transport systems and should not be used if the CSP is sensitive to shaking.***	Yes		19.3
	Quality Assurance and Quality Control			**18**

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		Observation	Inspector Notes	USP Reference(s)
81.0	**Quality Assurance and Quality Control (QA/QC):** Does the pharmacy's SOP on quality assurance and quality control meet the requirements in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		18 USP <1163>
81.1	Description of procedures for complaint handling, adverse events, and recalls that include corrective action, investigation, reporting, and documentation requirements.	Yes		18.1, 18.2
81.2	**QA/QC Out-Of-Specification (OOS) SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the severity of the problem and the urgency for implementation and completion of the recall.	Yes		18.1
81.3	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the distribution of any affected CSP, including the date and quantity of distribution.	Yes		18.1
81.4	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to identify patients who have received the CSP.	Yes		18.1
81.5	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process for the disposal and documentation of the recalled CSP.	Yes		18.1
81.6	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to investigate and document the reason for failure.	Yes		18.1

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		Observation	Inspector Notes	USP Reference(s)
82.0	Does the pharmacy ensure that QA and QC programs are conducted in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		18, 20
82.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of: adherence to procedures; prevention and detection of errors and other quality problems; evaluation of complaints and adverse events; and appropriate investigations and corrective actions."***	Yes		18
82.2	The pharmacy's QA/QC program is reviewed at least once every 12 months by the designated person(s) and the results of the review are documented.	Yes		18
82.3	The designated person(s) reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.	Yes		18.2, 20

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		Observation	Inspector Notes	USP Reference(s)
82.4	All complaints and adverse events are thoroughly investigated. ***Inspector note: Per USP <797>, the timeframe is specified in the facility SOP. Additionally, USP states, "The investigation must consider whether the quality problem extends to other CSPs."*** ***If facility SOP permits a long investigation period, include in the inspector notes the SOP's expected time frame to complete an investigation. State may have a more aggressive time frame to complete an investigation and report quality events to the state.***	Yes		18.2, 18.3, 20
82.5	The record of each complaint is maintained by the pharmacy regardless of the source of the complaint (eg, email, telephone, or mail) and includes the minimum required information. ***Inspector note: Per USP <797>, the complaint record must contain the following information:*** ***-Name of the complainant or other unique identifier;*** ***-Date the complaint was received;*** ***-Nature of the complaint;*** ***-The response to the complaint; and*** ***-Results of any investigation and any follow-up.*** ***In addition, to the extent that the information is known, the following should be recorded:*** ***-The name and strength of the CSP and the assigned internal identification number (eg, prescription, order, or lot number).*** ***If no, inspector should document what is missing in the notes column.***	Yes		18.2, 20

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		Observation	Inspector Notes	USP Reference(s)
82.6	The pharmacy's QA/QC program includes documentation of steps necessary for completing a recall, including reporting the recall to appropriate regulatory agencies. ***Inspector note: Per USP, "The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction."***	Yes		18.1, 18.2
83.0	If a CSP is dispensed or administered **before the results of release testing are known**, does the pharmacy ensure procedures for recalls and out-of-specification notifications are conducted and documented in compliance with USP <797> standards? ***Inspector note: Per USP <797>, if a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to notify, recall, and investigate.*** ***If no, go to compliance statements.***	Yes		18.1, 20
83.1	The pharmacy has a process in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, sterility, strength, purity, bacterial endotoxin, or other quality attributes).	Yes		18.1
83.2	The pharmacy has a process in place to recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy.	Yes		18.1
83.3	The pharmacy has a process in place to investigate if other lots are affected and recall if necessary.	Yes		18.1

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		Observation	Inspector Notes	USP Reference(s)
	Personnel Training and Evaluation - Verify records of all compounding personnel (up to 10). **Use the records tab to document records reviewed.**			2
84.0	Is the pharmacy's documented hand hygiene and garbing competency evaluations compliant with USP <797> standards? *Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.* *If no, refer to the records review worksheet (columns G-J) for details.*	Yes		2.2, 20 Box 1, Table 1
85.0	Is the pharmacy's documented aseptic manipulation competency evaluation compliant with USP <797> standards? *Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.* *If no, refer to the records review worksheet (columns K-O) for details.*	Yes		2.3, 20 Box 2, Table 1
86.0	Is the pharmacy's documented training program and ongoing competency evaluation compliant with USP <797> standards? *Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.* *If no, refer to the records review worksheet (columns P-S) for details.*	Yes		2, 2.1, 17 Table 2, Table 3

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Sterile Compounding Personnel Records Review

Select personnel with compounding responsibilities for your records review; preferably select staff performing compounding duties at time of inspection or staff identified during CR review.
- Recommend also pulling supervising personnel file.
- Inspector can consider pulling non-compounder employee file ("Other") who cleans and stocks compounding area but who does not compound (Note: frequency of competency assessment will be defined by pharmacy SOPs).

Review five (5) personnel files and document your observations.
- For applicants seeking a Class E-S Non-Resident Sterile Compounding Inspection (Texas Sampling), review a total of 10 personnel records.
- *Note: long-term employees may not have initial training available, if this is the case, you may select an alternative file. If an alternate file is not available, document length of service of long-term employee.

Inspector Note: soybean casein digest medium and trypticase soy broth are the same media.

Inspector Instructions

1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position.
2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.
3. Select the appropriate response for each item reviewed.
-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.
-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.
-Select "Missing" if the document is not present in the file.
-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.
4. Use the notes column to document any pertinent information.

Demonstrating Knowledge and Competency of Core Skills (Section 2.1)

USP requirements:
1. Personnel who perform or oversee compounding *or support activities* must be trained in the SOPs and trained on maintaining the quality of the environment (See Table 2).
2. Compounding personnel and supervising personnel must complete training needed to demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions (See Table 2 and Table 3). This must be completed initially and every 12 months in at least the following areas:
-Hand hygiene
-Garbing
-Cleaning and disinfection
-Calculations, measuring, and mixing
-Aseptic technique
-Achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components)
-Use of equipment
-Documentation of the compounding process (eg, master formulation and compounding records)
-Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area
-Proper use of PECs
-Principles of movement of materials and personnel within the compounding area
3. Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control (PEC) must complete ongoing training as required by the facility's SOPs (See Table 3).
4. Personnel compounding only immediate-use CSPs must complete training as required by the facility's SOPs (See Table 3).
5. All training and evaluations must be documented.

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Compounding SOPs	*Initial Training and Competency in Maintaining the Quality of the Environment	*Initial Training and Competency in Sterile Compounding Principles and Practices	Ongoing Training and Competency in Sterile Compounding Principles and Practices	Notes
				Compounders and Supervising Personnel: Initially and at least every 12 months Other Personnel (examples: persons who do not compound but clean/disinfect and restock or who perform in-process checks; persons who only compound immediate use): Initially and as defined by pharmacy SOPs				
#1	Pharmacist	Designated Person	Category 2 only	Yes	Yes	Yes	Yes	
#2	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	
#3								
#4								
#5								
#6								

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#7								
#8								

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Inspector Instructions	Hand Hygiene and Garbing Competency Evaluation (Section 2.2)
1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position. 2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency. 3. Select the appropriate response for each item reviewed. -Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards. -Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column. -Select "Missing" if the document is not present in the file. -Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column. 4. Use the notes column to document any pertinent information.	USP requirements: 1. The garbing and hand hygiene competency evaluation consists of a visual observation and gloved fingertip and thumb sampling (GFT) of both hands. 2. The initial competency evaluation consists of three (3) separate and complete hand hygiene observation, followed by a full garbing procedure and a GFT after garbing. The initial three (3) successful completions must be in succession—failure of any of the three (3) initial garbing competency evaluations requires repeat testing until personnel successfully complete three (3) evaluations in a row. 3. The pharmacy uses a microbiological growth media device (eg, plates, paddles, or slides) containing general microbial growth agar (eg, trypticase soy agar [TSA]) supplemented with neutralizing additives (eg, lecithin and polysorbate 80) that supports both bacterial and fungal growth. 4. The media device is incubated at 30°C-35°C for no less than 48h and then at 20°C-25°C for no less than an additional five days. 5. Failure is indicated by visual observation of improper hand hygiene and garbing procedures and/or GFT results that exceed the defined action levels. Action level after garbing: >0 cfu/total from both hands. 6. Documentation includes, at minimum: -Name of the person evaluated -Evaluation date and time -Media and components used including manufacturer, expiration date, and lot number -Starting temperature for each interval of incubation -Dates of incubation -Results (the number of cfu per hand must be recorded; microbial identification of the cfu is not required by the chapter for GFT) -Results of the evaluation and any corrective actions -Name of the observer and personnel reading and documenting the results

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Hand Hygiene and Garbing Visual Observation	*Initial GFT x 3 (Post hand washing and garbing)	Subsequent GFT (Post handwashing and garbing)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
				Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially at least every 3 months Supervising Personnel: Initially and at least every 12 months				
#1	Pharmacist	Designated Person	Category 2 only	Yes	Yes	Yes	Yes	
#2	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	
#3								
#4								
#5								
#6								
#7								
#8								
#9								
#10								

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Inspector Instructions

1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position.
2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.
3. Select the appropriate response for each item reviewed.
-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.
-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.
-Select "Missing" if the document is not present in the file.
-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.
4. Use the notes column to document any pertinent information.
5. Document in notes if initial aseptic manipulation competencies are present in files (*unless long-term employee).

Aseptic Manipulation Competency (Section 2.3)

USP requirements:
1. Media-fill testing procedures simulate the most difficult compounding procedures encountered by personnel.
2. The pharmacy conducts media-fill testing as described in Box 2.
3. The final containers are incubated at 20°C-25°C and 30°C-35°C for a minimum of seven days at each temperature band.
4. Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container closure unit(s) on or before 14 days.
5. Immediately following the media-fill test, GFT is performed on both hands and inside of an ISO Class 5 PEC. Failure is indicated by visual observation of GFT results that exceed defined action levels. Action level after media-fill testing: >3 cfu/total from both hands.
6. Immediately following the GFT, a surface sample of the direct compounding area inside the PEC is performed in accordance with USP standards for surface sample monitoring and action levels. Action level ISO Class 5: >3 cfu/media device.
7. Failure in the media fill, GFT, or surface sampling constitutes an overall failure of the aseptic manipulation competency.
8. Documentation includes, at minimum:
-Name of the person evaluated
-Evaluation date and time
-Media and components used including manufacturer, expiration date, and lot number
-Starting temperature for each interval of incubation
-Dates of incubation
-Results (for GFT, the number of cfu per hand must be recorded and for surface samples, the number of cfu per sample must be recorded. Note: microbial identification of the cfu is not required for media-fill testing)
-Results of the evaluation and any corrective actions
-Name of the observer and personnel reading and documenting the results

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Aseptic Manipulation Visual Observation	Media-fill	GFT (post media-fill)	Surface Sampling (post media-fill)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
				Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially and at least every 3 months Supervising Personnel: Initially and at least every 12 months					
#1	Pharmacist	Designated Person	Category 2 only	Yes	Yes	Yes	Yes	N/A	
#2	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	N/A	
#3									
#4									
#5									
#6									
#7									
#8									
#9									

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#10									

4RR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			■ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 04244		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: InfuCare Rx, LLC

Physical Address: 2540 Market Street, Ste. 1

City: Aston State: PA Zip: 19014

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-202-6017 Toll Free # (NAC 639.708, NRS 639.23286): 877-202-6017

Fax: 877-278-1544 Contact Email: licensing@infucarerx.com

Website: www.infucarerx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Andrew Wee

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22276

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Andrew Wee	NV Pharmacist Registration #: 22276
Name: Thomas McCool	NV Pharmacist Registration #: 22937
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: PA

Parent Company (if any): InfuCare Rx, Inc.

Corporation/Organization Name: InfuCare Rx, LLC

Mailing Address: 2540 Market Street, Ste. 1

City: Aston State: PA Zip: 19014

Telephone: 877-828-3940 Email: Licensing@infucarerx.com

Contact Person Name: Jessica Seefried

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Corporate Secretary and General Counsel (title) for InfuCare Rx, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Tiffany Scheppers

Print Name of Authorized Person

Tiffany Scheppers, Corporate Secretary

Original signature of Authorized Person (copies or stamps not accepted)

11 / 11 / 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tiffany Scheppers

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Tiffany Scheppers, Corporate Secretary

Original signature of Authorized Person (copies or stamps not accepted)

11 / 11 / 2025

Date

Board Use Only	Date Received: 12/8/25	Amount: $500 ck 1000002414

Corporate Officers			
Name	**Title**	**Address**	**Phone**
Dhara Patel	President, Director, and Treasurer	695 US Hwy 46, STE 100, Fairfield, NJ 07004	877-828-3940
Tiffany Scheppers	Secretary and General Counsel	695 US Hwy 46, STE 100, Fairfield, NJ 07004	877-828-3940

Pre- and Post- Sale for InfuCare Rx, LLC

Pre-Close Structure



Post-Close Structure



InfuCare Rx, LLC 2540 Market Street, Ste 1, Aston, PA 19014 List of Shareholders			
Name	**Address**	**Phone**	**Percent Ownership**
InfuCare Rx, Inc.	695 US Highway 46, Suite 100, Fairfield, NJ 07004	877-828-3940	100%

Pennsylvania Department of State

Bureau of Corporations and Charitable Organizations
PO Box 8722 | Harrisburg, PA 17105-8722
T:717-787-1057
dos.pa.gov/BusinessCharities

Regarding:	InfuCare Rx LLC
Request Type:	Subsistence Certificate
Request No.:	066173731
Receipt No.:	002240421
Filing Type:	Domestic Limited Liability Company
Filing Subtype:	Limited Liability Company
Initial Filing Date:	April 08, 2015
Status:	Active

Issuance Date: October 17, 2025
File No.: 0004346069

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

InfuCare Rx LLC

is currently subsisting on the records of the Department of State as of the issuance date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of my office to be affixed, the day and year above written

Albert Schmidt
Secretary of the Commonwealth

Verify this certificate online at www.file.dos.pa.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler InfuCare Rx, LLC

Pharmacy/Wholesaler License # (if applicable) PH04244

Physical Address 2540 Market Street, Ste. 1

City Aston State PA Zip 19014

Mailing Address (if different from physical address) P.O. Box 2578

City Secaucus State NJ Zip 07096

Telephone 877-202-6017 Website www.infucarerx.com

Licensing Company Email licensing@infucarerx.com

Section 2: Personal Information

First Andrew Middle Chi Last Wee

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth 04/20/1979 SSN or ITIN 097-66-3127 Sex ☑ M ☐ F ☐ X

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Philadelphia College of Pharmacy		08/00 - 05/04	
Address	**City**	**State**	**Zip**
600 S 43rd St	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Suny Buffalo		08/97 - 05/99	
Address	**City**	**State**	**Zip**
12 Capen Hall	Buffalo	NY	14260
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Liverpool High School		08/94 - 05/97	
Address	**City**	**State**	**Zip**
4338 Wetzel Road	Liverpool	NJ	13090
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
06/14 - Present				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
InfuCare Rx, LLC			07/18 - Present	
Business Address		**City**	**State**	**Zip**
2540 Market St. STE 1		Aston	PA	19014
Phone	**Title**		**Number of Employed Hours**	
877-828-3940	Pharmacist in Charge		21312	
Description of Duties				
Supervise the pharmacy staff to ensure accurate and safe job performance. Directs, coordinates, and supervises all pharmacy activities.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Andrew Chi Wee, **certify that as the designated representative for**

InfuCare Rx, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AW I am at least 21 years of age;
3. AW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Andrew Wee

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/21/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Wee

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/21/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Delaware

I, Jesse Harkins, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/21/2025

Date

Subscribed and Sworn to before me this 21st day of November.

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Jesse Harkins, Notary Public
Chester County
My commission expires February 24, 2029
Commission number 1452713
Member, Pennsylvania Association of Notaries

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site InfuCare Rx, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH0244

Physical Address 2540 Market Street, Ste. 1

City Aston State PA Zip 19014

Mailing Address (if different from physical address) P.O. Box 2578

City Secaucus State NJ Zip 07096

Telephone 877-202-6017 Website www.infucarerx.com

Licensing Company Email licensing@infucarerx.com

Section 2: Personal Information

First Dhara Middle Devendra Last Patel

Alias(es, nicknames, name changes, etc.) N/A

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Armstrong Atlantic State University		Unknown	
Address	**City**	**State**	**Zip**
11935 Abercorn St.	Savannah	GA	31419
Diploma/Degree obtained, if any			
Bachelors Degree in Liberal Arts			

School Name		From - To (MM/YY – MM/YY)	
Richmond Hill High School		Unknown	
Address	**City**	**State**	**Zip**
Unknown			
Diploma/Degree obtained, if any			
High School diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
Unknown-Present	[redacted]			
Unknown-Present				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
InfuCare Rx, Inc.			Present	
Business Address		**City**	**State**	**Zip**
695 US Hwy 46, STE 100		Fairfield	NJ	07004
Phone	**Title**			
877-828-3940	President			
Description of Duties				
President of InfuCare Rx, Inc.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dhara Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/2/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Passaic

I, Dhara Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/2/2025

Date

Subscribed and Sworn to before me this 2nd day of December, 2025.

Notary Public Signature

DANIEL ALBARRAN
Notary Public, State of New Jersey
My Commission Expires Dec 15, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: InfuCare Rx, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH0244

Physical Address: 2540 Market Street, Ste. 1

City: Aston State: PA Zip: 19014

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-202-6017 Website: www.infucarerx.com

Licensing Company Email: licensing@infucarerx.com

Section 2: Personal Information

First: Tiffany Middle: Samantha Last: Scheppers

Alias(es, nicknames, name changes, etc.): N/A

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Missouri St Louis		Unknown	
Address	City	State	Zip
1 University Blvd.	St. Louis	MO	63121-4400
Diploma/Degree obtained, if any			
MBA not completed			

School Name		From - To (MM/YY – MM/YY)	
St. Louis University School of Law		8/1996-5/1999	
Address	City	State	Zip
100 N Tucker Blvd	St. Louis	MO	63101
Diploma/Degree obtained, if any			
Juris Doctor			

School Name		From - To (MM/YY – MM/YY)	
St. Louis University		8/1993-5/1999	
Address	City	State	Zip
1 N Grand Blvd	St. Louis	MO	63101
Diploma/Degree obtained, if any			
Nursing			

School Name		From - To (MM/YY – MM/YY)	
Cornelia Connelly School of the Holy Child Jesus		1984-1988	
Address	City	State	Zip
2323 W Broadway	Anaheim	CA	92804
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/2015-present	[redacted]			
3/2013-8/2015				
1/2000-3/2013				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Infucare Rx Inc.			03/2021 - Present
Business Address	**City**	**State**	**Zip**
695 UsSHwy 46, STE 100	Fairfield	NJ	07004
Phone	**Title**		
877-327-8881	General Counsel and Corporate Secretary		

Description of Duties

Oversee all corporate, regulatory, employment, litigation, and compliance legal matters.

Business Name			From - To (MM/YY – MM/YY)
Asembia, LLC			07/2019 - 12/2020
Business Address	**City**	**State**	**Zip**
200 Park Ave #300	Florham Park	NJ	07932
Phone	**Title**		
973-564-8004	Senior Vice President, General Counsel and Chief Compliance Officer; Corporate Secretary		

Description of Duties

Oversee all corporate, regulatory, employment, litigation, and compliance legal matters; Current Officer acting as Corporate Secretary; Advised executive leadership and Board of Directors on complex regulatory compliance matters.

Business Name			From - To (MM/YY – MM/YY)
Outside General Counsel			03/2019 - 07/2019
Business Address	**City**	**State**	**Zip**
	Charlotte	NC	
Phone	**Title**		
314-808-3974	Outside General Counsel		

Description of Duties

Delivered outsourced general counsel and compliance services to, and temporary coverage for, in-house general counsel and chief compliance officer clients, re: health care, pharma, biotech and CRO/CSO companies on legal and regulatory.

Business Name			From - To (MM/YY – MM/YY)
SYNEOS HEALTH, INC			08/2012 - 03/2019
Business Address	**City**	**State**	**Zip**
1030 Sync Street	Morrisville	NC	27560
Phone	**Title**		
919-876-9300	Senior Associate General Counsel & Chief Compliance Officer; Commercial Division		

Description of Duties

Supervised legal and compliance teams across US, Canada, Europe and APAC, reporting directly to the General Counsel.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tiffany Scheppers

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/2025

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Mecklenburg

I, Tiffany Scheppers, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/19/2025

Date

Subscribed and Sworn to before me this 19 day of Nov 2025.

Notary Public Signature

My Commission Expires
Nov 7, 2029

NIMESH R. PATEL NOTARY PUBLIC MECKLENBURG COUNTY, N.C.

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: InfuCare Rx, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): PH04244

Physical Address: 2540 Market Street, Ste. 1

City: Aston State: PA Zip: 19014

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-202-6017 Toll Free # (NAC 639.708, NRS 639.23286): 877-202-6017

Fax: 877-278-1544 Contact Email: licensing@infucarerx.com

Website: www.infucarerx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Andrew Wee

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22276

Name of Designated Person(s) as defined by revised USP-797 guidelines: Scott Bell, Sherilyn Veder, Thomas McCool

Email of Designated Person(s): sbell@infucarerx.com, sveder@infucarerx.com, tmccool@infucarerx.com

Telephone of Designated Person(s): 877-202-6017

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

   ☑ Category 1 ☑ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ☑ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? **No** ☐ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ☑ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 8/5/25 Clean Room #1, 9/3/25 Clean Room #2

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☑ Yes ☐ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? N/A ☐ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Monthly

10. Will you be performing sterile hazardous drug compounding? ☐ Yes ☑ No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Amikacin Sulfate, Ampicillin Sodium, Avycaz, Azithromycin, Aztreonam, ceFAZolin Sodium, Cefepime HCl, cefOXitin, Sodium, cefTAZidime, cefTRIAXone , DAPTOmycin, Ertapenem, Gentamicin Sulfate, IMIPENEM/CILASTATIN, Meropenem, Micafungin Sodium, MYCAMINE, Nafcillin, Oxacillin Sodium, Penicillin G Potassium, PENICILLIN G, POTASSIUM, PFIZERPEN, PIPERACILLIN SODIUM/TAZOB, TEFLARO, Tigecycline, Unasyn, Vancomycin HCl, Zerbaxa, TPN, Hydration

12. What laboratory performs your sterility or endotoxin testing?

Name: N/A

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

13. What is your procedure for visual inspection of compounded sterile products?

We visually inspect each compounded sterile product under a black and white light. The visual inspection is done once the compounded sterile product is prepared (and again prior to shipping if stored in the refrigerator immediately after compounding).

14. How often do you perform glove fingertip and medial fill testing?

Every 6 months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Initially, staff members are trained to ensure qualification in compounded sterile preparations. The knowledge check is done via SoleSource training and the competency is completed via hands on visual observations. Ongoing training is done annually for knowledge check via SoleSource, and visual observation competencies via Simplifi. Additionally, gloved fingertip and thumb sampling and media fill is done every 6 months.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

A daily cleaning is done using a germicidal disinfectant (sterile TB1-3300) at all ISO 5 and ISO7 area, high tough areas, interior surfaces, pass through, work surfaces, floors,and sink. All the listed areas are then wiped using sterile Isopropyl Alcohol 70%. A monthly cleaning is done using a sproficidal agent (Peridox RTU) in all the areas for daily cleaning, ceilings, walls, doors, equipment outside PEC, storage bin, and furniture surfaces.

17. Who performs the sterile compounding process at your facility?

Compounding staff includes anyone that has completed all parts of the initial and onboarding training.

18. Who is responsible and accountable for the sterile compounding process at your facility?

Designated Person

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

The products are shipped in packaging to maintain the refrigerated temperature requirements. Ice bricks and bubble wrapping is also used to maintain the product efficacy.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A - we do not dispense any hazardous compounded medications		
2. Are you complying with all USP 800 guidelines?	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device: N/A - we do not dispense any hazardous compounded medications		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? N/A - we do not dispense any hazardous compounded medications

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?
N/A - we do not dispense any hazardous compounded medications

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:
N/A - we do not dispense any category 3 compounds

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?
N/A - we do not dispense any category 3 compounds

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?
N/A - we do not dispense any category 3 compounds

5. What is the frequency for completing surface sampling? N/A - we do not dispense any category 3 compounds		
6. What is the frequency for using sporicidal agents? N/A - we do not dispense any category 3 compounds		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Wee

Name of Person who Completed the Form

Pharmacist in Charge

Title

Andrew Wee

Signature (copies or stamps not accepted)

11 / 20 / 2025

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

CERTIFICATE *of* SIGNATURE

REF. NUMBER
ERWUW-F5MRS-ICNHD-NPASX

DOCUMENT COMPLETED BY ALL PARTIES ON
20 NOV 2025 17:40:01
UTC

SIGNER	TIMESTAMP	SIGNATURE
TIFFANY SCHEPPERS EMAIL TSCHEPPERS@INFUCARERX.COM	SENT 11 NOV 2025 16:53:56 VIEWED 11 NOV 2025 21:12:36 SIGNED 11 NOV 2025 21:13:09	Tiffany Scheppers, Corporate Secretary IP ADDRESS 172.72.172.164 LOCATION WAXHAW, UNITED STATES
RECIPIENT VERIFICATION	EMAIL VERIFIED 11 NOV 2025 21:12:36	
ANDREW WEE EMAIL AWEE@INFUCARERX.COM	SENT 11 NOV 2025 16:53:56 VIEWED 20 NOV 2025 17:39:25 SIGNED 20 NOV 2025 17:40:01	Andrew Wee IP ADDRESS 100.11.32.100 LOCATION ASTON MILLS, UNITED STATES
RECIPIENT VERIFICATION	EMAIL VERIFIED 20 NOV 2025 17:39:25	

Commonwealth of Pennsylvania- Department of State
Bureau of Professional and Occupational Affairs

Mailing Address P.O. Box 2649, Harrisburg, PA 17105 Toll Free: 1-833-DOS-BPOA

INFUCARE RX
ANDREW C WEE

License Number	: PP482586	Initial License Date : 09/11/2015	Expiration Date	: 08/31/2027
License Type	: Pharmacy		License Status as of 7/11/2025	: Active
Issued By	: State Board of Pharmacy			
Address	: 2540 MARKET ST STE ONE, Aston, PA 19014			

COMMONWEALTH OF PENNSYLVANIA • DEPARTMENT OF STATE •

Arion R. Claggett

Acting Commissioner Arion R. Claggett

Signature of Licensee

SCAN ME

Please verify the license by visiting https://www.pals.pa.gov/verify or by scanning the QR Code

20250710523

2230

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

P. O. Box 2649

Harrisburg, PA 17105-2649

10/15/2025

License Information

INFUCARE RX

2540 MARKET ST STE ONE
Aston, Pennsylvania 19014

Board/Commission:	State Board of Pharmacy	Status Effective Date:	09/11/2015
LicenseType:	Pharmacy	Issue Date:	09/11/2015
Specialty Type:	Inspected by Board	Expiration Date:	08/31/2027
License Number:	PP482586	Last Renewal:	07/10/2025
Status:	Active		

Prerequisite Information

Licensee	Relationship	License Type	License Number	License Status	Associated Date	License Expiration Date
ANDREW C WEE	Business Relationship	Pharmacist	RP439835	Active	07/27/2018	09/30/2026

Disciplinary Action Details

No disciplinary actions were found for this license.

This site is considered a primary source for verification of license credentials provided by the Pennsylvania Department of State.

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY
INFUCARE RX

Phone: Phone 1: 877 8283940
Owner: INFUCARE RX LLC

LICENSE
License No: PP482586
Profession: Pharmacy
License Type: Pharmacy
Inspection Type: Directed Routine
Inspection Date: 08/11/2025
Inspection Result: Passed

Remarks:

The undersigned licensee, designee, or other authorized representative of the licensee acknowledges the completion of this inspection and the results as indicated on the summary and checklist reports.

ROBERT MONTGOMERY	8/11/2025 11:42:09 AM	Andrew Wee - RP439835
Signature of Inspector	Date/Time	Signature of Owner/Representative

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY
INFUCARE RX

Phone: Phone 1: 877 8283940
Owner: INFUCARE RX LLC

LICENSE
License No: PP482586
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: Directed Routine

Inspection Date: 08/11/2025
Inspection Result: Passed

Remarks:

Question	Answer
Are all licenses current and posted?	YES
Is a "No Smoking" sign prominently posted?	YES
Is the generic equivalent sign and list of commonly used equivalents properly posted?	YES
Is there a refrigerator with temperature monitoring for drug storage only?	YES
Is hot and cold water available in the prescription area?	YES
Are current copies of all Federal, State, and Board statues and regulations pertaining to pharmacy practice available? (Internet access is acceptable)	YES
Are outdated drugs appropriately removed from active stock?	YES
Does the pharmacy meet all security requirements?	YES
Does the pharmacy have adequate equipment and supplies to enable it to properly prepare and dispense consistent with the pharmacy's scope of practice?	YES
Is the pharmacy in compliance with all sanitation, cleanliness, maintenance, and construction requirements?	YES
Do labels have all the required information and match the license record?	YES
Are all prescriptions verified by registered pharmacists?	YES
Is the name or initials of the dispensing pharmacist noted on the prescriptions?	YES
Are prescription files properly maintained? (electronic files are acceptable)	YES
Are transferred prescriptions properly recorded?	YES
Are Schedule II drugs securely locked in a substantially constructed cabinet or dispersed throughout the stock?	YES
Are there signed and dated protocols for each pharmacy technician?	YES
Does the pharmacy have an automated medication system?	NO
Does the pharmacy administer injectable medications, biologicals, or immunizations?	NO

Pharmacy Name:	InfuCare Rx LLC DBA InfuCare Rx
Pharmacy Address:	2540 Market St, Ste 1, Aston, PA, 19014
NABP Business e-Profile ID:	1309782
VPP Inspection Date(s):	9/16/2025
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	12	11	Dispense File for 2025 YTD attached. Total dispenses shipped to MD office in Nevada labeled for office use is 0.12%	NA	Y	Aston Dispense to NV 2025 YTD 10-22-25
Clarification or Further Explanation	23	57	ICRX does not order nor dispense controlled substances. We are attaching DEA Bi-Annual Controlled substances report completed 2/26/25	NA	Y	Aston Biannual Controlled Substance Inventory 2025
Clarification or Further Explanation	33.0	68	Designated personnel review all certification reports and sign an attestation in Simplifi 797 compliance Software. If any recommendations are made based off of the cleanroom report these will be documented in Simplifi 797 as well.	NA	Y	Aston Clean Room 1 DP Sign off of 8-25 Certification Report
Clarification or Further Explanation	33.7	70	Certification report does provide both ACPH for ISO 5, 7, and 8 environment. Information for this was split onto two pages on the report.Items for the ACPH for the ISO 7 and ISO 8 enviromnent are on page 7, the 2 ISO 5 hoods ACPH are listed on page 8 of the report. Report attached.	NA	Y	InfuCare Rx Clean Room 1 Certification Report 8-5-25
Updates/New SOPs or P&Ps	69	124	We do have MFR/CR's on file, but they were not merged into one document. We have made changes to the operations to merge the MFR into the compounding record. This includes a physical description of the final componded sterile product and BUD.	10/1/25	Y	Aston MFR/CR Examples 10-27-25
Updates/New SOPs or P&Ps	69.8	125	We do have MFR/CR's on file, but they were not merged into one document. We have made changes to the operations to merge the MFR into the compounding record. This includes a physical description of the final componded sterile product and BUD.	10/1/25	Y	Aston MFR/CR Examples 10-27-25
Updates/New SOPs or P&Ps	69.10	125	We do have MFR/CR's on file, but they were not merged into one document. We have made changes to the operations to merge the MFR into the compounding record. This includes a physical description of the final componded sterile product and BUD.	10/1/25	Y	Aston MFR/CR Examples 10-27-25
Updates/New SOPs or P&Ps	70	126	We do have MFR/CR's on file, but they were not merged into one document. We have made changes to the operations to merge the MFR into the compounding record. This includes a physical description of the final componded sterile product and BUD.	10/1/25	Y	Aston MFR/CR Examples 10-27-25
Updates/New SOPs or P&Ps	70.15	128	We do have MFR/CR's on file, but they were not merged into one document. We have made changes to the operations to merge the MFR into the compounding record. This includes a physical description of the final componded sterile product and BUD.	10/1/25	Y	Aston MFR/CR Examples 10-27-25

This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

Shipments to NV MD for office use.

Dispense Site Name	MRN	Patient State	Script Dispense Count Total	Total Scripts Dispensed YTD 10-22-25	Percent Dispensed to NV MD for office use
Aston (PA)	207496	NV	68	56044	0.12%

Aston Biannual Controlled Substance Inventory 2025 - Page 1 of 1

DEA Biennial Controlled Substance Inventory Form (Example)
For the Use of Controlled Substances in Research
A separate initial inventory is required for each registered location. Do not submit a copy of the biennial inventory to the DEA or IBPE unless requested

Date: 02/28/2025

DEA Registrant (Print Name): InfuCare Rx, LLC

DEA Registration Number: [redacted]

DEA Registrant Address: 2540 Market Street, STE 1 Aston, PA 19014
(As appears on DEA Form 223)

Inventory Performed by: Andrew Wee - Pharmacist In Charge
Print Name

Signature

Inventory Witness: [illegible]
Print Name

Signature

☑ Start of day ☐ End of day

Line No.[1]	Drug Information[2]		Controlled Substance Name and manufacture/Vendor	Unopened Containers[3]		Opened Containers[4,5,6]			Finished Form[7]
	DEA No.	Schedule		Qty.	Container Size	Qty.	Container Size	Remaining amount	
1			ZERO CONTROLS in stock						
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									

(1) Cross out the unused lines. Keep the biennial inventory record at the licensed-registered location. (2) Schedule I and II drugs must be separated from all other drugs or placed on a separate form. (3) Unopened containers of same substance, manufacturer, volume, and concentration can be listed together. (4) List open containers as separate line items. (5) Measure in weight (powder or crystals) or volume (liquids) or number of units (tablets or capsules). (6) For opened containers: If the substance is listed in Schedule I or II, make an exact count or measure of the contents. (7) Finished form refers to the strength and form of the item as commercially prepared.

Aston Biannual Controlled Substance Inventory 2025 - Page 1 of 1

Aston Clean Room 1 DP Sign off of 8-25 Certification Report - Page 1 of 1

ompounding Are	Task ID	Task Name	Task Criteria	Due Date	Completed Date	Completed By
lean Room 1	14566	***Semiannual Hood & Room Certification	All PECs and rooms have been certified according to CETA CAG-003-2006 guidelines and found to be operating within the regulations	08/31/2025 23:59	08/20/2025 15:16	Vedar DP, Sherilyn
lean Room 1	14566	***Semiannual Hood & Room Certification	Certification report has been reviewed for accuracy	08/31/2025 23:59	08/20/2025 15:16	Vedar DP, Sherilyn
lean Room 1	14566	***Semiannual Hood & Room Certification	All certification paperwork is current and on file in the pharmacy	08/31/2025 23:59	08/20/2025 15:16	Vedar DP, Sherilyn
lean Room 1	14566	***Semiannual Hood & Room Certification	Certifier has completed all testing and results are filed according to policy - airflow testing - HEPA filter integrity testing - total particle count testing - dynamic airflow smoke pattern test - room pressurization - additional PEC requirements	08/31/2025 23:59	08/20/2025 15:16	Vedar DP, Sherilyn

InfuCare RX Cleanroom Testing Report

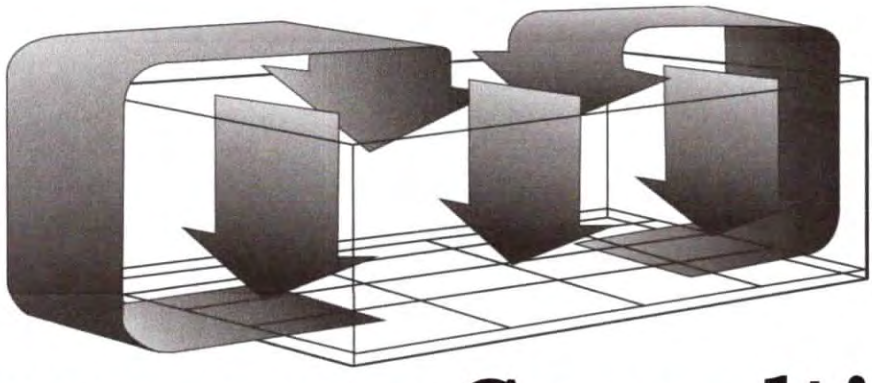
August 2025

Performed At:

InfuCare RX
2540 Market Street, Suite 1
Aston, Pennsylvania 19014

Prepared For:

Mr. Thomas McCool



Cleanroom Consulting Services

P.O. Box 394, Douglassville, Pennsylvania 19518
(800) 970-7629
(610) 385-1826 FAX
WWW.CleanroomConsulting.Com

Executive Summary

Cleanroom testing was completed on August 5, 2025 within the InfuCare RX cleanroom. This scheduled testing is part of a semi-annual rotation. This type of program is designed to furnish an operating baseline of readings. Any abnormal fluctuations from that baseline can be corrected quickly without a contamination crisis. The following points of interest are noted.

1. Testing was performed in the "Operational" cleanroom condition with the Labconco and Cleatech laminar flow hoods operating. "Operational" is the term used for testing a cleanroom in the state at which all machinery is operational and production workers are present. Up to two workers plus the tester were present.

2. Average temperature recorded in the main cleanroom was 66.62°. This average is considered generally acceptable. A room temperature average of 63° – 70° (USP-797) degrees Fahrenheit, depending upon product specifications, gowning requirements and worker comfort is recommended. It is recommended that the control system be evaluated by a qualified mechanical company.

3. Average relative humidity recorded in the main cleanroom was 41.05%. This average is considered to be generally on the slightly dry side of acceptable. The guidance in ISO Document 14644-4 "Cleanrooms and Associated Controlled Environments – Part 4 refers to a typical set range of less than 65.00% but higher than 30.00%. Generally, a relative humidity average of approximately 45.00% should be maintained (Unless product protection warrants otherwise (USP-797 less than 60%). Humidity varied during testing. It is recommended that the control system be evaluated by a qualified mechanical company.

4. All readings were taken with the Labconco and Cleatech laminar flow hoods operational with the white lights on. The UV light of the Labconco laminar flow hood was verified as functional.

5. Viable microbiological samples, both air and surface, were collected in the clean areas. A set of negative controls were also evaluated. All viable microbiological samples were taken in the "dynamic" condition.

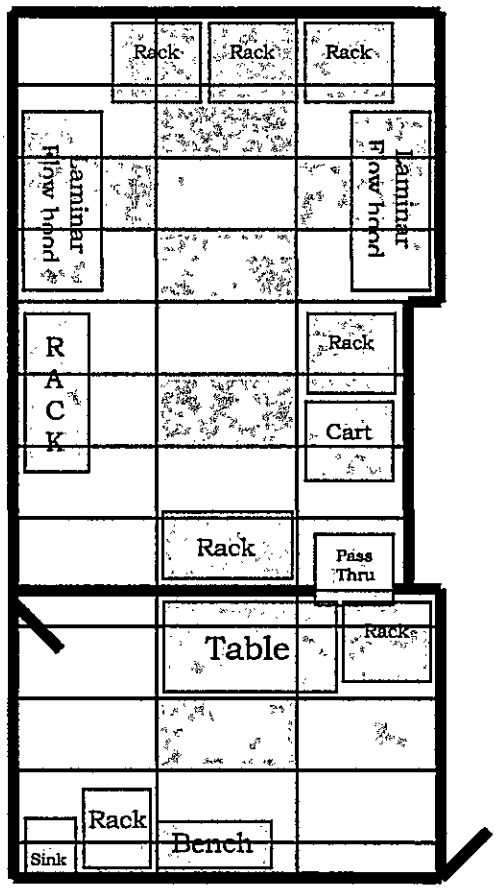
6. All equipment utilized for testing has been calibrated according to manufacturer recommendations and NIST traceable standards. Calibration certificates included.

7. All drawings are accurate representations but not to exact scale.

8. It is hypothesized that the Repeater Pump has previously damaged the HEPA filter in the lower right corner of the Cleatech laminar flow hood. These minor damages have been able to be repaired, thus far. This should be monitored. Care must always be taken to not to come in contact with the HEPA filter face in either laminar flow hood.

10. Airflow visualization studies using smoke were performed within the laminar flow hoods using a visual smoke. These studies were recorded and are included as attachments to this report.

11. It appears that indoor shoes are now being used as the standard clean area footwear.



Main Cleanroom

Gowning

HEPA Filter Leak Test Summary

PURPOSE: To verify that all HEPA filters, filter housings and mounting frames located in the clean areas are free from leakage.

PROCEDURE: The instruments were set up and operated per manufacturers' instructions. PAO aerosol generator output was introduced upstream of the HEPA filters and measured or calculated to establish leakage limits. The sample probe of the photometer was used to scan the entire downstream side of the HEPA filters, mounting frames and filter housing at a traverse rate of not more than 2 inches per second in slightly overlapping strokes. The probe was 1 inch in area and had a sample rate of 1 cubic foot per minute/28.3 liters per minute.

SPECIFICATIONS: Aerosol penetration shall not exceed 0.01% of the upstream concentration at any point. Repairs of any leakage greater than 0.01% of the upstream air are made using silicone caulking and/or filter media paper. The size of any repair shall be less than 5% of the filter face area and less than 1.5" in length or width.

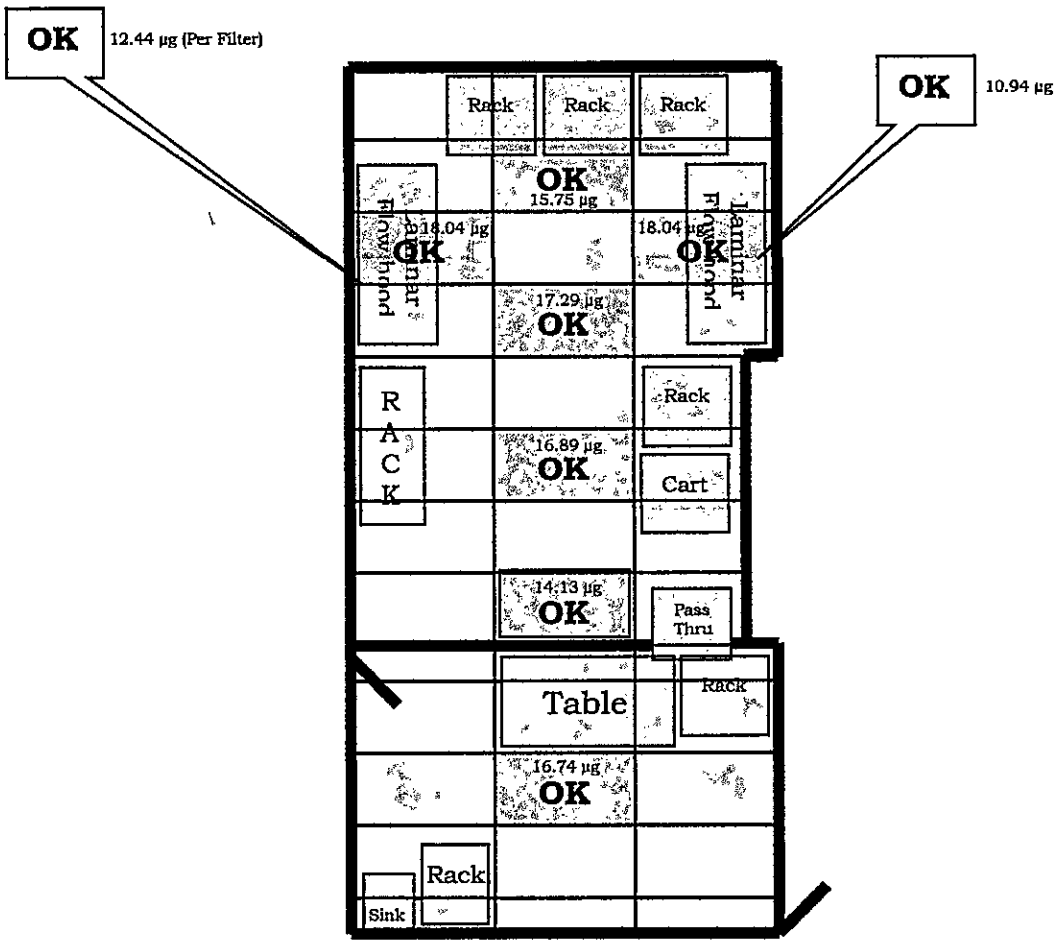
INSTRUMENTATION: 1 CFM/28.3 LPM Aerosol Photometer, Hand Held Sampling Probe, PAO aerosol Generator, Air Compressor

Model: ATI, TDA-2E
Calibration Date: August 9, 2024

INSTRUMENTATION SPECIFICATIONS: Penetration is measured in percent (%). The internal reference is 10% ± 1.0%. The sample flow rate is 28.3 LPM (1 CFM) ± 2.8 LPM.

RESULTS:

No leakage was detected in the HEPA filters located in the clean areas.


OK
12.44 µg (Per Filter)
OK
10.94 µg
Rack
Rack
Rack
OK
15.75 µg
Laminar Flow Hood
18.04 µg
OK
Laminar Flow Hood
18.04 µg
OK
17.29 µg
OK
R A C K
Rack
16.89 µg
OK
Cart
14.13 µg
OK
Pass Thru
Table
Rack
16.74 µg
OK
Rack
Sink

Airflow Velocity Test Summary

PURPOSE: To determine the velocity of air in feet per minute (FPM) delivered through each HEPA filter.

PROCEDURE: The air data multimeter and/or hot wire thermo-anemometer was used to sample the air flow rate on the appropriate test grid pattern of the in-ceiling HEPA filters and laminar flow hoods. The total room air volume was then calculated in cubic feet of air by multiplying the average filter velocity by the effective filter area. The uniformity range was calculated by taking the average air velocity and determining the percentage of individual readings that are ± 20% of that average.

INSTRUMENTATION: Electronic Air Data Multimeter, Hot Wire Thermo-Anemometer, ring stand

Model: Shortridge, ADM-870
Calibration Date: May 12, 2025

Model: TSI, 9535
Calibration Date: August 19, 2024

INSTRUMENTATION SPECIFICATIONS: Air Data Multimeter - Air velocity is measured in feet per minute (FPM) or meters per second (M/S) and corrected for local or standard density. The measurement range is 25 to 30,000 FPM with a pitot tube and 25 to 10,000 FPM with the Velprobe. The measurement range using the Velgrid is 25 to 2500 FPM. Accuracy is ±3% of readings and ±5% from 25 to 10,000 FPM.

Hot Wire Thermo-Anemometer - Air velocity is measured in feet per minute (FPM) or meters per second (M/S). The measurement range is 0 to 6,000 FPM with a 1 FPM resolution. Accuracy is ±3.0% of readings or ±3.0 FPM, whichever is greater.

RESULTS:

Room/Area	Velocity (FPM)	± 20% Uniformity Range	Air Volume (CFM)	Air Changes Per Hour (ACH)
Main Cleanroom	113.83	100.00%	4,961.65	197.95
Gowning Area	119.50	100.00%	868.17	67.83

Airflow Velocity Test Summary (Continued)

PURPOSE: To determine the velocity of air in feet per minute (FPM) delivered through each HEPA filter.

PROCEDURE: The air data multimeter and/or hot wire thermo-anemometer was used to sample the air flow rate on the appropriate test grid pattern of the in-ceiling HEPA filters and Labconco laminar flow hood. The total room air volume was then calculated in cubic feet of air by multiplying the average filter velocity by the effective filter area. The uniformity range was calculated by taking the average air velocity and determining the percentage of individual readings that are ± 20% of that average.

INSTRUMENTATION: Electronic Air Data Multimeter, Hot Wire Thermo-Anemometer, ring stand

Model: Shortridge, ADM-870
Calibration Date: May 12, 2025

Model: TSI, 9535
Calibration Date: August 19, 2024

INSTRUMENTATION SPECIFICATIONS: Air Data Multimeter - Air velocity is measured in feet per minute (FPM) or meters per second (M/S) and corrected for local or standard density. The measurement range is 25 to 30,000 FPM with a pitot tube and 25 to 10,000 FPM with the Velprobe. The measurement range using the Velgrid is 25 to 2500 FPM. Accuracy is ±3% of readings and ±5% from 25 to 10,000 FPM.

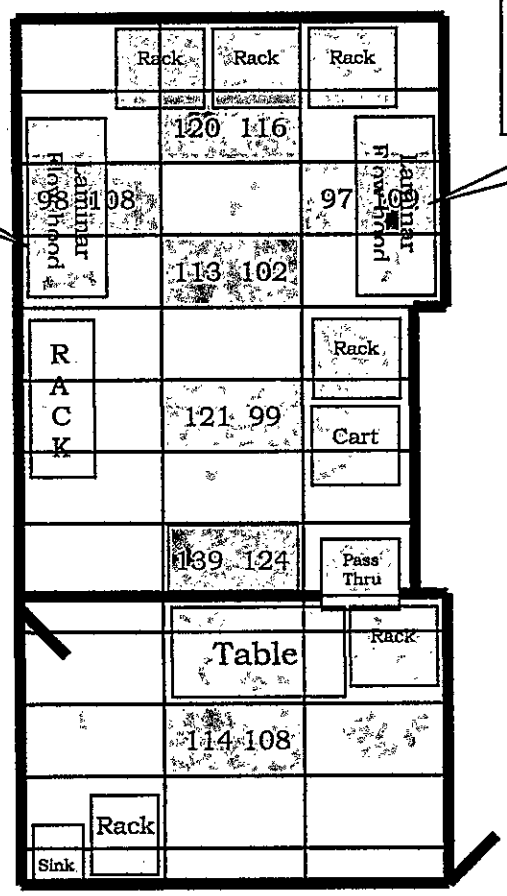
Hot Wire Thermo-Anemometer - Air velocity is measured in feet per minute (FPM) or meters per second (M/S). The measurement range is 0 to 6,000 FPM with a 1 FPM resolution. Accuracy is ±3.0% of readings or ±3.0 FPM, whichever is greater.

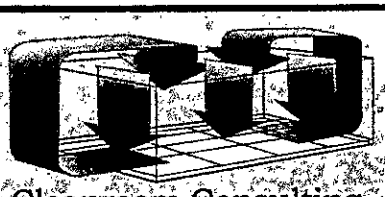
RESULTS:

Room/Area	Velocity (FPM)	± 20% Uniformity Range	Air Volume (CFM)	Air Changes Per Hour (ACH)
Labconco Laminar Flow Hood	94.75	100.00%	1,234.08	49.23
Cleatech Laminar Flow Hood	90.67	100.00%	1,085.04	43.29

87	87	93	87	88	92
87	89	98	93	89	95

85	95	87	82	81
99	109	109	109	96
95	109	102	105	93
94	104	109	112	100





Cleanroom Consulting Services
P.O. Box 394, Douglassville, Pennsylvania 19518 (800) 970-7629

Airflow Velocity (Feet Per Minute)

InfuCare RX Cleanroom

Aston, Pennsylvania

DATE: August 5, 2025

Room Pressurization Test Summary

PURPOSE: To verify that the cleanroom systems can maintain a specified positive pressure in inches water column (W.C.) to all outside surrounding less clean areas.

PROCEDURE: With all doors closed and the air handling system operating at design capacity, the pressure differential (in inches water column) between the cleanrooms and surrounding areas were measured. The direction of pressurization and the differential pressure to the nearest 0.0001" W.C. was recorded.

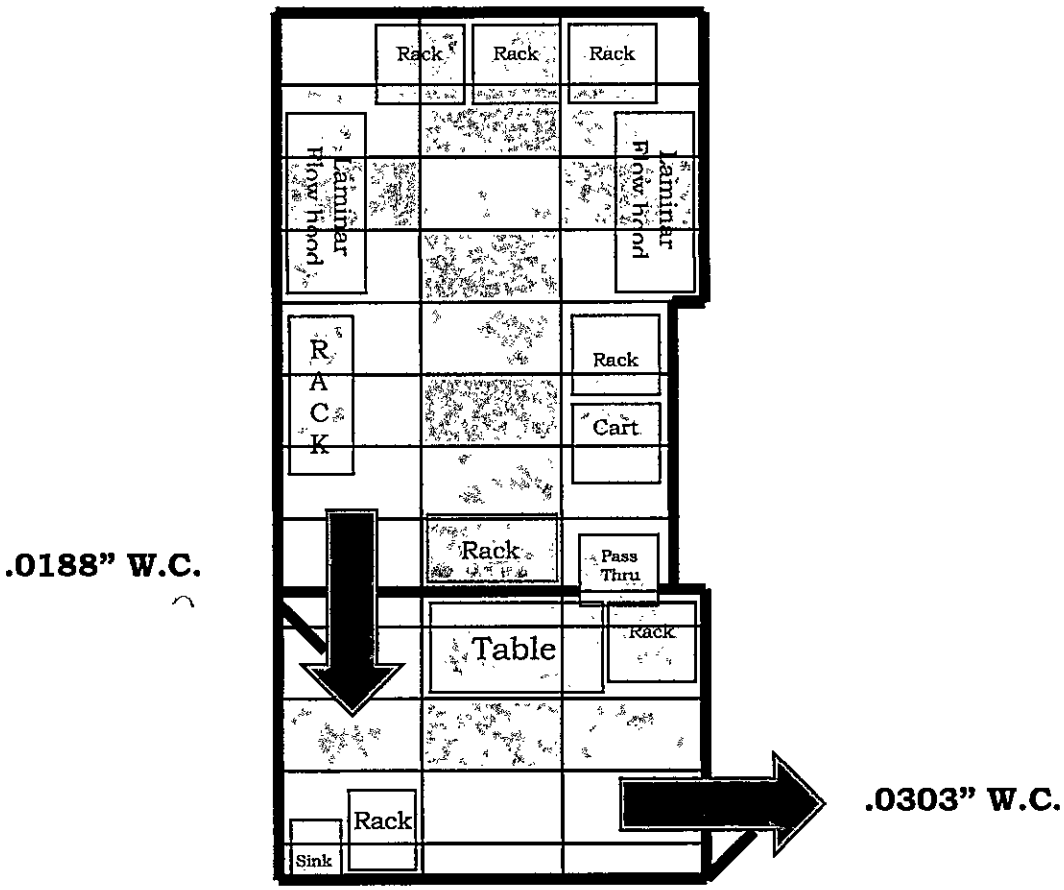
INSTRUMENTATION: Electronic Air Data Multimeter

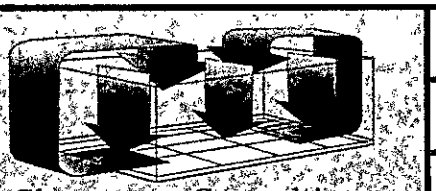
Model: Shortridge, ADM-870
Calibration Date: May 12, 2025

INSTRUMENTATION SPECIFICATIONS: Pressure differential is measured in inches of water column (W.C.) or Pascals (Pa). The measurement range is from 0.0001 to 60.00 inches W.C. Maximum safe pressures are 20 psid (900% full scale) and 60 psia common mode. Accuracy is ±2% of readings ± one digit.

RESULTS:

From Room/Area:	Relative to:	Reading
Main Cleanroom	Gowning Room	+.0188" W.C.
Gowning Room	Gowning Entrance	+.0303" W.C.





Cleanroom Consulting Services
P.O. Box 394, Douglassville, Pennsylvania 19518 (800) 970-7629

Room Pressurization (Inches Water Column)

InfuCare RX Cleanroom

Aston, Pennsylvania

DATE: August 5, 2025

Airborne Particle Count Test Summary

PURPOSE: To measure the airborne particle levels in microns (µ) within the clean areas in order to classify the area per ISO 14644-1 and/or ISO 14644-2.

PROCEDURE: The clean areas were divided into grids of equal proportion. The particle counter was set up and operated per manufacturers instructions. Particle counts were taken at the 0.5 micron size and larger and sampled at a rate of 1 cubic foot per minute/28.3 Liters per minute. All measurements were made under ambient conditions with no additional induced challenge. The particle counter probe was placed in the center of each test grid at approximately 36" above the floor using the tripod and sampled for one minute. The particle count at each grid location was recorded.

INSTRUMENTATION: 1 CFM/28.3 LPM laser particle counter, sampling probe, tripod

Model: Met One 2408
Calibration Date: August 7, 2024

INSTRUMENTATION SPECIFICATIONS: Particles are measured in microns (µ). The flow rate is 1 CFM/28.3 LPM ± 10% with less than a 5% coincidence loss at 400,000 particles per cubic foot/liters per minute of sampled air.

RESULTS:

A statistical analysis was calculated at the 0.5µ size for the following areas tested as described in ISO 14644-1 and/or ISO 14644-2. All readings were taken in the "Operational" condition.

Room/ Area	Size	Average Particle Count	Standard Deviation	Standard Error	95% Upper Confidence Limit	Classification
Main Cleanroom						
F^3	0.5µ	32.13	49.87	17.63	65.63	(Class 10,000)
M^3	0.5µ	1134.01	1760.50	622.43	2316.63	ISO-7
Gowning Area						
F^3	0.5µ	490.80	244.81	109.48	720.72	(Class 100,000)
M^3	0.5µ	17325.24	8641.96	3864.80	25441.32	ISO-8

Airborne Particle Count Test Summary (Continued)

PURPOSE: To measure the airborne particle levels in microns (µ) within the clean areas in order to classify the area per ISO 14644-1 and/or ISO 14644-2.

PROCEDURE: The clean areas were divided into grids of equal proportion. The particle counter was set up and operated per manufacturers instructions. Particle counts were taken at the 0.5 micron size and larger and sampled at a rate of 1 cubic foot per minute/28.3 Liters per minute. All measurements were made under ambient conditions with no additional induced challenge. The particle counter probe was placed in the center of each test grid at approximately 36" above the floor using the tripod and sampled for one minute. The particle count at each grid location was recorded.

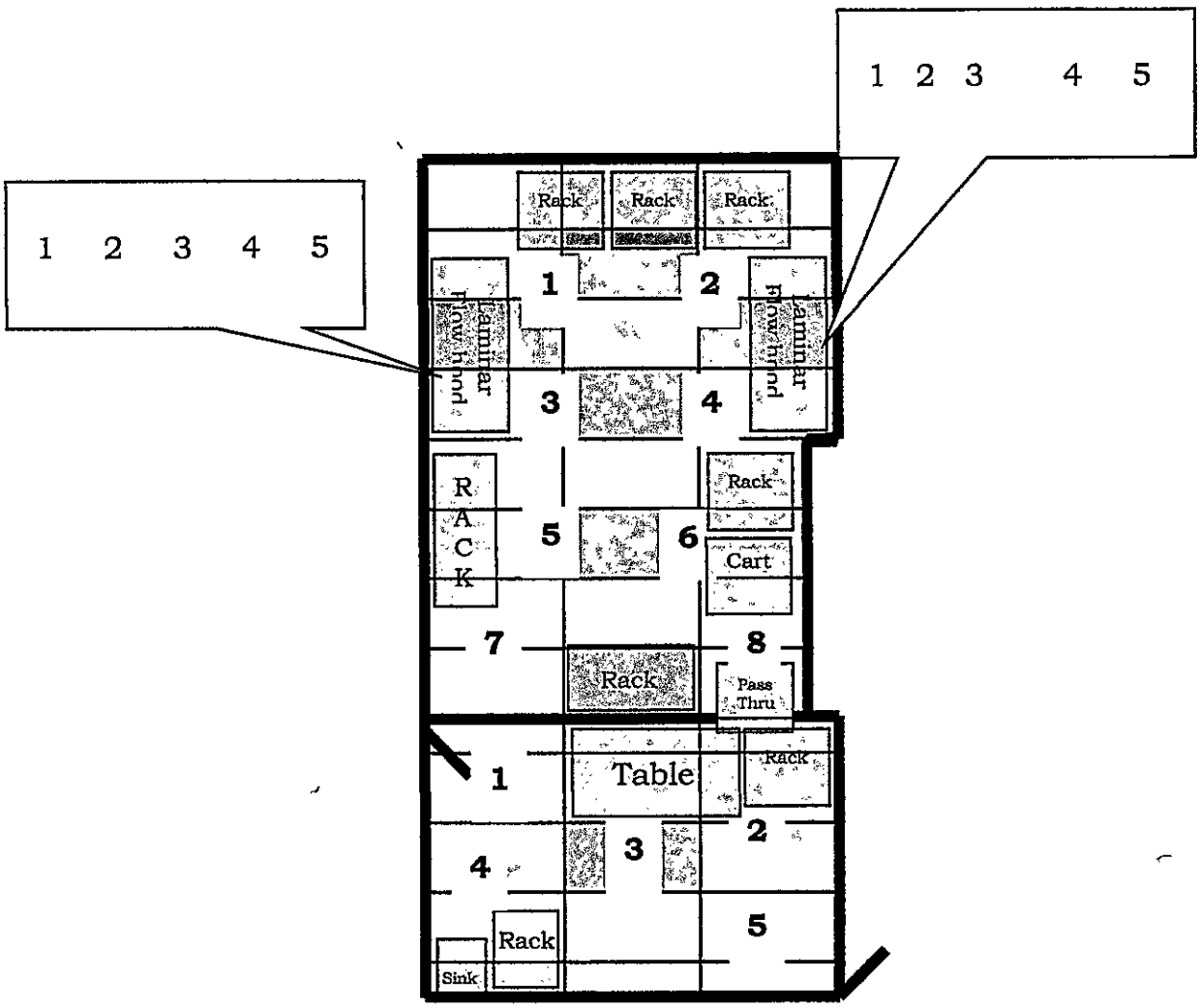
INSTRUMENTATION: 1 CFM/28.3 LPM laser particle counter, sampling probe, tripod

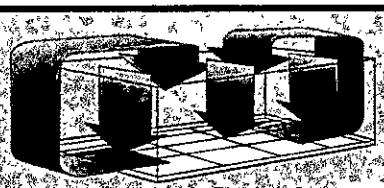
Model: Met One 2408
Calibration Date: August 7, 2024

INSTRUMENTATION SPECIFICATIONS: Particles are measured in microns (µ). The flow rate is 1 CFM/28.3 LPM ± 10% with less than a 5% coincidence loss at 400,000 particles per cubic foot/liters per minute of sampled air.

A statistical analysis was calculated at the 0.5µ size for the following areas tested as described in ISO 14644-1 and/or ISO 14644-2. All readings were taken in the "Operational" condition.

Room/ Area	Size	Average Particle Count	Standard Deviation	Standard Error	95% Upper Confidence Limit	Classification
Labconco Laminar Flow Hood						
F³	0.5µ	0.00	0.00	0.00	0.00	ISO-5
M³	0.5µ	0.00	0.00	0.00	0.00	(Class 100)
Cleatech Laminar Flow Hood						
F³	0.5µ	0.00	0.00	0.00	0.00	ISO-5
M³	0.5µ	0.00	0.00	0.00	0.00	(Class 100)





Cleanroom Consulting Services
P.O. Box 394, Douglassville, Pennsylvania 19518 (800) 970-7629

Particle Count Locations
InfuCare RX Cleanroom
Aston, Pennsylvania

DATE: August 5, 2025

Airborne Particle Counts
Pre-Testing Instrumentation Zero Count

Locations	0.5µ	1.0µ	5.0µ
1	0	0	0

Airborne Particle Counts
Post-Testing Instrumentation Zero Count

Locations	0.5µ	1.0µ	5.0µ
1	0	0	0

Airborne Particle Counts
Main Cleanroom (Operational)

Locations	F^3 0.5µ	1.0µ	5.0µ	M^3 0.5µ	1.0µ	5.0µ
1	35	25	14	1236	883	494
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	5	1	0	177	35	0
5	0	0	0	0	0	0
6	2	0	0	71	0	0
7	82	50	11	2895	1765	388
8	133	72	3	4695	2542	106

Airborne Particle Counts
Gowning Area (Operational)

	F^3			M^3		
Locations	**0.5µ**	**1.0µ**	**5.0µ**	**0.5µ**	**1.0µ**	**5.0µ**
1	730	411	43	25769	14508	1518
2	633	233	20	22345	8225	706
3	89	64	3	3142	2259	106
4	483	247	20	17050	8719	706
5	519	239	28	18321	8437	988

Airborne Particle Counts
Labconco Laminar Flow Hood (Operational)

	F^3			M^3		
Locations	**0.5µ**	**1.0µ**	**5.0µ**	**0.5µ**	**1.0µ**	**5.0µ**
1		0	0	0	0	0
2		0	0	0	0	0
3		0	0	0	0	0
4		0	0	0	0	0
5		0	0	0	0	0

Airborne Particle Counts
Cleatech Laminar Flow Hood (Operational)

Locations	F^3 0.5µ	1.0µ	5.0µ	M^3 0.5µ	1.0µ	5.0µ
1		0	0	0	0	0
2		0	0	0	0	0
3		0	0	0	0	0
4		0	0	0	0	0
5		0	0	0	0	0

Lighting Level Test Summary

PURPOSE: To determine the intensity of the fluorescent lights in foot candles (FC) at work level height within the clean areas.

PROCEDURE: A preliminary operating period of the lighting preceded this test in order to obtain proper seasoning of the fixtures. The clean areas were divided into grids of equal proportion. The illumination meter was placed in the center of each test grid at work level height (40"). The light levels were recorded.

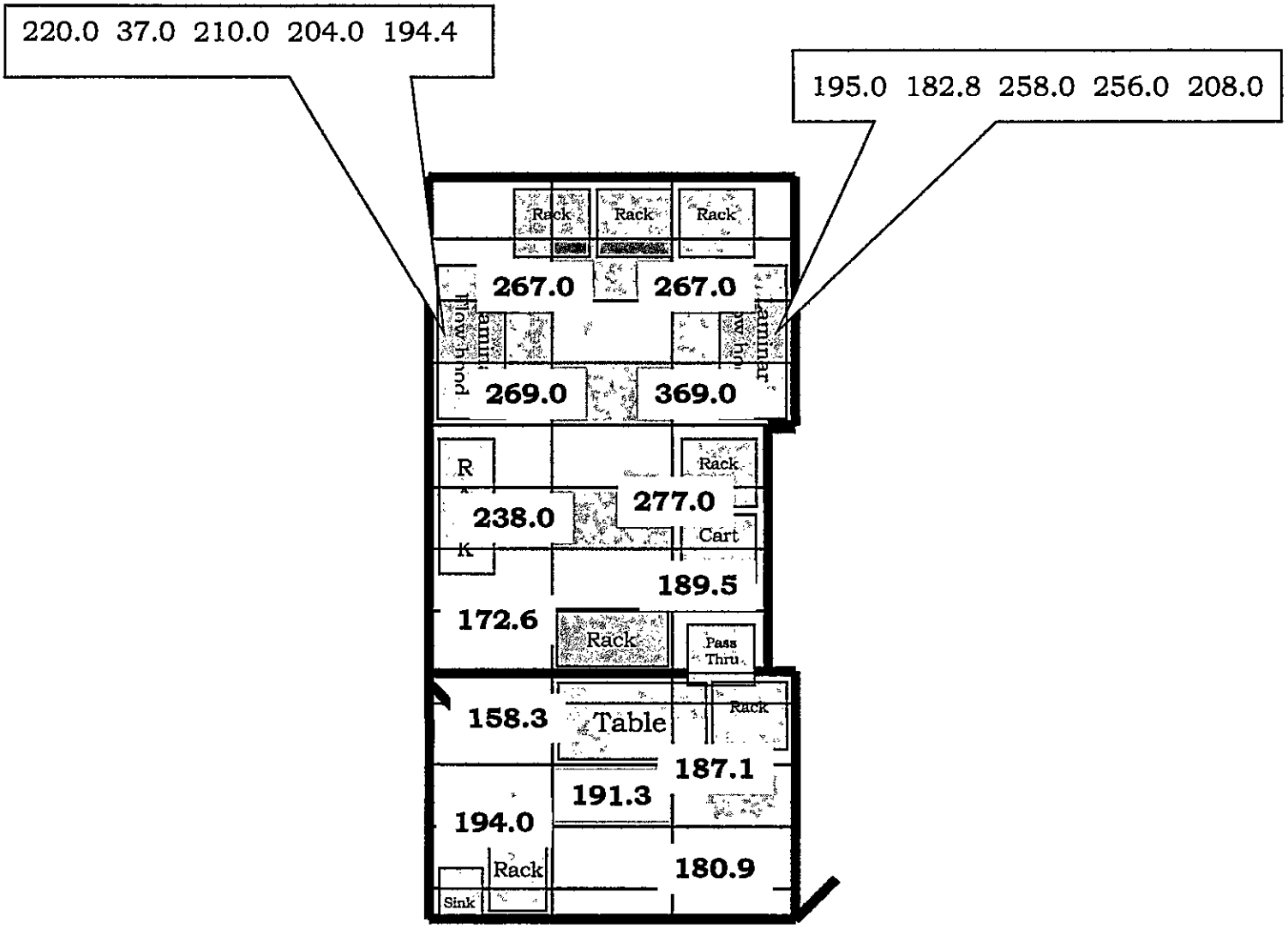
INSTRUMENTATION: Digital Illumination Meter

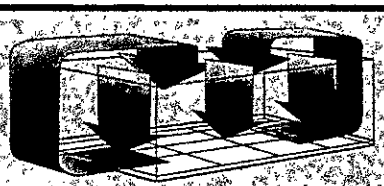
Model: Extech 401027
Calibration Date: August 2, 2024

INSTRUMENTATION SPECIFICATIONS: Light levels are measured in foot candles (FC). The accuracy is ±5% plus 4 digits full scale.

RESULTS:

Room/Area	Average Lighting Level (Foot Candles)
Main Cleanroom	257.39
Gowning Area	182.32
Labconco Laminar Flow Hood	219.96
Cleatech Laminar Flow Hood	213.08





Cleanroom Consulting Services
P.O. Box 394, Douglassville, Pennsylvania 19518 (800) 970-7629

Light Levels (Foot Candles)

InfuCare RX Cleanroom

Aston, Pennsylvania

DATE: August 5, 2025

Sound Level Test Summary

PURPOSE: To measure the sound levels in decibels in the "A" weighting mode (dBA) within the clean areas.

PROCEDURE: The clean areas were divided into grids of equal proportion. The sound level meter was set to record in the "A" weighting mode. The sound level meter was placed in the center of each test grid at a height of 40" above floor level. The sound levels were recorded.

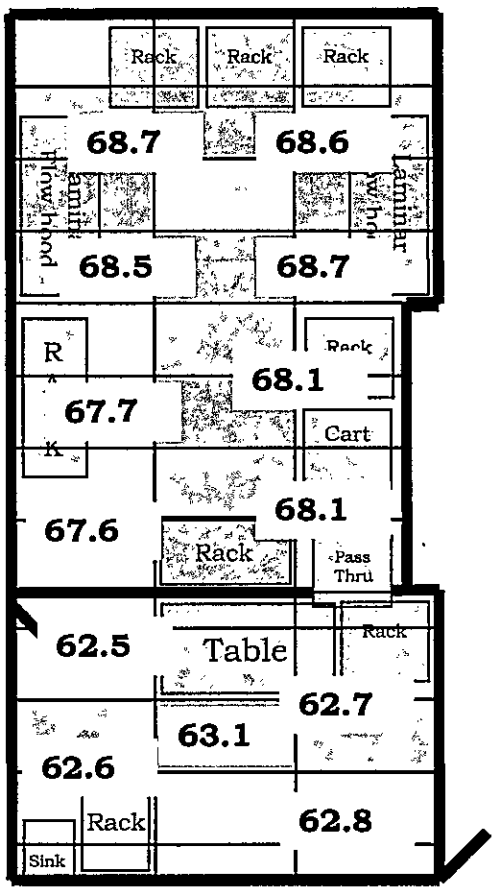
INSTRUMENTATION: Sound Level Meter

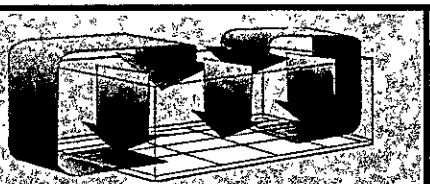
Model: Extech SL-510
Calibration Date: March 12, 2025

INSTRUMENTATION SPECIFICATIONS: Sound levels are measured in decibels within the "A" weighting mode, most sensitive to the human ear (dBA). The accuracy is ±1 dB at 1kHz frequency (Class 2 Standards, IEC 61672-2013 and ANSI/ASA S1.2/Part 1).

RESULTS:

Room/Area	**Average Sound Level (dBA)**
Main Cleanroom	68.25
Gowning Area	62.74





Cleanroom Consulting Services
P.O Box 394, Douglassville, Pennsylvania 19518 (800) 970-7629

Sound Levels (Decibels)

InfuCare RX Cleanroom

Aston, Pennsylvania

DATE: August 5, 2025

Temperature and Humidity Test Summary

PURPOSE: To verify the capability of the cleanroom air handling equipment to maintain temperature (°F) and relative humidity (%) within the design specifications.

PROCEDURE: The clean areas were divided into grids of equal proportion. The temperature and humidity probe was placed into the center of each test grid. Readings were taken at a distance of 36" above the floor. The temperature and humidity levels were recorded.

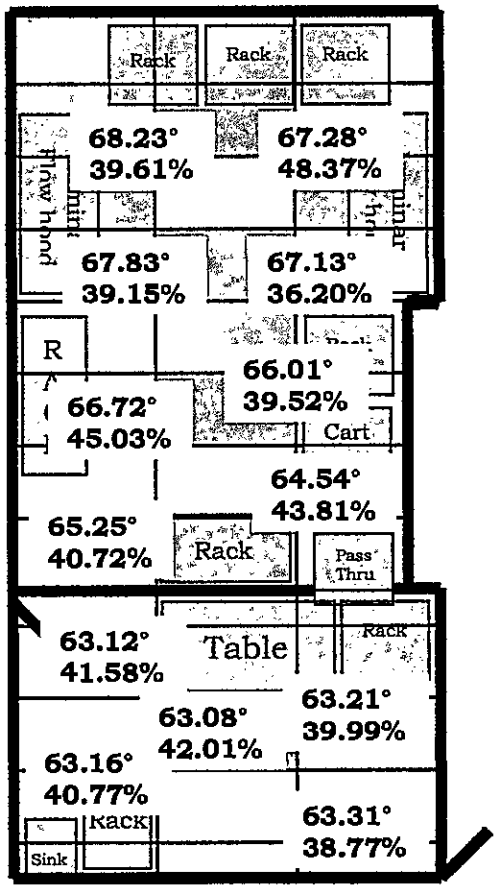
INSTRUMENTATION: Thermohygrometer

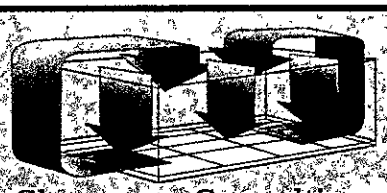
Model: Vaisala MI-70 With HMP-76 Probe
Calibration Date: January 6, 2025

INSTRUMENTATION SPECIFICATIONS: Temperature accuracy is ±.2°C at 20°C. Relative humidity accuracy is ±1% RH at 0% RH to 90% RH and ±1.7% RH at 90% RH to 100% RH.

RESULTS:

Room	Temperature (°F)	Humidity (%)
Main Cleanroom	66.62°	41.05%
Gowning Area	63.18°	40.82%





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P.O. Box 394, Douglassville, Pennsylvania 19518 (800) 970-7629

Temperature (°F), Relative Humidity (%)

InfuCare RX Cleanroom

Aston, Pennsylvania

DATE: August 5, 2025

Viable Microbiological Sample Summary

PURPOSE: To verify the levels of viable microbiological bacteria and fungi present at each plotted location.

PROCEDURE: Select clean area locations were chosen for sample collection. The air sampling equipment was setup per manufacturers instructions and placed into the center of each sample location. Tryptic soy irradiated standard collection contact plate collection agar was used. 1000 liters of air was sampled at all locations.

INSTRUMENTATION: PBI SAS Microbiological Sampler, tryptic soy contact plate agar

Model: PBI SAS Super 180
Calibration Date: April 1, 2025

INSTRUMENTATION SPECIFICATIONS: Airborne micro-organisms are collected on microbiological agar by impaction produced by aspiration. The nominal airflow rate is 100 liters per minute.

RESULTS:

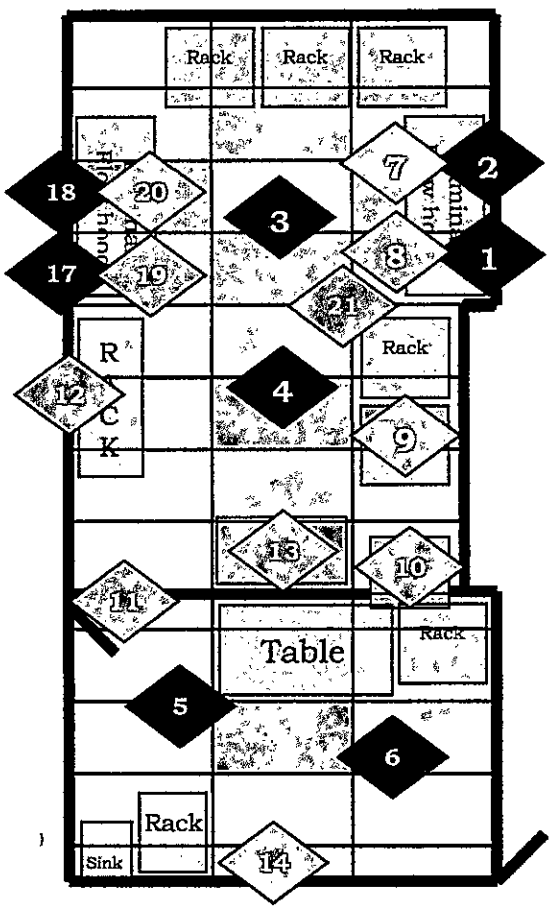
Room	(Raw Count) Bacteria	(Raw Count) Fungi
Sample 1	0	0
Sample 2	0	0
Sample 3	0	0
Sample 4	0	0
Sample 5	4	0
Sample 6	32	0
Sample 7	0	0
Sample 8	0	0
Sample 9	0	0
Sample 10	0	0
Sample 11	0	0
Sample 12	0	0
Sample 13	0	0
Sample 14	0	0
Sample 15 (Control #1)	0	0
Sample 16 (Control #2)	0	0
Sample 17	0	0
Sample 18	0	0
Sample 19	0	0
Sample 20	0	0
Sample 21	0	0

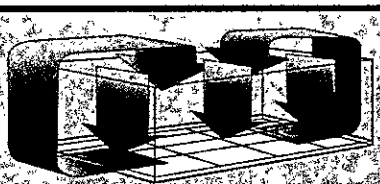
Viable Microbiological Sample Location Detail

Sample #	Description	Type	Volume	Date	Time
1	LFH (Labconco - R)	Air	1000 L	08/05/25	10:40 am
2	LFH (Labconco - L)	Air	1000 L	08/05/25	11:06 am
3	Main CR 1	Air	1000 L	08/05/25	11:25 am
4	Main CR 2	Air	1000 L	08/05/25	11:32 am
5	Gowning 1	Air	1000 L	08/05/25	11:38 am
6	Gowning 2	Air	1000 L	08/05/25	11:46 am
7	LFH Worksurface (Labconco - L)	Surface	N/A	08/05/25	11:03 am
8	LFH Worksurface (Labconco - R)	Surface	N/A	08/05/25	11:03 am
9	Cart	Surface	N/A	08/05/25	10:40 am
10	Pass Thru Worksurface	Surface	N/A	08/05/25	10:40 am
11	Door	Surface	N/A	08/05/25	10:44 am
12	Wall	Surface	N/A	08/05/25	10:44 am
13	Rack Worksurface	Surface	N/A	08/05/25	10:45 am
14	Bench	Surface	N/A	08/05/25	10:45 am
15	Control #1	N/A	N/A	08/05/25	10:35 am
16	Control #2	N/A	N/A	08/05/25	10:35 am
17	LFH (Cleatech - L)	Air	1000 L	08/05/25	11:10 am
18	LFH (Cleatech - R)	Air	1000 L	08/05/25	11:16 am
19	LFH Worksurface (Cleatech – L)	Surface	N/A	08/05/25	11:08 am
20	LFH Worksurface (Cleatech - R)	Surface	N/A	08/05/25	11:08 am
21	Ceiling Camera	Surface	N/A	08/05/25	10:46 am

15 **Control #1**

16 **Control #2**





Cleanroom Consulting Services
P.O. Box 394, Douglassville, Pennsylvania 19518 (800) 970-7629

Viable Microbiological Locations

InfuCare RX Cleanroom

Aston, Pennsylvania

DATE: August 5, 2025

FOCUS LABORATORIES

894 Maron Blvd, Suite 150
Allentown, PA 18109
(610) 866-7272
www.FOCUS-Lab.com

Test Report

Study Completed For:	Cleanroom Consulting Services P.O. Box 394 Douglassville, PA 19518	**Job Number:**	25-04213
		Sample Date:	05-Aug-2025
		Sample Time:	7:00 AM
Point Of Contact:	Rich Dewees richdewees@cleanroomconsulting.com (800) 970-7629	**Deviations Found:**	None
		Condition Of Samples Upon Receipt:	Good
		Viable Air Sampler:	SAS
Plan:	InfuCare RX	**Analysis Guideline:**	USP <797>

Media Type	Lot Number	Expiration Date	Sterility Status
CT3P IR	1011197800	2025-09-18	Pass

Incubation & Analysis Information
Samples were incubated at 30°C to 35°C from 3:37 pm on 05-Aug-2025 to 4:48 pm on 07-Aug-2025 and analyzed by D. Hanna.
Samples were incubated at 20°C to 25°C from 4:50 pm on 07-Aug-2025 to 3:30 pm on 12-Aug-2025 and analyzed by A. Infantino.
Data not found on this report are documented on the raw data forms for job number 25-04213.

	19
ALERT	0
	0
	0

FOCUS Laboratories is ISO/IEC 17025:2017 accredited by PJLA in the field of testing. Accreditation #77499
†Indicated specific test is outside the scope of ISO accreditation, however FOCUS is an FDA registered cGMP laboratory. This document is issued under the company's terms and conditions which were agreed upon during sample submission. FOCUS Laboratories' liability regarding this analysis is limited to the cost of the tests associated with this Test Report. The results are the property of the client listed above and FOCUS Laboratories. These results only relate to items tested above and apply to the samples as received. This report shall not be reproduced except in full without approval of FOCUS Laboratories.

FOCUS LABORATORIES

FOCUS Laboratories
894 Marcon Blvd, Suite 150
Allentown, PA 18109
Phone (610) 866-7272
info@FOCUS-lab.com

TEST REPORT

Client: Cleanroom Consulting Services
Address: Douglassville, PA
Plan: InfuCare RX
Analysis Guideline: USP <797>
Contact: Rich Dewees

Activity Level: Dynamic/Operational
Sample Date: 5-Aug-2025
Sample Time: 7:00 AM
Job Number: 25-04213
Viable Air Sampler: SAS

C	Contact/Surface Viable	GPNSFR	Gram Positive Non-sporeforming Rod
D	Dynamic/Air Viable	GPSFR	Gram Positive Sporeforming Rod
P	Personnel	NA	Not Applicable
S	Settle	SW	Swab

Sample ID	Type	Volume (L)	Status	Action Level ≥	Calculated Total Count*	Total Bacterial Count	Total Fungal Count	Mold Count	Yeast Like	Staphylococcus Like	Micrococcus Like	GPSFR Like	Gram Negative Rod Like	GPNSFR Like	Other Microbial	Identification
1 LFH (Right)	D	1000	Pass	2	<1	0	0									NA
2 LFH (Left)	D	1000	Pass	2	<1	0	0									NA
3 (Main CR 1)	D	1000	Pass	11	<1	0	0									NA
4 (Main CR 2)	D	1000	Pass	11	<1	0	0									NA
5 (Gowning 1)	D	1000	Pass	101	4	4	0	0	0	0	3	0	1	0	0	3 #1, 1 #4
6 (Gowning 2)	D	1000	Pass	101	32	30	0	0	0	10	13	0	1	6	0	13 #1, 9 #2, 6 #3, 1 #4
7 (LFH - Left)	C	NA	Pass	4	<1	0	0									NA
8 (LFH - Right)	C	NA	Pass	4	<1	0	0									NA
9 (Cart 1)	C	NA	Pass	6	<1	0	0									NA
10 (Pass-Thru)	C	NA	Pass	NE	<1	0	0									NA
11 (Door)	C	NA	Pass	6	<1	0	0									NA
12 (Wall)	C	NA	Pass	6	<1	0	0									NA
13 (Cart - 2)	C	NA	Pass	6	<1	0	0									NA
14 (Bench)	C	NA	Pass	51	<1	0	0									NA
17 (Cleatech LFH - Left)	D	1000	Pass	2	<1	0	0									NA

Shaded areas indicate no growth.

*Data Expression: D: CFU/m³, C/S/P: CFU/plate, SW: CFU/swab

Reviewed / Approved By FOCUS Laboratories / Date: 18Aug2025

FOCUS Laboratories
894 Marcon Blvd, Suite 150
Allentown, PA 18109
Phone (610) 866-7272
info@FOCUS-lab.com

FOCUS LABORATORIES

TEST REPORT

Client: Cleanroom Consulting Services
Address: Douglassville, PA
Plan: InfuCare RX
Analysis Guideline: USP <797>
Contact: Rich Dewees

Activity Level: Dynamic/Operational
Sample Date: 5-Aug-2025
Sample Time: 7:00 AM
Job Number: 25-04213
Viable Air Sampler: SAS

Sample ID	Type	Volume (L)	Status	Action Level ≥	Calculated Total Count*	Total Bacterial Count	Total Fungal Count	Mold Count	Yeast Like	Staphylococcus Like	Micrococcus Like	GPSPR Like	Gram Negative Rod Like	GPNSFR Like	Other Microbial	Identification
18 (Cleatech LRF - Right)	D	1000	*Pass*	2	<1	0	0									NA
19 (Cleatech LFH - Left)	C	NA	*Pass*	2	<1	0	0									NA
20 (Cleatech LFH - Right)	C	NA	*Pass*	2	<1	0	0									NA
21 (Ceiling Camera)	C	NA	*Pass*	2	<1	0	0									NA

Shaded areas indicate no growth.

#1= *Micrococcus luteus*
#2= *Staphylococcus hominis* ssp. *hominis*
#3= Unidentified Gram Positive Non-Sporeforming Rod
#4= *Acinetobacter ursingii* (33%) / *Comomonas testosteroni* (34%) / *Moraxella group* (33%)

*Data Expression: D: CFU/m³, C/S/P: CFU/plate, SW: CFU/swab

Reviewed / Approved By FOCUS Laboratories / Date: 18 Aug 2025

InfuCare Rx Clean Room 1 Certification Report 8-5-25 - Page 31 of 52

CERTIFICATE OF CALIBRATION AND TESTING

TSI Incorporated, 500 Cardigan Road, Shoreview, MN 55126 USA
Tel: 1-800-874-2811 1-651-490-2811 Fax: 1-651-490-3824 http://www.tsi.com

ENVIRONMENT CONDITIONS		
TEMPERATURE	72.3 (22.4)	°F (°C)
RELATIVE HUMIDITY	46	%RH
BAROMETRIC PRESSURE	29.25 (990.5)	inHg (hPa)

MODEL	9535
SERIAL NUMBER	T95351330006

☒ AS LEFT ☐ AS FOUND

☒ IN TOLERANCE ☐ OUT OF TOLERANCE

CALIBRATION VERIFICATION RESULTS

TEMPERATURE VERIFICATION — SYSTEM T-101 — *Units: °F (°C)*

#	STANDARD	MEASURED	ALLOWABLE RANGE	#	STANDARD	MEASURED	ALLOWABLE RANGE
1	32.0 (0.0)	32.0 (0.0)	31.5~32.6 (-0.3~0.3)	2	139.9 (59.9)	139.8 (59.9)	139.3~140.4 (59.6~60.2)

VELOCITY VERIFICATION — SYSTEM V-110 — *Units: ft/min (m/s)*

#	STANDARD	MEASURED	ALLOWABLE RANGE	#	STANDARD	MEASURED	ALLOWABLE RANGE
1	0 (0.00)	0 (0.00)	-3~3 (-0.02~0.02)	7	649 (3.30)	648 (3.29)	630~669 (3.20~3.40)
2	35 (0.18)	35 (0.18)	32~38 (0.16~0.19)	8	997 (5.06)	1002 (5.09)	967~1027 (4.91~5.22)
3	65 (0.33)	65 (0.33)	62~68 (0.31~0.34)	9	1475 (7.49)	1489 (7.57)	1430~1519 (7.27~7.72)
4	100 (0.51)	99 (0.50)	97~103 (0.49~0.52)	10	2503 (12.72)	2522 (12.815)	2428~2578 (12.33~13.10)
5	160 (0.81)	160 (0.81)	155~164 (0.79~0.84)	11	4477 (22.74)	4505 (22.89)	4342~4611 (22.06~23.42)
6	333 (1.69)	333 (1.69)	323~343 (1.64~1.74)	12	5900 (29.97)	5868 (29.81)	5723~6077 (29.07~30.87)

TSI does hereby certify that the above described instrument conforms to the original manufacturer's specification (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the United States National Institute of Standards and Technology (NIST) or has been verified with respect to instrumentation whose accuracy is traceable to NIST, or is derived from accepted values of physical constants. TSI's calibration system is registered to ISO 9001:2015.

Measurement Variable	System ID	Last Cal.	Cal. Due
Temperature	E010657	03-11-24	03-31-25
Temperature	E010656	03-11-24	03-31-25
Temperature	E004402	04-10-24	10-31-24
Pressure	E004041	08-19-24	02-28-25

Measurement Variable	System ID	Last Cal.	Cal. Due
Temperature	E010658	03-11-24	03-31-25
DC Voltage	E001658	02-06-24	08-31-25
Pressure	E001658	08-14-24	02-28-25
Velocity	E010408	12-14-21	12-31-24

Hayley

CALIBRATED

August 19, 2024

DATE

DOC ID: DEFAULT_GLOBAL_CHECK

TSI P/N 2300157

International Light Technologies
A DIVISION OF LABSPHERE

CALIBRATION CERTIFICATE

OPTICAL CALIBRATION CERTIFICATE

International Light Technologies certifies that the calibration results published in this certificate were obtained using equipment capable of producing results that are traceable through NIST to the International System of Units (SI). ILT is Accredited to ISO/IEC 17025:2017. Calibration conforms to ANSI/NCSL Z540.1-1994 and ANSI/NCSL Z540.3-2006.subclause 5.3

Rendered-to: CLEANROOM CONSULTING SERVICES

Detector: EXTECH LIGHT METER #Q474430 Input Optic: N/A #

Filter: N/A # Misc.: N/A #

(CYIS) PHOTOPIC ILLUMINANCE RESPONSE CORRECTION FACTOR AS CALIBRATED ON: 02-Aug-2024

With a lamp output of 255 fc, the EXTECH METER 401027 #Q474430 read as found 242 fc. Correction Factor as left: Multiply all readings by 1.054 and use the units lux. NO ADJUSTMENTS WERE MADE. Calibration Due: 8/2/2025

3.23% *Change In Sensitivity From Previous Calibration Dated: 16-Aug-2023

Tolerance As Found: ☑ In ☐ Out Tolerance As Left: ☑ In ☐ Out

REFERENCE PLANE: Front

* ILT's Simple Accept Decision Rule Applies, Unless Stated Above. Difference includes intrinsic detector change, NIST recertification updates, lab experimental error or modifications to the hardware adjustments.

PRIMARY STANDARD: U.S. National Institute of Standards and Technology Detector Response
SED033 #4528/Y #16218 - November 5, 2015 - NIST Test No.: 685/287261-15/1 - Calibration Due: November 5, 2025

ILT Transfer Uncertainty to Customer = +/- 4.3% plus NIST Uncertainty of: +/- 0.5% Confidence Level of Uncertainty is 95% (k=2)

LIGHT SOURCE: 1W 1000W QTH LAMP OUTPUT: 255 lm/ft2

INSTRUMENTATION: #6400/Y PROCEDURE: OP-0112

TEMPERATURE: 22.8 degrees C HUMIDITY: 55%

CALIBRATED BY: J - Hoyt

Calibration Technician: Jon Hoyt

THIS CERTIFICATE APPLIES ONLY TO THE ITEMS IDENTIFIED AND SHALL NOT BE REPRODUCED EXCEPT IN FULL, WITHOUT THE SPECIFIC WRITTEN APPROVAL BY INTERNATIONAL LIGHT TECHNOLOGIES, INC.

Calibration Date: 8/2/2024 Certificate No: 408025608 Sales Order #: 185407

ilac-MRA PJLA Calibration Accreditation # 66765

International Light Technologies
10 Technology Drive, Peabody, MA 01960 USA
P: 978-818-6180 W: internationallight.com

CIH Equipment Company Inc

1806 South Highland Avenue, Clearwater, FL 33756, USA
PH: 727-584-5063, Toll Free: 888-873-2443
Website: https://cihequipment.com

CERTIFICATE OF CALIBRATION

Certificate No. : UNTL/04273/24

Calibrated Date: 08-07-2024

Customer Name & Address	: Cleanroom Consulting Services 101 Woodbridge Lane Douglassville, PA 19518	Date of Issue	: 08-07-2024
Received Date	: 08-01-2024	Type	: 03 Particle
Recommended Due Date	: 08-07-2025	Manufacturer	: MetOne
Location	: At Lab	Model Number	: A2408-1-115-1
Data Type	: As Left	Serial Number	: 980700086

Work Procedure: 03-Base-Particle (m)

Reference Equipment(s) used:

Equipment Name	Serial No.	Traceability	Certificate No.	Calibration Due Date
Particle Counter	8038130316		300545480	10-24-2024
Particle: 0.3 µm		Polyscience Inc.	Cat #07306	04-06-2029
Mass Flow Meter	4040 0112 010		300552827	11-20-2024

Traceability Statement:

CIH Equipment Company Inc. certifies that the instrument listed above meets or exceeds manufacturing tolerance limits as stated in the referenced test procedure (unless otherwise noted). This instrument has been calibrated using standards with accuracies traceable to the National Institute of Standards and Technology. CIH Equipment Company Inc. calibration system is A2LA accredited to ISO/IEC 17025-2017, ANSI/NCSL Z540-1-1994. This report may not be reproduced, except in full, without the written approval CIH Equipment Company Inc. This calibration was done by comparing the unit under test to the listed calibration standards, there was no sampling used in this calibration. The result reported herein apply only to the calibration of the items described above and no limitations of use apply to the calibration unit. A PASS (in tolerance) or FAIL (out of tolerance) result indicates all measured values fall within or outside unmodified limits. The statement of compliance does not take the reported measurement uncertainty into account. In addition, reported uncertainties do not include instabilities due to transportation, usage, passage of time etc.

Technician Name :
Robert V Marcolini

Approved By :
Vivian M Hoenshell

CIH Equipment Company Inc
1806 South Highland Avenue, Clearwater, FL 33756, USA
PH: 727-584-5063, Toll Free: 888-873-2443
Website: https://cihequipment.com

CERTIFICATE OF CALIBRATION

Certificate No. : UNTL/04273/24

Calibrated Date: 08-07-2024

Calibration Results (As Left)

Particle Calibration Data

Lab Conditions : 75.4°F 54.0% RH 29.78 in.Hg
Flow Rate (Nom/Act) (L/min) : 28.30/28.28
Tolerance (0.3 µm) : 50% ±20%
Tolerance (>0.3 µm) : 40.0%

Particle Size	Reference Data	Measured Data	Error	Result
0.5 µm	377442	516074	138632.00	Pass
1.0 µm	31032	29949	1083.00	Pass
5.0 µm	196	203	7.00	Pass

TEC Services, Inc.
25 Little Avenue
New Oxford, PA 17350
Phone: 717-624-3191
Fax: 717-624-3549
www.tecservicesinc.com

Controlled Environment Products
Calibration & Services

EQUIPMENT CALIBRATION REPORT

Date Received:	8/1/24	Date Returned:	8/12/24
Customer:	Cleanroom Consulting Services	Contact:	Rich Dewees
Address:	PO Box 394	Phone #:	610-223-6620
	Douglassville,PA 19518	Customer PO #:	RCD-2634
Manufacturer:	Air Techniques	Model #:	TDA-2E
Instrument Type:	Aerosol Photometer	Serial #:	9914

NIST Traceable calibration performed to the above instrument per IEST-RP-CC013 and TEC Services' SOP's.

INSTRUMENT DATA

		As Found	Final	Mfg. Tolerances
Straylight	(N/A)	.030%	.024%	Not Applicable
Internal Ref.	(3)	11.0%	10.0%	10.0% ± 1.0%
Sample Flow	(1)	29.0	29.0	28.3 ± 2.8 SLPM
0.01%	(1)	1.00×10^{-9}	1.00×10^{-9}	$1.0 \pm .05 \times 10^{-9}$ *
0.1%	(1)	1.00×10^{-8}	1.00×10^{-8}	$1.0 \pm .05 \times 10^{-8}$ *
1.0%	(1)	1.00×10^{-7}	1.00×10^{-7}	$1.0 \pm .05 \times 10^{-7}$ *
10%	(1)	1.00×10^{-6}	1.00×10^{-6}	$1.0 \pm .05 \times 10^{-6}$ *
100%	(1)	1.00×10^{-5}	1.00×10^{-5}	$1.0 \pm .05 \times 10^{-5}$ *

(1) In Tolerance (2) Out of Tolerance (3) No effect on instrument operation (N/A) Not Applicable * Amperes

Received In Tolerance: ☒ **Yes** ☐ **No** ☐ **Not Operable**
☐ **Not Applicable – NEW INSTRUMENT**

Calibrated for: ☒ PAO ☐ DOP Temperature: 23.0 ° C Relative Humidity: 42.0 %

MAINTENANCE PERFORMED

☒ Clean / Rebuild Chamber ☒ Realign Optics ☒ Flush Hoses
☒ Check Wiring & Hardware ☐ Replace Gaskets ☒ Replace Cell Lamp
☐ Not Applicable - NEW INSTRUMENT

Notes: _____

FINAL VERIFICATION PERFORMED

☒ Leak Test Sampling System ☒ Test Scanning Probe ☒ Perform Voltage Check
☒ Verify Max Gain Stability ☒ Performance Test

NIST TRACEABLE EQUIPMENT USED

Description	Model	Serial #	Certificate #	Cal Date	Due Date
Picoampere Source	Keithley 6220	1272482	2348569-1	02 FEB 24	02 FEB 25
Digital Multimeter	Fluke 87-V	64740006	U476015-00-01	04 APR 24	04 APR 25
Thermohygrometer	Extech 445715	CP244467	1756326	17 MAY 24	17 MAY 25
Flowmeter	TSI 4043	40431950011	300547919	25 OCT 23	25 OCT 24

Calibrated per Procedure: ☒ TEC001 ☐ TEC002 ☐ TEC003 ☐ TEC004 ☒ TEC005
☒ TEC006 ☒ TEC007 ☒ TEC008 ☒ TEC009 ☒ TEC010

CALIBRATION BY: Phillip Burn DATE: 8/9/24 DUE DATE: 8/9/25

InfuCare Rx

AIRDATA MULTIMETER CERTIFICATE OF RECALIBRATION

Customer ID: 011733 S/N: M94962

Customer: CLEANROOM CONSULTING SERVICES City: DOUGLASSVILLE State: PA

As-Received Model #: ADM-870 Converted to Model #: Order #: R250408

PO #: Customer Eqpt ID#: Calibration Due Date: _____

This instrument has been calibrated using Calibration Standards which are traceable to NIST (National Institute of Standards and Technology). Test accuracy ratio is 4:1 for pressures and temperature. Quality Assurance Program and calibration procedures meet the requirements for ANSI/NCSL Z540-1, ISO 17025, MIL-STD 45662A and manufacturer's specifications. Calibration accuracy is certified when meters are used with properly functioning accessories only. All Uncertainties are expressed in expanded terms (twice the calculated uncertainty). This report shall not be reproduced, except in full, without the written approval of Shortridge Instruments, Inc. Results relate only to the item calibrated. For limitations on use, see Shortridge Instruments, Inc. Instruction Manual for the use of AirData Multimeters. Procedure used: Procedure for Differential Pressure, Absolute Pressure and Temperature Recalibration of AirData Multimeters SIP-CP02 Revision: 30 Dated: 04/04/16.

Calibration Technician(s): S.Babb Calibration Date: 05/12/2025

Calibration Approved by: Maria Smith Title: QA Mgr Approval Date: 05/12/2025

As-Received	FINAL	
Test Date:	Test Date: 05/12/2025	Test Date:
Test By: N/A	Test By: S.Babb	Test By: N/A
Ambient Temperature °F Rh %	Ambient Temperature 73 °F Rh 27 %	Ambient Temperature °F Rh %
Barometric Pressure in Hg	Barometric Pressure 28.28 in Hg	Barometric Pressure in Hg
All within spec: YES NO NA	All within spec: (YES) NO	All within spec: YES NO

ABSOLUTE PRESSURE TEST (in Hg)

TEST METER TOLERANCE = ± 2.0 % ± .1 in Hg AS-RECEIVED TEST WITHIN SI SPECIFICATION YES NO (N/A – See Additional Form)

Pressure Standard: Heise #02-R	S/N: 41741/42451	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #12A-R	S/N: 45605/48491-1	As-Rcvd	(Test 2)	Test 3
Pressure Standard: Heise #04-R	S/N: 41743/42453	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #14-R	S/N: 43412/45043-3	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #06-R	S/N: 41742/42452-1	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #16-R	S/N: 43413/45044	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #08-R	S/N: 42186/43328	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #18-R	S/N: 44581/46845-2	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #10-R	S/N: 42203/43352	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #20-R	S/N: 44582/46847	As-Rcvd	Test 2	Test 3

Approx Set Pt	Standard	Test Meter	% Diff	Standard	Test Meter	% Diff	Standard	Test Meter	% Diff
14.0		N/A		14.07	14.1	.21		N/A	
28.4				28.28	28.3	.07			
40.0				40.39	40.4	.02			

DIFFERENTIAL PRESSURE TEST (in wc)

TEST METER TOLERANCE = ± 2.0 % ± 0.001 in wc AS-RECEIVED TEST WITHIN SI SPECIFICATION YES NO (N/A – See Additional Form)

Pressure Standard: Heise #01-L	S/N: 41739/42449	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #11-L	S/N: 43165/44551-1	As-Rcvd	(Test 2)	Test 3
Pressure Standard: Heise #01-R	S/N: 41739/42446	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #11-R	S/N: 43165/44730	As-Rcvd	(Test 2)	Test 3
Pressure Standard: Heise #02-L	S/N: 41741/42454	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #12A-L	S/N: 45605/48490-1	As-Rcvd	(Test 2)	Test 3
Pressure Standard: Heise #03A-L	S/N: 45570/48461	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #13-L	S/N: 43415/45041	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #03A-R	S/N: 45570/48460	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #13-R	S/N: 43415/45039	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #04-L	S/N: 41743/42456	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #14-L	S/N: 43412/45045	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #05-L	S/N: 41740/42450	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #15-L	S/N: 43416/45042	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #05-R	S/N: 41740/42447	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #15-R	S/N: 43416/45040-1	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #08-L	S/N: 41742/42455	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #16-L	S/N: 43413/45046	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #07-L	S/N: 42185/42186	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #17-L	S/N: 44579/46842	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #07-R	S/N: 42185/43326	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #17-R	S/N: 44579/46841	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #08-L	S/N: 42186/43329	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #18-L	S/N: 44581/46846	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #09-L	S/N: 42202/43351	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #19-L	S/N: 44580/46844	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #09-R	S/N: 42202/43350	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #19-R	S/N: 44580/46843	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #10-L	S/N: 42203/43353	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #20-L	S/N: 44582/46848	As-Rcvd	Test 2	Test 3

Approx Set Pt	Standard	Test Meter	% Diff	Standard	Test Meter	% Diff	Standard	Test Meter	% Diff
0.0500				.0506	.0505	-.20			
0.1250				.1254	.1253	-.08			
0.2250				.2252	.2252	.00			
1.000		N/A		1.005	1.004	-.10		N/A	
2.000				2.008	2.004	-.20			
3.600				3.615	3.603	-.33			
4.400				4.415	4.417	.05			
27.00				27.13	27.17	.15			
50.00				50.03	49.62	-.82			
Overange	NA		NA	NA	✓	NA	NA		NA

AIRDATA MULTIMETER CERTIFICATE OF RECALIBRATION

S/N: M94962

Order #: R250408

LOW VELOCITY CONFIRMATION (FPM)

TEST METER TOLERANCE = ± 3.0% ± 7 FPM AS-RECEIVED TEST WITHIN SI SPECIFICATION YES NO (N/A – See Additional Form)

Vel Eqv Trans Std: S/N: M02009	As-Rcvd	Test 2	Test 3	Vel Eqv Trans Std: S/N: M10897	As-Rcvd	Test 2	Test 3
Vel Eqv Trans Std: S/N: M02903	As-Rcvd	Test 2	Test 3	Vel Eqv Trans Std: S/N: M10901	As-Rcvd	(Test 2)	Test 3
Vel Eqv Trans Std: S/N: M10839	As-Rcvd	Test 2	Test 3	Vel Eqv Trans Std: S/N: M13492	As-Rcvd	Test 2	Test 3
Vel Eqv Trans Std: S/N: M10840	As-Rcvd	Test 2	Test 3	Vel Eqv Trans Std: S/N: M19325	As-Rcvd	Test 2	Test 3

Approx Set Point	Standard	Test Meter	Diff	Standard	Test Meter	Diff	Standard	Test Meter	Diff
100		N/A		104	105	1		N/A	
500				506	505	-1			

ADM-880C, ADM-870/870C and ADM-860/860C models are read in AirFoil Mode. ADM-850/850L models are read in Pitot Tube Mode.

TEMPERATURE TEST - AIRDATA MULTIMETER (° F)

TEST METER TOLERANCE = ± 0.2° F AS-RECEIVED TEST WITHIN SI SPECIFICATION YES NO (N/A – See Additional Form)

RTD Simulator: S/N 249	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 250	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 253	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 254	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 256	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 257	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 292	As-Rcvd	(Test 2)	Test 3	Set Point: (35.6° F)	95° F	154.4° F
RTD Simulator: S/N 293	As-Rcvd	(Test 2)	Test 3	Set Point: 35.6° F	(95° F)	154.4° F
RTD Simulator: S/N 294	As-Rcvd	(Test 2)	Test 3	Set Point: 35.6° F	95° F	(154.4° F)
RTD Simulator: S/N 313	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 314	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 315	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 316	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 317	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 318	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F

RTD Simulator Temperature Equivalent Set Point	Test Meter	Difference	Test Meter	Difference	Test Meter	Difference
35.60		N/A	35.6	.0		N/A
95.00			95.0	.0		
154.40			154.5	.1		

There were no additions to or deviations from the specified calibration procedure during the calibration process.

Any calibration due date shown is specified by the customer.

The enclosed ADM Calibration Equipment form(s) that lists the Standards for Pressures, Low Velocity, and Temperature is/are an integral part of this calibration and must remain with this Certificate of Recalibration. There may be more than one such form included that pertains to this calibration.

Any additional information required pertaining to this calibration or to any repairs performed may be included in other documentation. If applicable, these documents may include, but not be limited to an AirData Multimeter Recalibration Notes form, and/or a Repair Record Notes form.

NOTES: _____

AIRDATA MULTIMETER CERTIFICATE OF RECALIBRATION

Customer ID: 011733 S/N: M94962

Customer: CLEANROOM CONSULTING SERVICES City: DOUGLASSVILLE State: PA

As-Received Model #: ADM-870 Converted to Model #: Order #: R250408

PO #: Customer Eqpt ID#: Calibration Due Date: _____

This instrument has been calibrated using Calibration Standards which are traceable to NIST (National Institute of Standards and Technology). Test accuracy ratio is 4:1 for pressures and temperature. Quality Assurance Program and calibration procedures meet the requirements for ANSI/NCSL Z540-1, ISO 17025, MIL-STD 45662A and manufacturer's specifications. Calibration accuracy is certified when meters are used with properly functioning accessories only. All Uncertainties are expressed in expanded terms (twice the calculated uncertainty). This report shall not be reproduced, except in full, without the written approval of Shortridge Instruments, Inc. Results relate only to the item calibrated. For limitations on use, see Shortridge Instruments, Inc. Instruction Manual for the use of AirData Multimeters. Procedure used: Procedure for Differential Pressure, Absolute Pressure and Temperature Recalibration of AirData Multimeters SIP-CP02 Revision: 30 Dated: 04/04/16

Calibration Technician(s): A. Jaramillo Calibration Date: 05/12/2025

Calibration Approved by: Dana Smith Title: QA Mgr Date: 05/12/2025

As-Received By A. Jaramillo	Test By _____	Test By _____
Date 05/21/2025 Rh 30 %	Date _____ Rh ____ %	Date _____ Rh ____ %
Ambient Temperature 74 °F	Ambient Temperature N/A °F	Ambient Temperature N/A °F
Barometric Pressure 28.40 in Hg	Barometric Pressure _____ in Hg	Barometric Pressure _____ in Hg
All within spec (YES) NO NA	All within spec YES NO	All within spec YES NO

ABSOLUTE PRESSURE TEST (in Hg)

TEST METER TOLERANCE = ± 2.0 % ± .1 in Hg AS-RECEIVED TEST WITHIN SPEC (YES) NO N/A See Notes

Pressure Standard: Heise #02-R	S/N: 41741/42451	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #12A-R	S/N: 45605/48491	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #04-R	S/N: 41743/42453	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #14-R	S/N: 43412/45043-3	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #06-R	S/N: 41742/42452-1	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #16-R	S/N: 43413/45044	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #08-R	S/N: 42186/43328	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #18-R	S/N: 44581/46845-2	(As-Rcvd)	Test 2	Test 3
Pressure Standard: Heise #10-R	S/N: 42203/43352	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #20-R	S/N: 44582/46847	As-Rcvd	Test 2	Test 3

Approx Set Pt	Standard	Test Meter	% Diff	Standard	Test Meter	% Diff	Standard	Test Meter	% Diff
14.0	14.05	14.2	1.07				N/A		
28.4	28.40	28.6	.70						
40.0	40.07	40.2	.32						

DIFFERENTIAL PRESSURE TEST (in wc)

TEST METER TOLERANCE = ± 2.0 % ± 0.001 in wc AS-RECEIVED TEST WITHIN SPEC (YES) NO N/A See Notes

Pressure Standard: Heise #01-L	S/N: 41739/42449	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #11-L	S/N: 43165/44551-1	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #01-R	S/N: 41739/42448	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #11-R	S/N: 43185/44730	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #02-L	S/N: 41741/42454	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #12A-L	S/N: 45605/48490-1	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #03A-L	S/N: 45570/48461	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #13-L	S/N: 43415/45041	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #03A-R	S/N: 45570/48460	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #13-R	S/N: 43415/45039	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #04-L	S/N: 41743/42456	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #14-L	S/N: 43412/45045	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #05-L	S/N: 41740/42450	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #15-L	S/N: 43416/45042	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #05-R	S/N: 41740/42447	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #15-R	S/N: 43416/45040-1	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #06-L	S/N: 41742/42455	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #16-L	S/N: 43413/45046	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #07-L	S/N: 42185/42186	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #17-L	S/N: 44579/46842	(As-Rcvd)	Test 2	Test 3
Pressure Standard: Heise #07-R	S/N: 42185/43326	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #17-R	S/N: 44579/46841	(As-Rcvd)	Test 2	Test 3
Pressure Standard: Heise #08-L	S/N: 42186/43329	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #18-L	S/N: 44581/46846	(As-Rcvd)	Test 2	Test 3
Pressure Standard: Heise #09-L	S/N: 42202/43351	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #19-L	S/N: 44580/46844	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #09-R	S/N: 42202/43350	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #19-R	S/N: 44580/46843	As-Rcvd	Test 2	Test 3
Pressure Standard: Heise #10-L	S/N: 42203/43353	As-Rcvd	Test 2	Test 3	Pressure Standard: Heise #20-L	S/N: 44582/46848	As-Rcvd	Test 2	Test 3

Approx Set Pt	Standard	Test Meter	% Diff	Standard	Test Meter	% Diff	Standard	Test Meter	% Diff
0.0500	.0512	.05094	-.59						
0.1250	.1258	.1256	-.16						
0.2250	.2258	.2251	-.31						
1.000	1.004	1.005	-.40				N/A		
2.000	2.006	2.002	-.20						
3.600	3.604	3.600	-.11						
4.400	4.409	4.416	.16						
27.00	27.12	27.07	-.18						
50.00	50.04	49.96	-.16						
Overange	NA	✓	NA	NA		NA	NA		NA

Shortridge Instruments, Inc.
7855 East Redfield Road Scottsdale, Arizona 85260
(480) 991-6744 • Fax (480) 443-1267 • www.shortridge.com

AIRDATA MULTIMETER CERTIFICATE OF RECALIBRATION

S/N: M94962

Order #: R250408

LOW VELOCITY CONFIRMATION (FPM)

TEST METER TOLERANCE = ± 3.0% ± 7 FPM AS-RECEIVED TEST WITHIN SPEC (YES) NO N/A See Notes

Vel Eqv Trans Std: S/N: M02009	As-Rcvd	Test 2	Test 3	Vel Eqv Trans Std: S/N: M10897	As-Rcvd	Test 2	Test 3
Vel Eqv Trans Std: S/N: M02903	As-Rcvd	Test 2	Test 3	Vel Eqv Trans Std: S/N: M10901	As-Rcvd	Test 2	Test 3
Vel Eqv Trans Std: S/N: M10839	As-Rcvd	Test 2	Test 3	Vel Eqv Trans Std: S/N: M13492	As-Rcvd	Test 2	Test 3
Vel Eqv Trans Std: S/N: M10840	(As-Rcvd)	Test 2	Test 3	Vel Eqv Trans Std: S/N: M19325	As-Rcvd	Test 2	Test 3

Approx Set Point	Standard	Test Meter	Diff	Standard	Test Meter	Diff	Standard	Test Meter	Diff
100	105	107	2				N/A		
500	508	507	-1						

ADM-880C, ADM-870/870C and ADM-860/860C models are read in AirFoil Mode. ADM-850/850L models are read in Pitot Tube Mode.

TEMPERATURE TEST - AIRDATA MULTIMETER (° F)

TEST METER TOLERANCE = ± 0.2° F AS-RECEIVED TEST WITHIN SPEC (YES) NO N/A See Notes

RTD Simulator: S/N 249	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 250	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 253	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 254	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 256	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 257	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 292	(As-Rcvd)	Test 2	Test 3	Set Point: (35.6° F)	95° F	154.4° F
RTD Simulator: S/N 293	(As-Rcvd)	Test 2	Test 3	Set Point: 35.6° F	(95° F)	154.4° F
RTD Simulator: S/N 294	(As-Rcvd)	Test 2	Test 3	Set Point: 35.6° F	95° F	(154.4° F)
RTD Simulator: S/N 313	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 314	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 315	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 316	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 317	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F
RTD Simulator: S/N 318	As-Rcvd	Test 2	Test 3	Set Point: 35.6° F	95° F	154.4° F

RTD Simulator Temperature Equivalent Set Point	Test Meter	Difference	Test Meter	Difference	Test Meter	Difference
35.60	35.6	.0			N/A	
95.00	95.0	.0				
154.40	154.5	.1				

There were no additions to or deviations from the specified calibration procedure during the calibration process.

Any calibration due date shown is specified by the customer.

The enclosed ADM Calibration Standards for Pressure and Temperature form(s) is/are an integral part of this calibration and must remain with this Certificate of Calibration. There may be more than one such form included that pertains to this calibration.

Any additional information required pertaining to this calibration or to any repairs performed may be included in other documentation. If applicable, these documents may include, but not be limited to an AirData Multimeter Recalibration Notes form, and/or a Repair Record Notes form.

NOTES: _____

Shortridge Instruments, Inc.
7855 East Redfield Road Scottsdale, Arizona 85260
(480) 991-6744 • Fax (480) 443-1267 • www.shortridge.com

Order Number: R2504O8 Serial Number: m294962 Test Type: Initial As-Received (Final)

Measuring & Test Equipment that was used during the calibration of the customer's equipmpent shown above is circled under each test mode on the calibration certificates.

ABSOLUTE PRESSURE STANDARDS

ADM #02-R	S/N: 41741/42451	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/13/24	Due Date: 08/2025
ADM #04-R	S/N: 41743/42453	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 05/28/24	Due Date: 05/2025
ADM #06-R	S/N: 41742/42452-1	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 02/24/25	Due Date: 02/2026
ADM #08-R	S/N: 42186/43328	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 10/18/24	Due Date: 10/2025
ADM #10-R	S/N: 42203/43352	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/22/24	Due Date: 08/2025
ADM #12A-R	S/N: 45605/48491-1	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 03/25/25	Due Date: 03/2026
ADM #14-R	S/N: 43412/45043-3	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 06/07/24	Due Date: 06/2025
ADM #16-R	S/N: 43413/45044	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 06/24/24	Due Date: 06/2025
ADM #18-R	S/N: 44581/46845-2	Heise Model: PPM-2	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 04/09/24	Due Date: 04/2025
ADM #20-R	S/N: 44582/46847	Heise Model: PPM-2	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 09/23/24	Due Date: 09/2025
#02-R, 04-R, 06-R, 08-R, 10-R, 12A-R, 14-R, 16-R			Rated Accuracy: 0.05% fs (0.0305 in Hg)	Range: 0-30 psia	Resolution: 0.01	Uncertainty: < 0.0358
#18-R, 20-R			Rated Accuracy: 0.05% fs (0.0305 in Hg)	Range: 0-60 in Hg	Resolution: 0.001	Uncertainty: < 0.0358

DIFFERENTIAL PRESSURE STANDARDS

ADM #01-L	S/N: 41739/42449	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/14/24	Due Date: 08/2025
ADM #01-R	S/N: 41739/42446	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/14/24	Due Date: 08/2025
ADM #02-L	S/N: 41741/42454	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/14/24	Due Date: 08/2025
ADM #03A-L	S/N: 45570/48461	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 05/24/24	Due Date: 05/2025
ADM #03A-R	S/N: 45570/48460	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 05/16/24	Due Date: 05/2025
ADM #04-L	S/N: 41743/42456	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 05/10/24	Due Date: 05/2025
ADM #05-L	S/N: 41740/42450	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 02/24/25	Due Date: 02/2026
ADM #05-R	S/N: 41740/42447	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 02/24/25	Due Date: 02/2026
ADM #06-L	S/N: 41742/42455	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 02/24/25	Due Date: 02/2026
ADM #07-L	S/N: 42185/42186	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 10/31/24	Due Date: 10/2025
ADM #07-R	S/N: 42185/43326	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 10/31/24	Due Date: 10/2025
ADM #08-L	S/N: 42186/43329	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 10/29/24	Due Date: 10/2025
ADM #09-L	S/N: 42202/43351	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/23/24	Due Date: 08/2025
ADM #09-R	S/N: 42202/43350	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/23/24	Due Date: 08/2025
ADM #10-L	S/N: 42203/43353	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/23/24	Due Date: 08/2025
ADM #11-L	S/N: 43165/44551-1	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 03/25/25	Due Date: 03/2026
ADM #11-R	S/N: 43185/44730	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 03/26/25	Due Date: 03/2026
ADM #12A-L	S/N: 45605/48490-1	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 03/26/25	Due Date: 03/2026
ADM #13-L	S/N: 43415/45041	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 06/21/24	Due Date: 06/2025
ADM #13-R	S/N: 43415/45039	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 06/21/24	Due Date: 06/2025
ADM #14-L	S/N: 43412/45045	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 06/20/24	Due Date: 06/2025
ADM #15-L	S/N: 43416/45042	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 06/26/24	Due Date: 06/2025
ADM #15-R	S/N: 43416/45040-1	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 06/26/24	Due Date: 06/2025
ADM #16-L	S/N: 43413/45046	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 06/26/24	Due Date: 06/2025
ADM #17-L	S/N: 44579/46842	Heise Model: PPM-1	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 04/04/24	Due Date: 04/2025
ADM #17-R	S/N: 44579/46841	Heise Model: PPM-1	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 04/04/24	Due Date: 04/2025
ADM #16-L	S/N: 44581/46846	Heise Model: PPM-1	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 04/04/24	Due Date: 04/2025
ADM #19-L	S/N: 44580/46844	Heise Model: PPM-1	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 09/23/24	Due Date: 09/2025
ADM #19-R	S/N: 44580/46843	Heise Model: PPM-1	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 09/23/24	Due Date: 09/2025
ADM #20-L	S/N: 44582/46848	Heise Model: PPM-1	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 09/23/24	Due Date: 09/2025
#01-L, 03A-L, 05-L, 07-L, 09-L, 11-L, 13-L, 15-L, 17-L, 19-L			Rated Accuracy: > 0.07% fs (0.000175 in wc)	Range: 0.0-0.25 in wc	Res.: 0.00001	Uncertainty: < 0.00035
#01-R, 03A-R, 05-R, 07-R, 09-R, 11-R, 13-R, 15-R, 17-R, 19-R			Rated Accuracy: > 0.06% fs (0.003 in wc)	Range: 0.0-5.0 in wc	Res.: 0.0001	Uncertainty: < 0.00348
#02-L, 04-L, 06-L, 08-L, 10-L, 12A-L, 14-L, 16-L, 18-L, 20-L			Rated Accuracy: > 0.06% fs (0.03 in wc)	Range: 0.0-50.0 in wc	Res.: 0.001	Uncertainty: < 0.0346

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7855 East Redfield Road Scottsdale, Arizona 85260 • (480) 991-6744 • Fax (480) 443-1267 • www.shortridge.com

Customer Order Number, Meter Serial Number, and Test Type are referenced on page 1.

LOW VELOCITY EQUIVALENT CONFIRMATION STANDARDS

Vel Eqv Transfer Standard S/N: M02008	Model ADM-870C	Mfgd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 08/30/24	Due Date: 08/2025
Vel Eqv Transfer Standard S/N: M02803	Model ADM-870C	Mfgd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 12/18/24	Due Date: 12/2025
Vel Eqv Transfer Standard S/N: M10839	Model ADM-870C	Mfgd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 10/25/24	Due Date: 10/2025
Vel Eqv Transfer Standard S/N: M10840	Model ADM-870C	Mfgd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 10/29/24	Due Date: 10/2025
Vel Eqv Transfer Standard S/N: M10897	Model ADM-870C	Mfg'd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 01/22/25	Due Date: 01/2026
Vel Eqv Transfer Standard S/N: M10901	Model ADM-870C	Mfg'd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 12/19/24	Due Date: 12/2025
Vel Eqv Transfer Standard S/N: M13492	Model ADM-870C	Mfg'd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 09/05/24	Due Date: 08/2025
Vel Eqv Transfer Standard S/N: M19325	Model ADM-870C	Mfgd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 06/06/24	Due Date: 06/2025
Rated Accuracy: Velocity ± 1.5 % ± 3.5 fpm		Range: 100-5000 fpm Resolution: 0.1	Uncertainty: <5.00 fpm at 100 fpm; <7.50 fpm at 500 fpm	

TEMPERATURE STANDARDS

RTD Simulator S/N: 249	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 04/11/24	Due Date: 04/2026
RTD Simulator S/N: 250	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 04/11/24	Due Date: 04/2026
RTD Simulator S/N: 253	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 04/11/24	Due Date: 04/2026
RTD Simulator S/N: 254	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 08/20/24	Due Date: 08/2026
RTD Simulator S/N: 256	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 08/20/24	Due Date: 08/2026
RTD Simulator S/N: 257	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 08/20/24	Due Date: 08/2026
RTD Simulator S/N: 292	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 01/15/24	Due Date: 01/2026
RTD Simulator S/N: 293	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 01/15/24	Due Date: 01/2026
RTD Simulator S/N: 294	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 01/15/24	Due Date: 01/2026
RTD Simulator S/N: 313	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 03/25/22	Due Date: 03/2026
RTD Simulator S/N: 314	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 03/25/22	Due Date: 03/2026
RTD Simulator S/N: 315	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 03/25/22	Due Date: 03/2026
RTD Simulator S/N: 316	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 06/08/22	Due Date: 05/2026
RTD Simulator S/N: 317	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 05/23/22	Due Date: 05/2026
RTD Simulator S/N: 318	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 05/23/22	Due Date: 05/2026
Rated Accuracy: 0.025% of setting		Range: 100.00 Ω to 11111.10 Ω		Resolution: 0.01 Ω	Uncertainty: ≤ 32 ppm

Thermometer #1 S/N 8A089/Thermistor S/N A410660	Model 1504/5610	Mfgd by Hart Scientific	Calibrated by Fluke	Calibration Date: 04/09/24	Due Date: 04/2026
Thermometer #2 S/N 8B104/Thermistor S/N 871507	Model 1504/5610	Mfgd by Hart Scientific	Calibrated by Fluke	Calibration Date: 12/18/24	Due Date: 12/2026
Thermometer #5 S/N B11780/Thermistor S/N B10505	Model 1504/5610	Mfgd by Hart Scientific	Calibrated by Fluke	Calibration Date: 06/27/24	Due Date: 06/2026
Thermometer #6 S/N B11782/Thermistor S/N B10509	Model 1504/5610	Mfgd by Hart Scientific	Calibrated by Fluke	Calibration Date: 09/21/24	Due Date: 09/2026
Thermometer #7 S/N B49938/Thermistor S/N B482202	Model 1504/5610	Mfgd and Calibrated by Fluke		Calibration Date: 02/05/24	Due Date: 02/2026
Rated Accuracy(combined): 0.0324° F		Range: 32° F to 176° F	Resolution: 0.001° F	Combined Uncertainty with Baths: ≤ 0.040° F	

Temp Transfer Standard S/N M00136	Model ADM-870	Mfgd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 10/25/24	Due Date: 10/2025
Temp Transfer Standard S/N M96100	Model ADM-870	Mfgd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 03/20/25	Due Date: 03/2026
Rated Accuracy: 0.03° F	Range: 33° F to 158° F		Resolution: 0.01° F	Uncertainty: < 0.023° F

Total combined Uncertainty for MultiTemp and TemProbe testing : ≤ 0.046° F

This form may include information for measuring and test equipment that has been removed from service while undergoing a scheduled calibration. The detailed information for the measuring and test equipment is not removed from this form while the equipment is not in service. This form is updated with the new calibration information prior to the measuring and test equipment being placed back into service.

This form has a revision number and revision date in the bottom left corner which may be changed when equipment information is updated. This form also has a date in the bottom right corner that is updated when calibration dates and calibration due date information on this form require an update. If this form is updated during a customer's calibration, two of these forms will be included, one for the As-Received Test and one for the Final Test.

This form must remain with the calibration documents corresponding to the Order Number and Meter Serial Number referenced on page 1.

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Shortridge Instruments, Inc. AirData Multimeter Calibration Equipment

Order Number: R250408 Serial Number: M94962 Test Type: Initial (As-Received) Final

ABSOLUTE PRESSURE STANDAROS

ADM #02-R	S/N: 41741/42451	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/13/24	Due Date: 08/2025
ADM #04-R	S/N: 41743/42453	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 05/28/24	Due Date: 05/2025
ADM #06-R	S/N: 41742/42452-1	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 12/11/24	Due Date: 12/2025
ADM #08-R	S/N: 42186/43328	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 10/18/24	Due Date: 10/2025
ADM #10-R	S/N: 42203/43352	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/22/24	Due Date: 08/2025
ADM #12A-R	S/N: 45605/48491	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 11/02/23	Due Date: 11/2024
ADM #14-R	S/N: 43412/45043-3	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 06/07/24	Due Date: 06/2025
ADM #16-R	S/N: 43413/45044	Heise Model: PPM-2	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/24/24	Due Date: 08/2025
ADM #18-R	S/N: 44581/46845-2	Heise Model: PPM-2	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 04/09/24	Due Date: 04/2025
ADM #20-R	S/N: 44582/46847	Heise Model: PPM-2	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 09/23/24	Due Date: 09/2025
#02-R, 04-R, 06-R, 08-R, 10-R, 12A-R, 14-R, 16-R		Rated Accuracy: 0.05% fs (0.0305 in Hg)	Range: 0-30 psia		Resolution: 0.01	Uncertainty: < 0.0358
#18-R, 20-R		Rated Accuracy: 0.05% fs (0.0305 in Hg)	Range: 0-60 in Hg		Resolution: 0.001	Uncertainty: < 0.0358

DIFFERENTIAL PRESSURE STANDARDS

ADM #01-L	S/N: 41739/42449	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/14/24	Due Date: 08/2025
ADM #01-R	S/N: 41739/42446	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/14/24	Due Date: 08/2025
ADM #02-L	S/N: 41741/42454	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/14/24	Due Date: 08/2025
ADM #03A-L	S/N: 45570/48461	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 05/24/24	Due Date: 05/2025
ADM #03A-R	S/N: 45570/48460	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 05/16/24	Due Date: 05/2025
ADM #04-L	S/N: 41743/42456	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 05/10/24	Due Date: 05/2025
ADM #05-L	S/N: 41740/42450	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 12/13/24	Due Date: 12/2025
ADM #05-R	S/N: 41740/42447	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 12/13/24	Due Date: 12/2025
ADM #06-L	S/N: 41742/42455	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 12/13/24	Due Date: 12/2025
ADM #07-L	S/N: 42185/42186	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 10/31/24	Due Date: 10/2025
ADM #07-R	S/N: 42185/43326	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 10/31/24	Due Date: 10/2025
ADM #08-L	S/N: 42186/43329	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 10/29/24	Due Date: 10/2025
ADM #09-L	S/N: 42202/43351	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/23/24	Due Date: 08/2025
ADM #09-R	S/N: 42202/43350	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/23/24	Due Date: 08/2025
ADM #10-L	S/N: 42203/43353	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/23/24	Due Date: 08/2025
ADM #11-L	S/N: 43165/44551-1	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 11/07/23	Due Date: 11/2024
ADM #11-R	S/N: 43165/44730	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 11/07/23	Due Date: 11/2024
ADM #12A-L	S/N: 45605/48490-1	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 11/03/23	Due Date: 11/2024
ADM #13-L	S/N: 43415/45041	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/21/24	Due Date: 08/2025
ADM #13-R	S/N: 43415/45039	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 06/21/24	Due Date: 06/2025
ADM #14-L	S/N: 43412/45045	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 08/20/24	Due Date: 08/2025
ADM #15-L	S/N: 43416/45042	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 06/26/24	Due Date: 06/2025
ADM #15-R	S/N: 43416/45040-1	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 06/26/24	Due Date: 06/2025
ADM #16-L	S/N: 43413/45046	Heise Model: PPM-1	Mfgd by Dresser Industries	Calibrated by Ashcroft	Calibration Date: 06/26/24	Due Date: 06/2025
ADM #17-L	S/N: 44579/46842	Heise Model: PPM-1	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 04/04/24	Due Date: 04/2025
ADM #17-R	S/N: 44579/46841	Heise Model: PPM-1	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 04/04/24	Due Date: 04/2025
ADM #18-L	S/N: 44581/46846	Heise Model: PPM-1	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 04/04/24	Due Date: 04/2025
ADM #19-L	S/N: 44580/46844	Heise Model: PPM-1	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 09/23/24	Due Date: 09/2025
ADM #19-R	S/N: 44580/46843	Heise Model: PPM-1	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 09/23/24	Due Date: 09/2025
ADM #20-L	S/N: 44582/46848	Heise Model: PPM-1	Mfgd & Calibrated by Ashcroft, Inc.		Calibration Date: 09/23/24	Due Date: 09/2025
#01-L, 03A-L, 05-L, 07-L, 09-L, 11-L, 13-L, 15-L, 17-L, 19-L		Rated Accuracy: > 0.07% fs (0.000175 in wc)	Range: 0.0-0.25 in wc	Res.: 0.00001		Uncertainty: < 0.00035
#01-R, 03A-R, 05-R, 07-R, 09-R, 11-R, 13-R, 15-R, 17-R, 19-R		Rated Accuracy: > 0.06% fs (0.003 in wc)	Range: 0.0-5.0 in wc	Res.: 0.0001		Uncertainty: < 0.00346
#02-L, 04-L, 06-L, 08-L, 10-L, 12A-L, 14-L, 16-L, 18-L, 20-L		Rated Accuracy: > 0.06% fs (0.03 in wc)	Range: 0.0-50.0 in wc	Res.: 0.001		Uncertainty: < 0.0346

Shortridge Instruments, Inc.
7855 East Redfield Road Scottsdale, Arizona 85260
(480) 991-6744 • Fax (480) 443-1267 • www.shortridge.com

Customer Order Number, Meter Serial Number, and Test Type are referenced on page 1

LOW VELOCITY EQUIVALENT CONFIRMATION STANDARDS

Vel Eqv Transfer Standard S/N: M02009	Model ADM-870C	Mfgd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 08/30/24	Due Date: 08/2025
Vel Eqv Transfer Standard S/N: M02903	Model ADM-870C	Mfgd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 12/19/24	Due Date: 12/2025
Vel Eqv Transfer Standard S/N: M10839	Model ADM-870C	Mfgd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 10/25/24	Due Date: 10/2025
Vel Eqv Transfer Standard S/N: M10840	Model ADM-870C	Mfgd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 10/29/24	Due Date: 10/2025
Vel Eqv Transfer Standard S/N: M10897	Model ADM-870C	Mfg'd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 01/22/25	Due Date: 01/2026
Vel Eqv Transfer Standard S/N: M10901	Model ADM-870C	Mfg'd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 12/19/24	Due Date: 12/2025
Vel Eqv Transfer Standard S/N: M13492	Model ADM-870C	Mfg'd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 09/05/24	Due Date: 08/2025
Vel Eqv Transfer Standard S/N: M19325	Model ADM-870C	Mfgd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 08/08/24	Due Date: 08/2025
Rated Accuracy: Velocity ± 1.5 % ± 3.5 fpm		Range: 100-5000 fpm	Resolution: 0.1	Uncertainty: <5.00 fpm at 100 fpm; <7.50 fpm at 500 fpm

TEMPERATURE STANDARDS

RTD Simulator S/N: 249	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 04/11/24	Due Date: 04/2028
RTD Simulator S/N: 250	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 04/11/24	Due Date: 04/2028
RTD Simulator S/N: 253	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 04/11/24	Due Date: 04/2028
RTD Simulator S/N: 254	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 08/20/24	Due Date: 08/2028
RTD Simulator S/N: 256	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 08/20/24	Due Date: 08/2028
RTD Simulator S/N: 257	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 08/20/24	Due Date: 08/2028
RTD Simulator S/N: 292	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 01/15/24	Due Date: 01/2028
RTD Simulator S/N: 293	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 01/15/24	Due Date: 01/2028
RTD Simulator S/N: 294	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 01/15/24	Due Date: 01/2028
RTD Simulator S/N: 313	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 03/25/22	Due Date: 03/2026
RTD Simulator S/N: 314	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 03/25/22	Due Date: 03/2026
RTD Simulator S/N: 315	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 03/25/22	Due Date: 03/2026
RTD Simulator S/N: 316	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 06/06/22	Due Date: 05/2026
RTD Simulator S/N: 317	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 05/23/22	Due Date: 05/2026
RTD Simulator S/N: 318	Model RTD-1000/500	Mfgd by General Resistance	Calibrated by IET Labs	Calibration Date: 05/23/22	Due Date: 05/2026
Rated Accuracy: 0.025% of setting		Range: 100.00 Ω to 11111.10 Ω		Resolution: 0.01 Ω	Uncertainty: ≤ 32 ppm

Thermometer #1 S/N 8A089/Thermistor S/N A410660	Model 1504/5610	Mfgd by Hart Scientific	Calibrated by Fluke	Calibration Date: 04/09/24	Due Date: 04/2026
Thermometer #2 S/N 8B104/Thermistor S/N 871507	Model 1504/5610	Mfgd by Hart Scientific	Calibrated by Fluke	Calibration Date: 12/19/24	Due Date: 12/2026
Thermometer #5 S/N B11780/Thermistor S/N B10505	Model 1504/5610	Mfgd by Hart Scientific	Calibrated by Fluke	Calibration Date: 06/27/24	Due Date: 06/2026
Thermometer #6 S/N B11782/Thermistor S/N B10509	Model 1504/5610	Mfgd by Hart Scientific	Calibrated by Fluke	Calibration Date: 09/21/24	Due Date: 09/2026
Thermometer #7 S/N B49938/Thermistor S/N B482202	Model 1504/5610	Mfgd and Calibrated by Fluke		Calibration Date: 02/05/24	Due Date: 02/2026
Rated Accuracy(combined): 0.0324° F		Range: 32° F to 176° F	Resolution: 0.001° F	Combined Uncertainty with Baths: ≤ 0.040° F	

Temp Transfer Standard S/N M00136	Model ADM-870	Mfgd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 10/25/24	Due Date: 10/2025
Temp Transfer Standard S/N M98100	Model ADM-870	Mfgd & Calibrated by Shortridge Instruments, Inc.	Calibration Date: 03/21/24	Due Date: 03/2025
Rated Accuracy: 0.03° F	Range: 33° F to 158° F	Resolution: 0.01° F	Uncertainty: < 0.023° F	

Total combined Uncertainty for MultiTemp and TemProbe testing : ≤ 0.046° F

This form must remain with the Certificate of Calibration corresponding to the Customer Order Number and Meter Serial Number referenced on page 1.

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Certificate of Calibration

ISO 9001 CERTIFIED

NISTLab/SAI
Winer-Greene Engineering Services

Order Number: 20250918
Certificate Number 164605

Issued To: CLEANROOM CONSULTING SERVICES
101 WOODBRIDGE LN
DOUGLASSVILLE, PA 19518-8776

Date Received: 2/24/2025
Date Issued: 3/12/2025
Valid thru end of: Mar 2026

Equipment: Manufacturer: EXTECH
Model Number: SL510
SerialNumber: Q639612
Control #

Test Conditions :
Temperature: 20.2 C
Humidity: 36.6 %
Barometric Pressure: 1006.7 mBar

As Found:
FULLY FUNCTIONAL AND IN TOLERANCE.

As Returned:
FULLY FUNCTIONAL AND WITHIN TOLERANCE.

Special Conditions:
NONE

Work Performed:
CALIBRATED PER CALIBRATION PROCEDURE SL-001

CALIBRATED TO: MANUFACTURERS SPECIFICATIONS

MeasurementUncertainties: ACOUSTIC 1.0 DB, FREQUENCY +/- 0.1 HZ, DC VOLTAGE 0.1%, AC VOLTAGE 0.5%

Device, Description, Report Number, Date Due
Reference Standards:
1004, QUEST QE-4170, 1" PRECISION MICROPHONE, 20230618-148768, 10/24/2025
1009, 8903B, AUDIO GENERATOR, 1600265, 4/30/2025
1024, HP 3456A, PRECISION DIGITAL VOLTMETER, 1600266, 4/30/2025
1051, 1800, TYPE 1 SOUND LEVEL METER, 20242258-163826, 1/31/2026
1052, OB-100, 1:1 OCTAVE BAND FILTER, 20242258-163825, 1/31/2026
1053, Nor1525, NORSONIC TYPE NOR1525 IEC/ANSI CALIBRATION SYSTEM., CAL 022-2022-16316, 6/12/2025

Reviewed by: _____ 3/12/2026

Authorized Signature: Brian Stanhope

This report certifies that all calibration equipment used in the test is traceable to the National Institue of Standards (NIST) , and applies only to the unit identified under "Equipment" above. This report must not be reproduced except in it's entirety without express written approval.

VAISALA

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CALIBRATION CERTIFICATE

This certificate may only be reproduced in full, except with the prior written permission by the issuing laboratory.

Certificate Number BOS250210024

Case Number:	00827026
Customer:	Cleanroom Consulting Services
Address:	P.O. Box 394 Douglassville, PA 19518 US
Manufacturer:	Vaisala Oyj
Instrument:	Humidity and Temperature Probe HMP76
Serial Number:	S0340152
Issue Date:	2025-01-06
Calibration Date:	2025-01-06
Recalibration Date:	2026-01-06

Approved by:

Carlos Dos Santos
Service Technician

Note(s):
Service report as an attachment.

The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k = 2,which for a normal distribution corresponds to a coverage probability of approximately 95 %. The measurement results are traceable to the international system of units (SI) through national metrology institutes (NIST USA, MIKES Finland, or equivalent) or via ISO/IEC 17025 accredited calibration laboratories.

Procedure instructions: PI217623

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As Left Results

Humidity calibration results

Reference Humidity [%rh]	Reference Temperature [°C]	Observed Humidity [%rh]	Observed Temperature [°C]	Humidity Error [%rh]	Acceptance Limit [%rh]	Pass/Fail
15.0	19.54	15.2	19.54	0.2	±1.0	Pass
33.0	19.54	33.4	19.54	0.4	±1.0	Pass
54.1	19.54	54.3	19.54	0.2	±1.0	Pass
75.2	19.55	75.2	19.55	0.0	±1.0	Pass
94.9	19.56	95.3	19.55	0.4	±1.7	Pass

Temperature calibration results

Reference Temperature [°C]	Observed Temperature [°C]	Error [°C]	Acceptance Limit [°C]	Pass/Fail
19.55	19.55	0.00	±0.20	Pass

Reference equipment used in calibration

Type	Instrument Number	Certificate Number	Calibration Date	Calibration Due Date
GE Drück DPS 823B	16738	K008-H02129	2024-04-13	2025-04-30
Pt-100 sensor	17003	240201-17003	2024-02-01	2025-02-28
PTU307	17294	240712-PTU307-M0930328	2024-07-12	2025-01-31
Pt-100 sensor	17465	240201-17465	2024-02-01	2025-02-28
PXI-4070	17569	3022270	2024-02-06	2025-02-28

Calibration uncertainty (k=2, ~95 % confidence level):
Humidity ±0.7 %rh @ 0...60 %rh, ±0.8 %rh @ 60...80 %rh, ±0.9 %rh @ 80...95 %rh
Temperature ±0.09 °C

Ambient conditions:

Humidity [%rh]	Temperature [°C]	Pressure [hPa]
41 ± 4	22 ± 2	1002 ± 20

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Calibration note(s):

The humidity calibration was done by comparing the instrument humidity readings to the reference humidity generator readings in the Vaisala laboratory's permanent facility. The reference humidity readings were calculated based on two-pressure humidity generation principle using the measurement results of saturator pressure and temperature and calibration chamber pressure and temperature.

The temperature(s) of the instrument was calibrated by comparing the instruments's temperature readings to a reference thermometer.

Before measurements the instrument was allowed to stabilize to the conditions of the laboratory with power supply on. The purge function was run before the calibration if the instrument has the chemical purge option.

The measurement results were obtained from the measured values or the results were calculated from the measured values by using adjustment coefficients. The reference and instrument readings are averages of at least five independent observations. All relative humidity readings below freezing are compliant to WMO humidity calculation method. The dew point readings are frost point readings when dew point is below 0 °C if the readings are given as a dew point.

The 0 %rh humidity was measured in dry nitrogen gas or dry gas using the humidity meter as a reference if the 0 %rh humidity point was measured

The calibration uncertainty represents the situation at the time and conditions of calibration. When using the instrument at different conditions and at different time the effect of the conditions and stability of the instrument shall be evaluated separately. The calibration results and the statement of conformity with specification/acceptance limit relate only to the calibrated instrument and the calibration points.

The statement of conformity is based on simple acceptance, whether the calibration result is within or outside the manufacturer's specification/acceptance limits. The calibration uncertainty is not taken into account in the statement of conformity. The probability of accepting a non-conforming result or rejecting a conforming result can be as large as 50 % with this acceptance rule when the calibration result is close to the acceptance limit.

Pass or - = The calibration result is equal or within the manufacturer's acceptance limit.
Fail or * = The calibration result is outside the manufacturer's acceptance limit.
N/A = The calibration result acceptance limit is not specified.

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BIOSCIENCE INTERNATIONAL

Innovative Microbiology Products

April 1, 2025

BIOSCIENCE INTERNATIONAL, INC.
SHIPMENT PACKING LIST

SHIP TO: Cleanroom Consulting Services

DESCRIPTION	QUANTITY
ISO 17025 Accredited Calibration & Full PM Service SAS Super 180, Serial #: 10-D-06805; Head #: 4	1

Service Notes:

- The unit was received, inspected and found to be within manufacturer specifications (177.9 L/m); please see attached calibration certificate for details.
- Performed ISO 17025 accredited calibration in wind tunnel.
- Performed full PM checklist, tightened hardware, stress tested battery, battery charger and all components.

Please contact Customer Support at support@biosci-intl.com or 301-231-7400 with any questions.

IT IS A PLEASURE TO SERVE YOU!

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BIOSCIENCE INTERNATIONAL

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CERTIFICATE OF CALIBRATION

Model:	SAS Super 180
Air Sampler Serial #:	10-D-06805
Air Sampler Head Serial #:	4
Customer:	Cleanroom Consulting Services
Customer Asset ID #:	n/a
Calibration performed at:	Woodglen site (see address above)

Cal. Date:	1 Apr 2025	
Cal. Due:	1 Apr 2026	(12 months)
Procedure:	EOP-030	
Certificate #:	10-D-06805-3748	
Volume sampled (L):	1000	
Calibrated w/media type:	BMX TSA w/L & P80	
Plate Lot #:	1011006110	
Plate Exp Date:	5/13/2025	

	As Found	*In Tolerance*	*As Left*	*In Tolerance*	*Acceptable Range*
Battery output (Volts):	10.0	n/a	9.7	n/a	>8.2
Temperature (F°):	73.6	n/a	73.6	n/a	59 - 95
Barometric pressure (in. HG):	30.10	n/a	30.10	n/a	n/a
Time to sample 1000 Liters (min)	5.62	n/a	5.56	n/a	n/a
Temp. & Pressure Standardization Factor:	1.00	n/a	1.00	n/a	n/a
Air velocity reading (ft/min)	99.0	n/a	100.0	n/a	n/a
Air velocity reading (m/sec)	0.503	n/a	0.508	n/a	n/a
Standardized air velocity reading (m/sec)	0.503	n/a	0.508	n/a	n/a
Standardized Air Flow (L/min)	177.9	**Yes**	179.7	**Yes**	171 - 189

Additional service-related notes: Please see footnote below regarding +/-2% interchangeability of heads and media types.

Bioscience International certifies that the above described instrument conforms to the original manufacturer's tolerances for the parameters listed (not applicable to As Found data) & has been calibrated in accordance with ISO 17025:2017 guidelines under accredited conditions (pursuant to Bioscience International's A2LA certificate 5699.01) using standards whose accuracies are traceable to the International System of Units (SIs) through the U.S. National Institute of Standards & Technology or international equivalent, have been verified with respect to instrumentation whose accuracy is traceable to NIST, or are derived from accepted values of physical constants. CMC test uncertainty is +/-2.2%. Instruments are calibrated with a test uncertainty ratio of 4:1 or greater whenever possible. In all cases, statistical methods are used to minimize uncertainty using the best commercially available methods. The decision rule used is Simple Acceptance as defined in ILAC GB with a measurement uncertainty value that will never exceed 50% of the tolerance unless otherwise specified. Voltage readings are for preventative maintenance purposes & not part of the calibration; values other than voltage, temperature, pressure, & air velocity are calculated values. All sampling heads may be used interchangeably with +/-2% equivalence as long as they have the same hole count/size and are kept clean/free of obstructions. Calibration results relate only to the items listed above; the instrument should be recalibrated prior to switching media sizes (e.g., from 90mm Petri dishes to 55mm contact plates or vice versa).

Measurement Standards

ID	*Description*	*Last Cal.*	*Cal. Due*
W-T95451906004	Velocity	9/23/2024	9/23/2025
W-6530-240523257	Temperature & Pressure	7/3/2024	7/3/2026

Work performed by / date: Bambica Fernando 01 APR 2025 Reviewed by / date: [signature] 01 APR 2025

CERTIFICATE OF CALIBRATION

TSI Incorporated, 500 Cardigan Road, Shoreview, MN 55126 USA
Tel: 1-800-874-2811 1-651-490-2811 Fax: 1-651-490-3824 http://www.tsi.com

ANAB ACCREDITED

CUSTOMER NAME:	CERTIFICATE NUMBER	300628660
BIOSCIENCE INTRNTL 11333 WOODGLEN DR STE 201 ROCKVILLE MD 20852-3071 USA	DATE OF CALIBRATION	23 SEPTEMBER, 2024
	PAGE	1 OF 1

ENVIRONMENT CONDITIONS		
TEMPERATURE	72.17 (22.3)	°F (°C)
RELATIVE HUMIDITY	42	%RH
BAROMETRIC PRESSURE	29.10 (985.4)	inHg (hPa)

MODEL	9545
SERIAL NUMBER	T95451906004

☒ AS LEFT ☒ IN TOLERANCE
☐ AS FOUND ☐ OUT OF TOLERANCE

– CALIBRATION VERIFICATION RESULTS –

TEMPERATURE VERIFICATION			SYSTEM T-101				Unit: °F (°C)
METHOD USED: 10000006234							
UNCERTAINTY: +/-0.22 DEGREES F (0.12 C)							
#	STANDARD	MEASURED	ALLOWABLE RANGE	#	STANDARD	MEASURED	ALLOWABLE RANGE
1	32.0 (0.0)	32.0 (0.0)	31.5~32.6 (-0.3~0.3)	2	139.9 (59.9)	140.0 (60.0)	139.3~140.4 (59.6~60.2)

HUMIDITY VERIFICATION			SYSTEM H-102				Unit: %RH
METHOD USED: 10000006233							
UNCERTAINTY: 0.5% + 1.07 %RH							
#	STANDARD	MEASURED	ALLOWABLE RANGE	#	STANDARD	MEASURED	ALLOWABLE RANGE
1	10.0	10.3	7.0~13.0	4	70.0	70.8	67.0~73.0
2	30.1	30.9	27.1~33.1	5	90.0	90.0	87.0~93.0
3	50.0	51.1	47.0~53.0				

VELOCITY VERIFICATION			SYSTEM V-111				Unit: ft/min (m/s)
METHOD USED: 10000006237							
UNCERTAINTY: +/-2.6 %							
#	STANDARD	MEASURED	ALLOWABLE RANGE	#	STANDARD	MEASURED	ALLOWABLE RANGE
1	† 1 (0.01)	0 (0.00)	-2~4 (-0.01~0.02)	7	653 (3.32)	653 (3.31)	634~673 (3.22~3.42)
2	35 (0.18)	36 (0.18)	32~38 (0.16~0.20)	8	997 (5.07)	997 (5.07)	967~1027 (4.91~5.22)
3	65 (0.33)	65 (0.33)	62~68 (0.31~0.34)	9	1472 (7.48)	1471 (7.47)	1428~1516 (7.25~7.70)
4	99 (0.50)	98 (0.50)	96~102 (0.49~0.52)	10	2494 (12.67)	2485 (12.62)	2419~2569 (12.29~13.05)
5	161 (0.82)	160 (0.81)	156~166 (0.79~0.84)	11	4503 (22.88)	4504 (22.88)	4368~4639 (22.19~23.56)
6	329 (1.67)	326 (1.66)	319~339 (1.62~1.72)	12	5809 (29.51)	5799 (29.46)	5635~5983 (28.62~30.40)

† Bin excluded from ISO 17025 calibrations.

TSI Incorporated does hereby certify that the above described instrument conforms to the manufacturer's specifications (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the International System of Units (SI) through the National Institute of Standards and Technology within the limitations of NIST's calibration services or have been derived from accepted values of natural physical constants or have been derived by the ratio type of self-calibration techniques. TSI is registered to ISO 9001:2015. TSI is accredited to ISO 17025:2017 by ANAB Certificate Number AC-2850.

The aforementioned uncertainty values represent expanded uncertainty and are based on a standard uncertainty multiplied by a coverage factor k=2 providing a confidence level of approximately 95%. This report may not be reproduced unless permission is obtained in writing from the TSI calibration service department issuing this report. The unit is found to have passed when the readings are within the specification limits of the device as presented as the allowable range stated with each measurement above. The customer shall assess the results and uncertainty in order to determine if the results meet their needs.

Measurement Variable	System ID	Last Cal.	Cal. Due
Temperature	E010657	03-11-24	03-31-25
Temperature	E010656	03-11-24	03-31-25
DC Voltage	E004018	06-13-24	06-30-25
Pressure	E003541	07-12-24	01-31-25
Velocity	E010408	12-14-21	12-31-24

Measurement Variable	System ID	Last Cal.	Cal. Due
Temperature	E010658	03-11-24	03-31-25
Humidity	E011511	05-25-24	11-30-24
Temperature	E004398	04-10-24	10-31-24
Pressure	E011250	07-12-24	01-31-25

Performed By	Signature	Approved By	Signature	Date Issued
Kalvin Kallungal	Kalvin Kallungal	Ly Soung	Ly Soung	09-23-2024

DOC. ID: CERT_DEFAULT
END OF REPORT

TSI P/N 2300157

ilac-MRA A2LA ACCREDITED A2LA Certificate No. 1750.01 Calibration

Calibration complies with ISO/IEC 17025, ANSI/NCSL Z540-1, and 9001

Cert. No.: 6530-15243718

Traceable® Certificate of Calibration for Digital Barometer

Manufactured for and distributed by : Traceable® Products 12554 Galveston Rd B230, Webster, TX 77598

Instrument Identification:

Model: 6530,68000-49 S/N: 240523257 Manufacturer: Control Company

Standards/Equipment:

Description	Serial Number	Due Date	NIST Traceable Reference
Digital Barometer	D4540001	14 Nov 2024	1000498202
Chilled Mirror Hygrometer	44654/2H3737	09 Feb 2025	22198
Climate Chamber	W613.0046		
Digital Thermometer	200821229	23 Jan 2025	4000-14784177

Certificate Information:

Technician: 57 Procedure: CAL-31 Cal Date: 03 Jul 2024 Cal Due Date: 03 Jul 2026

Test Conditions: 62.62%RH 23.86°C 1017mBar

Calibration Data: (New Instrument)

Unit(s)	Nominal	As Found	In Tol	Nominal	As Left	In Tol	Min	Max	±U	TUR
%RH	N.A.	N.A.		50.50	53	Y	48	54	0.74	>4:1
°C	N.A.	N.A.		25.08	25.1	Y	24.68	25.48	0.05	>4:1
mb/hPa	N.A.	N.A.		805.20	805	Y	801	809	0.62	>4:1
mb/hPa	N.A.	N.A.		910.05	911	Y	906	914	0.62	>4:1
mb/hPa	N.A.	N.A.		1018.45	1020	Y	1014	1022	0.62	>4:1

This certificate indicates Traceability to standards provided by (NIST) National Institute of Standards and Technology and/or a National Standards Laboratory.

A Test Uncertainty Ratio of at least 4:1 is maintained unless otherwise stated and is calculated using the expanded measurement uncertainty. Uncertainty evaluation includes the instrument under test and is calculated in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement : (GUM). The uncertainty represents an expanded uncertainty using a coverage factor k=2 to approximate a 95% confidence level. Conformance based on Simple Acceptance as a Decision Rule, as defined in ILAC G8, with a measurement uncertainty value that will not exceed 50% of the tolerance unless otherwise stated by the customer. The results contained herein relate only to the item calibrated. This certificate shall not be reproduced except in full, without written approval of Control Company.

Nominal=Standard's Reading; As Left=Instrument's Reading; In Tol=In Tolerance; Min/Max=Acceptance Range; ± U=Expanded Measurement Uncertainty; TUR=Test Uncertainty Ratio; Accuracy=±(Max-Min)/2; Min=As Left Nominal(Rounded) – Tolerance; Max= As Left Nominal(Rounded) + Tolerance;

Nicol Rodriguez

Nicol Rodriguez, Quality Manager

Note :

Maintaining Accuracy:

In our opinion once calibrated your Digital Barometer should maintain its accuracy. There is no exact way to determine how long calibration will be maintained. Digital Barometer change little, if any at all, but can be affected by aging, temperature, shock, and contamination.

Recalibration:

For factory calibration and re-certification traceable to National Institute of Standards and Technology contact Control Company.

Issue Date : 03 Jul 2024

CONTROL COMPANY 12554 Galveston RD Suite B230 Webster TX USA 77598
Phone 281 482-1714 Fax 281 482-9448 sales@control3.com www.traceable.com

Control Company is an ISO/IEC 17025:2017 Calibration Laboratory Accredited by (A2LA) American Association for Laboratory Accreditation, Certificate No. 1750.01.
Control Company is ISO 9001:2015 Quality Certified by DNV GL, Certificate No. CERT-01805-2008-AQ-HOU-ANAB.
International Laboratory Accreditation Cooperation - Multilateral Recognition Arrangement (ILAC-MRA).

Traceable® is a registered trademark of Control Company

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InfuCare Rx

PHARMACY WORK ORDER / COMPOUNDING RECORD

Rx # 268459: CefTRIAxone 2gm in SWFI 20ml syringe QTY: 7

NAME	TEST, FAST TX	**PRESCRIBER**	D. Lakhani, **NPI** 1033422324
MRN	202703	**ACCESS**	
PHONE	877-469-6032	**DIAGNOSIS**	Hereditary factor VIII deficiency
AGE	45	**HT**	0 in. / 0 cm
DOB	01/01/1980	**WT**	0 lbs. / 0 kg
GENDER	Male	**BSA**	0m²
RX TYPE	ATB	**DAYS DISPENSED**	7
DRUG	cefTRIAXone Sodium	**DOSES / DAY**	1
DOSE	2 Gm	**DOSES PREPARED**	7
ROUTE	IV	**DOSES / CONTAINER**	1
FREQ	Every 24 hours	**CONTAINERS PREPARED**	7
START	10/28/2025	**COMPOUNDING DATE**	10/28/2025 **DOSE START** 10/29/2025
STOP		**DELIVERY DATE**	10/29/2025 **AT**
DELIVERY #	1	**DELIVERY LASTS THRU**	11/04/2025

ALLERGIES

PRESCRIPTION INFORMATION / MEDICATION REVIEW

ADMINISTRATION DIRECTIONS Infuse entire content of a syringe (Ceftriaxone 2gm) IV via slow IV-push over at least 10 minutes once every 24 hours as directed through _____.
Generic of Rocephin
This medication has been compounded by pharmacy.

STORAGE Refrig. remove 1-2h before use

NOTES

DRUG STABLE THRU 11/07/2025

RPH INITIALS SP

FINAL CONC.	0 Gm/ml
AMT / DOSE	2 Gm / Dose
AMT / DAY	2 Gm / Day
AMT / m² / DAY	
AMT / Kg / DAY	
# OF CONTAINERS	7
QTY / CONTAINER	0
VOLUME TOTALS	0 ml / Day N/A ml / Kg / Day N/A ml / m² / Day

RPH INITIALS - Double Check First Fill _____ **RPH INITIALS - Double Check First Refill** _____

DRUGS / SUPPLIES USED

ITEM DESCRIPTION	NDC #	MANUFACTURER	LOT#	EXP. DATE	QTY
cefTRIAXone 2gm SDV**	60505-6149-04	APOTEX	5003KFPHL1	10/31/2027	5
Syringe 30mL Luer-Lok Tip #302832		BD - Becton Dickinson			7
cefTRIAXone 2gm SDV**	60505-6149-04	APOTEX	5003KFPHL1	10/31/2027	2
Red Syr Cap LL SC2000		B.Braun			7
Sterile Water 1000mL	00264-7850-00	B. BRAUN MEDICAL	J5H772	11/30/2027	1

COMPOUNDING INSTRUCTIONS

For each cefTRIAXone 2gm SDV** vial, reconstitute with 19.2 ml Sterile Water for Injection for a resulting concentration of 0.1 Gm/ml.
Total Prep: 7 vials of cefTRIAXone 2gm SDV** x 2 Gm = 14 Gm in 140 mls of solution (0.1 Gm/ml). 20 mls per dose x 7 doses = 140 mls.
1 dose(s) per container. For each container: add 20 mls (2 Gm) reconstituted solution to each Syringe 30mL Luer-Lok Tip #302832 container.Ceftriaxone 2gm IV Syringe

Physical Appearance of final preparation: Yellow, clear solution in syringe.

This Product was prepared within an ISO class 5 Laminar air flow hood or ISO class 7 clean room and proper aseptic procedures were used at all times to prevent bacterial contamination. BUD of 10 days determined by USP 797 and ESPD 7th edition.

Technician: _____ **Pharmacist:** _____

Date: _____ **Date:** _____

Date Printed: 10/28/2025

InfuCare Rx
PHARMACY WORK ORDER / COMPOUNDING RECORD

Rx # 268472: Daptomycin 500mg in NS 10ml syringe QTY: 7

NAME	TEST, FAST TX	**PRESCRIBER**	D. Lakhani, **NPI** 1033422324
MRN	202703	**ACCESS**	
PHONE	877-469-6032	**DIAGNOSIS**	Hereditary factor VIII deficiency
AGE	45	**HT**	0 in. / 0 cm
DOB	01/01/1980	**WT**	0 lbs. / 0 kg
GENDER	Male	**BSA**	0m²
RX TYPE	ATB	**DAYS DISPENSED**	7
DRUG	DAPTOmycin	**DOSES / DAY**	1
DOSE	500 mg	**DOSES PREPARED**	7
ROUTE	IV	**DOSES / CONTAINER**	1
FREQ	Every 24 hours	**CONTAINERS PREPARED**	7
START	10/28/2025	**COMPOUNDING DATE**	10/28/2025 **DOSE START** 10/29/2025
STOP		**DELIVERY DATE**	10/29/2025 **AT**
DELIVERY #	1	**DELIVERY LASTS THRU**	11/04/2025

ALLERGIES

PRESCRIPTION INFORMATION / MEDICATION REVIEW

ADMINISTRATION DIRECTIONS	Infuse entire content of a syringe (Daptomycin 500mg) IV via slow IV-push over 3-5 minutes once daily as directed through ____. Generic of Cubicin. This medication has been compounded by pharmacy.	**FINAL CONC.**	0 mg/ml
		AMT / DOSE	500 mg / Dose
		AMT / DAY	500 mg / Day
		AMT / m² / DAY	
		AMT / Kg / DAY	
		# OF CONTAINERS	7
STORAGE	Refrig. remove 1-2h before use	**QTY / CONTAINER**	0
NOTES		**VOLUME TOTALS**	0 ml / Day N/A ml / Kg / Day N/A ml / m² / Day
DRUG STABLE THRU	11/07/2025		
RPH INITIALS	SP		

RPH INITIALS - Double Check First Fill _____ **RPH INITIALS - Double Check First Refill** _____

DRUGS / SUPPLIES USED

ITEM DESCRIPTION	NDC #	MANUFACTURER	LOT#	EXP. DATE	QTY
DAPTOmycin 500mg SDV**	60505-6229-04	APOTEX	JA2V4017A	05/31/2026	1
Syringe 30mL Luer-Lok Tip #302832		BD - Becton Dickinson			7
DAPTOmycin 500mg SDV**	60505-6229-04	APOTEX	JA2V4023B	07/31/2026	6
Red Syr Cap LL SC2000		B.Braun			7
Sodium Chlor 0.9% 500mL Non-DEHP	00264-7800-10	B. BRAUN MEDICAL	J5C767	08/31/2027	1

COMPOUNDING INSTRUCTIONS

For each DAPTOmycin 500mg SDV** vial, reconstitute with 10 ml SODIUM CHLORIDE for a resulting concentration of 50 mg/ml. Total Prep: 7 vials of DAPTOmycin 500mg SDV** x 500 mg = 3,500 mg in 70 mls of solution (50 mg/ml). 10 mls per dose x 7 doses = 70 mls.
1 dose(s) per container. For each container: add 10 mls (500 mg) reconstituted solution to each Syringe 30mL Luer-Lok Tip #302832 container.Daptomycin 500mg in NSS 10mL Syringe
Physical Appearance of final preparation: Yellow, clear solution in syringe.
Inspect for integrity, cap and label.

This Product was prepared within an ISO class 5 Laminar air flow hood or ISO class 7 clean room and proper aseptic procedures were used at all times to prevent bacterial contamination. BUD of 10 days determined by USP 797 and ESPD 7th edition.

Technician: _____ **Pharmacist:** _____

Date: _____ **Date:** _____

Date Printed: 10/28/2025

InfuCare Rx
PHARMACY WORK ORDER / COMPOUNDING RECORD
Rx # 268481: Ertapenem 1gm in NS 100ml elastomeric QTY: 7

NAME	TEST, FAST TX	**PRESCRIBER**	D. Lakhani, **NPI** 1033422324
MRN	202703	**ACCESS**	
PHONE	877-469-6032	**DIAGNOSIS**	Hereditary factor VIII deficiency
AGE	45	**HT**	0 in. / 0 cm
DOB	01/01/1980	**WT**	0 lbs. / 0 kg
GENDER	Male	**BSA**	0m²
RX TYPE	ATB	**DAYS DISPENSED**	7
DRUG	ERTAPENEM SODIUM	**DOSES / DAY**	1
DOSE	1 Gm	**DOSES PREPARED**	7
ROUTE	IV	**DOSES / CONTAINER**	1
FREQ	Every 24 hours	**CONTAINERS PREPARED**	7
START	10/28/2025	**COMPOUNDING DATE**	10/28/2025 **DOSE START** 10/29/2025
STOP		**DELIVERY DATE**	10/29/2025 **AT**
DELIVERY #	1	**DELIVERY LASTS THRU**	11/04/2025

ALLERGIES

PRESCRIPTION INFORMATION / MEDICATION REVIEW

ADMINISTRATION DIRECTIONS Infuse entire content of elastomeric device (Ertapenem 1gm) IV over approximately 30 minutes once daily as directed through _____.
Generic of Invanz
This medication has been compounded by pharmacy

STORAGE Refrig. remove 1-2h before use

NOTES

DRUG STABLE THRU 11/04/2025

RPH INITIALS SP

FINAL CONC.	0 Gm/ml
AMT / DOSE	1 Gm / Dose
AMT / DAY	1 Gm / Day
AMT / m² / DAY	
AMT / Kg / DAY	
# OF CONTAINERS	7
QTY / CONTAINER	0
VOLUME TOTALS	1 ml / Day N/A ml / Kg / Day N/A ml / m² / Day

RPH INITIALS - Double Check First Fill _____ **RPH INITIALS - Double Check First Refill** _____

DRUGS / SUPPLIES USED

ITEM DESCRIPTION	NDC #	MANUFACTURER	LOT#	EXP. DATE	QTY
Ertapenem Sod Inj Sol 1gm SDV	42023-0221-10	PAR STERILE	B000607	01/31/2026	7
Sterile Water For Inj 1000mL Bag **	00990-7990-09	ICU MEDICAL	1018660-92	06/30/2026	1
Sodium Chloride 0.9% 1000mL**	00338-0049-04	BAXTER HEALTHCARE	Y472234	10/31/2026	1
Elastomeric 100/100 4540046-02	- -	B.Braun			7

COMPOUNDING INSTRUCTIONS

Etrapenem 1gm/100mL Easypump.

Reconstitute each Etrapenem 1gm vial with SWFI 10mL. Mix well. Add NSS 90mL to each Elastomeric Easypump 100mL/hr 100mL. Withdraw 10mL Ertapenem and add to Easypump. Release clamp to prime Easypump until air bubbles are released and solution is ready to be infused. Inspect for integrity. Clamp, cap and label. Final concentration: 1gm/100mL.
Physical Appearance of final preparation: clear solution in Easypump and primed for infusion.

This Product was prepared within an ISO class 5 Laminar air flow hood or ISO class 7 clean room and proper aseptic procedures were used at all times to prevent bacterial contamination. BUD of 7 days determined by USP 797 and ESPD 7th edition.

Technician: _____ **Pharmacist:** _____

Date: _____ **Date:** _____

Date Printed: 10/28/2025

InfuCare Rx
PHARMACY WORK ORDER / COMPOUNDING RECORD

Rx # 268484: Vancomycin 1 gm in NSS 250mL Bag QTY: 7

NAME	TEST, FAST TX	**PRESCRIBER**	D. Lakhani, **NPI** 1033422324
MRN	202703	**ACCESS**	
PHONE	877-469-6032	**DIAGNOSIS**	Hereditary factor VIII deficiency
AGE	45	**HT**	0 in. / 0 cm
DOB	01/01/1980	**WT**	0 lbs. / 0 kg
GENDER	Male	**BSA**	0m²
RX TYPE	ATB	**DAYS DISPENSED**	7
DRUG	VANCOMYCIN HYDROCHLORIDE	**DOSES / DAY**	1
DOSE	1 g	**DOSES PREPARED**	7
ROUTE	IV	**DOSES / CONTAINER**	1
FREQ	Every 24 hours	**CONTAINERS PREPARED**	7
START	10/28/2025	**COMPOUNDING DATE**	10/28/2025 **DOSE START AT** 10/29/2025
STOP		**DELIVERY DATE**	10/29/2025
DELIVERY #	1	**DELIVERY LASTS THRU**	11/04/2025

ALLERGIES

PRESCRIPTION INFORMATION / MEDICATION REVIEW

ADMINISTRATION DIRECTIONS	Infuse Vancomycin 1gm (in NSS 250mL) IV via PICC over 1 hour once daily via Curlin pump as directed by physician.	**FINAL CONC.**	0 g/ml
		AMT / DOSE	1 g / Dose
		AMT / DAY	1 g / Day
		AMT / m² / DAY	
	This Medication was Compounded in this Pharmacy	**AMT / Kg / DAY**	
		# OF CONTAINERS	7
STORAGE	Keep Refrigerated	**QTY / CONTAINER**	0
NOTES		**VOLUME TOTALS**	1 ml / Day N/A ml / Kg / Day N/A ml / m² / Day
DRUG STABLE THRU	11/07/2025		
RPH INITIALS	SP		

RPH INITIALS - Double Check First Fill _____ **RPH INITIALS - Double Check First Refill** _____

DRUGS / SUPPLIES USED

ITEM DESCRIPTION	NDC #	MANUFACTURER	LOT#	EXP. DATE	QTY
Vancomycin 1gm	63323-0284-20	FRESENIUS KABI USA	6133711	12/31/2026	7
Sterile Water 1000mL	00264-7850-00	B. BRAUN MEDICAL	J5H643	11/30/2027	1
Sodium Chloride 0.9% 250mL ((L8002)	00264-7800-20	B.Braun	J5D823	03/31/2027	7

COMPOUNDING INSTRUCTIONS

Vancomycin 1gm/250mL bag.

Reconstitute each Vancomycin 1 gm vials with SWFI 10ml. Mix well. Withdraw 10mL Vancomycin and add to NSS 250mL bag. Add foil seal and label. Inspect for integrity, cap and label. Final Concentration: 1gm/250mL.

Physical Appearance of final preparation: Clear.

This Product was prepared within an ISO class 5 Laminar air flow hood or ISO class 7 clean room and proper aseptic procedures were used at all times to prevent bacterial contamination. BUD of 10 days determined by USP 797 and ESPD 7th edition.

Technician: _____ **Pharmacist:** _____

Date: _____ **Date:** _____

Date Printed: 10/28/2025

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	1309782		**Inspection Information**
Legal Business Name:	Infucare RX LLC	**Conference Call Date:**	9/15/2025
Doing Business As (DBA):	Infucare RX	**Start Time: 24-hour format (13:00)**	14:00
Address:	2540 Market St, Ste 1	**End Time: 24-hour format (13:00)**	14:53
City:	Aston	**Onsite Inspection Date(s):**	9/16/2025
State:	Pennsylvania	**Start Time(s): 24-hour format (13:00)**	10:00
Zip Code:	19014	**End Time(s): 24-hour format (13:00)**	16:35
Telephone number:	877/828-3940	**Inspector Name(s):**	Fred Massoomi, RPh
Toll free number:	877/828-3940	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	877/828-3941	**Observer Name/Affiliation (if applicable):**	N/A
Website:	www.infucarerx.com	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information	
The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.	
General Pharmacy - 11.00 and 57.00 **Sterile** - 33.0, 33.7, 69.0, 69.8, 69.10, 70.0, 70.15	
Additional information on NABP's Inspection website.	
NABP Disclaimer: NABP can only verify the authenticity of an Inspection Report if it is transmitted directly from NABP to an intended recipient. NABP cannot verify the authenticity of an Inspection Report transmitted from any other party.	

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			X
Monday	9:00	17:00	
Tuesday	9:00	17:00	
Wednesday	9:00	17:00	
Thursday	9:00	17:00	
Friday	9:00	17:00	
Saturday			X

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Andrew Wee	awee@infucarerx.com	145001
Nonsterile Designated person(s)	N/A	N/A	N/A
Sterile Designated person(s)	Sherilyn Vedar & Thomas McCool	Svedar@infucarerx.com, tmccool@infucarerx.com	Not shared
Hazardous Designated person(s)	N/A	N/A	N/A

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Andrew Wee	PIC	Y
2	Thomas McCool	Area General Manager/Designated Person	Y
3	Bonjoo Koo	Pharmacist	Y
4	Domenica Trombetta-Bell	Pharmacist	Y
5	Sherilyn Vedar	Designated Person	Y
6	Roshni Tailor	Pharmacist	Y
7	Chris Fantini	Pharmacy Technician	Y
8	Scott Bell	Pharmacist	Y
9	Kim Miller	Pharmacist	Y
10	Jessica Vazquez	Pharmacist	Y

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present:
4 Pharmacists; 13 Pharmacy Technicians; 12 Pharmacy Service Representatives; 6 Warehouse Personnel; 2 Nurses; 2 Intake Personnel; 1 Administrative Assistant; 2 Facility Personnel

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Business Licensure Information for State of Residence and Federal
(board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Pennsylvania State Board of Pharmacy	Infucare RX	Pharmacy	PP482586 & 8/31/2027
Drug Enforcement Administration	Infucare RX	Controlled Substance - Pharmacy	FI5571256 & 11/30/2027

Inspector Notes: List states in which Non-Resident licenses are held: AL, AK, AZ, AR, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, MA, MD, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OK, OR, RI, SC, SD, TN, UT, VT, VA, WA, WV, WI, WY. The pharmacy does not distribute or dispense to Puerto Rico. There is insulin stocked in the pharmacy, and the DP states the pharmacy has not ordered ReliOn insulin. The DP stated there are no platforms used that are a marketplace for pharmacies to buy, sell, or bid on short date and overstock prescription products, and no price labels for any such platforms were observed. The pharmacy does not compound semaglutide, tirzepatide, survodutide or retatrutide products. The pharmacy does not repackage biological products, but does provide biological products in a ready use formulation (ex., Immunoglobulin).

Documents collected as part of the Inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
N/A	N/A

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Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply	
Traditional retail		Central Fill/Processing/Shared Services	
Open to the Public		Nuclear Pharmacy	
Closed Door	X	Specialty Pharmacy	X
Drive-through window		White bagging/ clear bagging	X
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)	X	Wholesale Distributor	
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)		Provide prescription drugs for "Office Use" (eg distributes)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	
Telepharmacy	X	Sterile Compounding	X
Internet Pharmacy		Sterile Hazardous Drug Compounding	

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	X
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	X
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	x
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous		Category 1 CSPs	
Nonaqueous		Category 2 CSPs	X
Specific types:		Category 3 CSPs	
Solid oral preparations		Types of CSPs:	
Liquid oral preparations		Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	X
Topical preparations:		Blood-derived or other biological material (eg autologous serum)	
Nasal and sinus preparations:		Sterile injections/ sterile infusions	X
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/ Pellets	
		Other (please list):	

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Facility Size in Square Feet *(can be approximated)* and Number of PECs		Personnel	
Total Pharmacy size:	1,412	Total Pharmacists:	12
Nonsterile Compounding Room size:	N/A	Number of Compounding Pharmacists:	8
Nonsterile Compounding powder hoods number:	0	Total Student Interns:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	N/A	Total Technicians:	14
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	0	Number of Compounding Technicians:	8
Sterile Compounding Ante Room size:	Anteroom #1: 105 Anteroom #2: 88	Of technicians, how many are nationally certified?	1
Sterile Compounding Clean/Buffer Room size:	Buffer Room #1: 240 Buffer Room #2: 299	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number LAFW hoods/areas:	Cleanroom #1: 2 Cleanroom #2: 3	Total Other Unlicensed Personnel:	24
Sterile Compounding Number BSC hoods:	0	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	1:1
Sterile Compounding Number CAI/CACI hoods:	0	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs):	Pharmacy has 2 cleanroom suites with separate anterooms and positive pressure buffer rooms. The 2 cleanrooms are adjacent to each other.
Negative Pressure Sterile HD Room size:	N/A		
Sterile HD Compounding Number of BSC hoods:	0		
Sterile HD Compounding Number of CACI hoods:	0		

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	Inspector performed hand hygiene and garbed to facility requirements and entered Cleanroom #2: ISO 8 Anteroom and ISO 7 Buffer Room.

Volume Dispensed

Total Prescriptions Dispensed/day:	285	Total Orders Distributed/day:	5
% Veterinary Prescriptions	0%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	0%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	0%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	10%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	0%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):

Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)	0	0	July 2025
Alaska (AK)	0	0	July 2025
Arizona (AZ)	18	0	July 2025
Arkansas (AR)	0	0	July 2025
California (CA)			
Colorado (CO)	4	0	July 2025
Connecticut (CT)	14	0	July 2025
Delaware (DE)	939	0	July 2025
District of Columbia (DC)	13	0	July 2025
Florida (FL)	38	0	July 2025
Georgia (GA)	14	0	July 2025
Hawaii (HI)	0	0	July 2025
Idaho (ID)	27	0	July 2025
Illinois (IL)	18	0	July 2025
Indiana (IN)	0	0	July 2025
Iowa (IA)	0	0	July 2025
Kansas (KS)	0	0	July 2025
Kentucky (KY)	6	0	July 2025
Louisiana (LA)	0	0	July 2025
Maine (ME)	37	0	July 2025
Maryland (MD)	85	0	July 2025
Massachusetts (MA)	2	0	July 2025
Michigan (MI)	0	0	July 2025
Minnesota (MN)	4	0	July 2025
Mississippi (MS)	0	0	July 2025
Missouri (MO)	0	0	July 2025
Montana (MT)	0	0	July 2025

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States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: If not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)	0	0	July 2025
Nevada (NV)	98	4	July 2025
New Hampshire (NH)	0	0	July 2025
New Jersey (NJ)	1,634	0	July 2025
New Mexico (NM)	14	0	July 2025
New York (NY)	323	0	July 2025
North Carolina (NC)	99	0	July 2025
North Dakota (ND)	0	0	July 2025
Ohio (OH)	0	0	July 2025
Oklahoma (OK)	16	0	July 2025
Oregon (OR)	0	0	July 2025
Pennsylvania (PA)	2,569	0	July 2025
Rhode Island (RI)	0	0	July 2025
South Carolina (SC)	15	0	July 2025
South Dakota (SD)	0	0	July 2025
Tennessee (TN)	10	0	July 2025
Texas (TX)			
Utah (UT)	0	0	July 2025
Vermont (VT)	0	0	July 2025
Virginia (VA)	63	0	July 2025
Washington (WA)	9	0	July 2025
West Virginia (WV)	0	0	July 2025
Wisconsin (WI)	4	0	July 2025
Wyoming (WY)	0	0	July 2025
Other:			

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Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Infucare RX LLC dba Infucare RX

e-Profile ID: 1309782

Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Notes
General Pharmacy			
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	The PIC is scheduled on site for 40 hours per week.
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	Yes	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	Yes	Patients are able to request refills through the Health.Infucare.com app for patients who have opted into using this service. Approximately 20% patients use the app.
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		Thomas McCool, Area General Manager; John Hopkins, National Director of Pharmacy Operations; Jessica Seefried, National Audit Manager; Kathi Seefried, National Audit Manager; Sejal Patel, Clinical Manager; Aaron Callahan, National Materials Management Specialist; Roshni Tailor, Pharmacist; Chris Fantini, Pharmacy Technician; Sherilyn Vader, Pharmacy Technician Designated Person; Andrew Wee, PIC

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e-Profile ID: 1309782

Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Notes
Types of Practice Additional Questions	**If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	Yes	Estimated volume stated as 15% dispensed for administration of the total dispensed in PA.
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	Yes	The pharmacy does not distribute prescriptions within PA. The pharmacy provides IV immunoglobulin to one physician clinic in Nevada which accounts for 100% provided to other states since the pharmacy does not distribute prescriptions to other states.
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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Facility Name: Infucare RX LLC dba Infucare RX

e-Profile ID: 1309782

Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Notes
General Operations and Licensure	**If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	N/A	The pharmacy is a closed door pharmacy.
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	The last PA BOP inspection was on 8/11/2025. The pharmacy is inspected annually.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	No deficiencies noted.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	Yes	PMP waivers for states that allow for it.

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Facility Name: Infucare RX LLC dba Infucare RX

e-Profile ID: 1309782

Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Notes
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	Yes	DEA visited the pharmacy with no formal inspection on 11/2/2022. No deficiencies and no frequency is in place for repeat inspections.
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	URAC accreditation inspection for Specialty Pharmacy Accreditation 5.0 Accreditation was conducted on 9/18/2024. ACHC Home Infusion Therapy Accreditation inspection was conducted on 10/29/2024.
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records ere kept. If not on site, where?*	No	Records are kept in paper form for 3 years on-site and then the records are transferred to Iron Mountain for 10 years. Records are kept electronically indefinitely.

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e-Profile ID: 1309782

Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Notes
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	No	
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronically.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronically.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Clinical software CPR+ will not allow records to be deleted once dispensed.
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	Yes	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	The pharmacy compliance team does a review monthly of registered BOP statute and regulatory changes to make modifications. This is defined in SOP 2.1 Regulatory Compliance.

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e-Profile ID: 1309782

Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Notes
Personnel	**If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Infucare Rx corporate office has a licensing compliance team to review the status of all personnel and their licensures and registrations.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	Infucare Rx corporate office has a licensing team to review the status of all personnel and licensing and registrations are validated each month.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	N/A	
Facility and Security	**If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	The pharmacy has ADT for security and alarm systems for all doors, motion sensors, glass break, and cameras. Verkada provides the personnel badge system for the exterior doors and pharmacy doors.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	N/A	The pharmacy does not have any controlled substances on-site.
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	A pharmacist would come on site and secure the medications and have the medications. The operations team would provide guidance depending upon the incident. A pharmacist would remain on-site until medications are secured or transferred to the Pine Brook, NJ location.

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Facility Name: Infucare RX LLC dba Infucare RX
e-Profile ID: 1309782
Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Notes
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Inmar
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Medical Waste Management Provider: Daniels Health Medical Waste Disposal. The provider comes on-site quarterly to remove wastes.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	N/A	

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Facility Name: Infucare RX LLC dba Infucare RX
e-Profile ID: 1309782
Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Notes
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	The temperature of the drug storage area at inspection was 68.1°F.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	The pharmacy uses Temp Stick data probes to continuously monitor temperatures. The probes are set to a range of 68° to 77 °F for controlled room temperature. If there is an excursion en email and text alert is sent to the PIC, Area General Manager and assigned pharmacy staff. Alerts will go off every hour until resolved. For extended excursions the PIC and pharmacist will come on site to relocate medications to an area with a suitable temperature.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	The pharmacy uses Temp Stick data probes to continuously monitor temperatures. The probes are set to e range of 36° to 46 °F for refrigerator temperature. If there is an excursion an email and text alert is sent to the PIC, Area General Manager and assigned pharmacy staff. Alerts will go off every hour until resolved. For extended excursions the PIC and pharmacist will come on site to relocate medications to an area with a suitable temperature.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	Refrigerator #1: 39.6°F; Refrigerator #2: 41.0°F; Refrigerator #3: 40.9°F; Refrigerator #4: 38.4°F; Refrigerator #5: 43.6°F; Refrigerator #6 37.4°F; Refrigerator #7: 39.0°F; Refrigerator #8: 39.2°F; Refrigerator #9: 41.5°F; Refrigerator #10: 40.8°F; Refrigerator #11: 41.7°F; Refrigerator #12: 39.3°F

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Facility Name: Infucare RX LLC dba Infucare RX
e-Profile ID: 1309782
Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Notes
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	Ice packs are stored in the freezers for shipping.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	An alert will go off and staff will determine if materials can be moved to an alternative refrigerator on-site or if the products need to be sent to the Pine Brook, NJ location.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	The pharmacy has a redundant HVAC unit for each cleanroom suite. The pharmacy has a preventative maintenance program with Oliver Mechanical Services for each HVAC unit. The pharmacy has a contractile agreement with Oliver Mechanical for emergency services. If HVAC units incidents cannot be addressed in a timely manner all drugs will be moved to the Pine Brook, NJ location.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	For temperature and/or humidity excursions, historical information is reviewed to determine the estimated time out of specification. All drugs in the affected area(s) will be quarantined and reviewed for viability and integrity with the manufacturer of each drug prior to use.
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such es robotics, Baker cells, etc)? *List numbers and types.*	Yes	The pharmacy has 4 Baxter repeater pumps for sterile compounding and 2 Apex TPN compounding devices.
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	Yes	

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Facility Name: Infucare RX LLC dba Infucare RX

e-Profile ID: 1309782

Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Notes
Product Receipt and Inventory	**If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	The InfuCare RX Corporate Compliance Purchasing Team establishes the agreements with vendors.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	Yes	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	Yes	The pharmacy participates with internal drug transfers between other InfuCare RX pharmacy locations.
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	Wholesalers: Cencora (Amerisource Bergen), McKesson, CuraScript.
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Yes	Tracelink warehouses the transaction information and the data in Tracelink is used in addition to the transactions documents from the wholesalers and manufacturers.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	No	
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	Yes	The pharmacy procurement department has connected with each manufacturer to verify they are licensed in PA.

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		Observation	Notes
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	Yes	The pharmacy procurement department has connected with each wholesaler and manufacturer to verify they are registered with the FDA.
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	The pharmacy SOP 201 Receiving Pharmaceutical Products via Tracelink - OPUS Software describes the process for verifying suspect or illegitimate drugs which includes the processes of quarantining drugs and notification to FDA and the wholesaler, when applicable.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	None to date.
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	Yes	The site will keep transaction data documents for 6 years electronically. At inspection reviewed 10 drugs for transaction data purchased from Cencora.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	The pharmacy SOP 201 Receiving Pharmaceutical Products via Tracelink - OPUS Software describes the process for verifying suspect or illegitimate drugs which includes the processes of quarantining drugs and notification to FDA and the wholesaler, when applicable.
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	N/A	
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	N/A	

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		Observation	Notes
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	N/A	
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetuel inventory in computer, etc).*	Yes	The pharmacy conducts a monthly inventory to track and identify variances.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	All incidents of diversion are reviewed by corporate human resources. Depending upon the situation, diversion events may be reported to the licensing/registration board if it is healthcare provider and potentially to local law enforcement.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	N/A	

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		Observation	Notes
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	N/A	
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Unknown	The Area General Manager stated zero inventory is conducted annually. The inspector did not view the most current zero inventory.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	The pharmacy checks for outdates monthly and includes OTC products.

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		Observation	Notes
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?	[redacted]	Monthly inspections are performed on all stock.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	No	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	

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Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Notes
Prescription Processing	**If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Patient profile data are entered by either the patient intake team, pharmacists or patient service representatives. The data is updated constantly with changes to orders.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	N/A	
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	If there is a question on the validity of a prescription order the pharmacy staff will call the prescribing individual directly. If there is suspicion of a suspicious prescription or prescriber the pharmacy leadership will notify the medical board of the state.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	Prescriptions orders are documented in the medical clinical notes by contacting the prescribers office directly.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	SureScripts transfers electronic prescriptions to CPR+ for non-controlled products.

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		Observation	Notes
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	N/A	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	Orders are verified by a pharmacists on entry and at dispensing.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	DURs take place at the time of entry into the system and at each medication order change.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	No	
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	Lexicomp electronic, ASHP Guidelines, USP Compounding Compendium.
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	The pharmacy does have waivers to states that allow for entry of data into the state PMP programs.

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		Observation	Notes
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	N/A	
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	The DURs can be overridden by a pharmacist and it is electronically documented and time stamped in CPR+.
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	Medispan
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	N/A	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	N/A	
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	Orders are verified by a pharmacists on entry and at dispensing at the time shipping.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	CPR+ generates the label based on the order entry verified by the pharmacist.

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		Observation	Notes
70.00	**Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	CPR+ is the pharmacy computer system.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	The pharmacy uses Iron Mountain to destroy all PHI information documents.
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	

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		Observation	Notes
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all new prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	
75.01	Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
76.00	Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	

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		Observation	Notes
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	N/A	
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	N/A	
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Patient counseling is provided on the telephone for new orders. A patient packet is sent with each order which has a toll-free number to a pharmacist.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Patient counseling is provided on the telephone for new orders. A patient packet is sent with each order which has a toll-free number to a pharmacist.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	CPR+ automatically prints off the PPIs with medication labels and patient information.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	Yes	Pharmacy has pre-printed MedGuides and it is documented within CPR+ that it is sent with the medication orders.
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	Yes	Tysabri, Soliris, Ultomiris
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	Counseling interactions are documented in CPR+.

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		Observation	Notes
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	Yes	The pharmacy has a 24 hour, on-call pharmacist. After hours the toll free number goes to the pharmacist on-call to call the patient or caregiver back.
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	

Quality Assurance/Quality Improvement Program

If any part of a question is no, enter "No" and explain the observation.

87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	Thomas McCool, Area General Manager /Designated Person oversees the CQI program.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	SOPs are available in electronic form.

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Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Infucare RX LLC dba Infucare RX
e-Profile ID: 1309782
Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Notes
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	The pharmacy uses an electronic documentation system Healthicity.
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	

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88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	Thomas McCool, Area General Manager oversees the QRE events. Data is rolled up to the corporate level to assess trends for remediation to assess if the QRE is local or a national event. The roll up data are reviewed quarterly by the Quality Management Team at corporate.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	

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91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	All local QRE events are reported to the corporate Quality Management Team. The corporate Quality Management Team would assess if a QRE event would require reporting the PA BOP.
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	Yes	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	Yes	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

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Sterile Compounding Inspection for USP <797>

Facility Name: Infucare RX LLC dba Infucare RX
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		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)		**Please note NABP did not review each SOP for alignment on USP <797>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have a designated person(s) who meets the requirements in compliance with USP <797> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals (ie, the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions."*** *If no, go to compliance statements.*	Yes		1.1.3, 2
1.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		18
1.2	The designated person(s) is responsible and accountable for the performance and operation of the facility. ***Per USP, "The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality."***	Yes		2, 4.2, 4.5

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		Observation	Inspector Notes	USP Reference(s)
1.3	The designated person(s) is responsible for personnel performing sterile compounding or other related functions (eg, quality checks and prescription dispensing of compounded preparations).	Yes		2, 17
1.4	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented.	Yes		2, 17
1.5	The designated person(s) ensures that SOP revisions are implemented.	Yes		2, 17
1.6	The designated person(s) communicates all SOP revisions to all impacted personnel. ***Inspector note: USP <797> recommends that personnel should also document acknowledgment and communication of SOP changes and revisions.***	Yes		2, 17
1.7	The designated person(s) ensures that personnel demonstrate competency in performing every procedure that relates to their job function.	Yes		2, 17
1.8	The designated person(s) ensures that corrective actions are taken if problems, deviations, out-of-range results, failures, or errors are identified. ***Inspector note: Per USP, "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective."***	Yes		2, 5, 12

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		Observation	Inspector Notes	USP Reference(s)
2.0	Has the pharmacy developed and implemented SOPs that describe sterile compounding processes and other support activities in compliance with USP <797> standards? ***Inspector note: In order for this to be answered yes, all topics must be addressed if applicable to their business practices.*** *If no, document "missing" in Inspector Notes* *If yes, document the name, number, and version of each SOP in the Inspector Notes.*	Yes		17
2.1	**Scope of Practice:** Types of CSPs that are prepared (eg, immediate use, allergenic extracts, Category 1, Category 2, Category 3). Roles and responsibilities of the designated person(s).		SOP 9.4 Scope of Services and PM; SOP 401 Sterile Preparation; SOP 402 Establishing Categories; SOP 613 Designated Person	1.5
2.2	**Personnel Training and Evaluation:** Description of initial and ongoing training and competency for the designated person(s), compounding personnel, personnel with direct oversight of compounding personnel, and personnel who only perform restocking or cleaning, and disinfecting duties outside of the primary engineering control (PEC). Description of media-fill testing procedures, hand hygiene and garbing competency, and aseptic manipulation competency. Training and competency assessment of personnel on all sterilization methods and equipment used by the facility. Frequency of training is defined.		SOP 604 Competency Testing in Aseptic Manipulation	2, 2.2, 10 Box 1, Box 2, Table 2, Table 3

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		Observation	Inspector Notes	USP Reference(s)
2.3	**Personal Hygiene and Garbing:** Description of the required garb, manner of storage, and order of garbing, including disinfection procedures for reusing goggles, respirators, and other reusable equipment. ***Inspector note: Per USP, the RABS (or pharmaceutical isolator) sleeve and glove changes should (not required) be changed per the manufacturer's recommendations and defined in the facility's SOPs.***		SOP 403 Cleanroom Cleansing and Garbing	3, 3.3
2.4	**Facility Design and Engineering Controls:** Description of design requirements to maintain air quality standards and procedures for evaluating, maintaining, and certifying the areas used for compounding.		SOP 404 Working in Cleanroom; SOP 405 Primary Engineering Control	4, 4.2
2.5	**Certification and Recertification:** Description of sampling sites and procedures.		SOP 406 Maintenance and Certification of the Cleanroom	5, 5.1
2.6	**Microbiological Air and Surface Monitoring:** Description of the pharmacy's microbiological air and surface monitoring program which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (eg, surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective actions and documentation requirements.		SOP 603 Environmental Monitoring - Viable Sample	6, 6.1, 6.2, 6.3

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		Observation	Inspector Notes	USP Reference(s)
2.7	**Cleaning, Disinfection, and Application of Sporicidal Disinfectants and Sterile 70% IPA:** Description of procedures for cleaning, disinfecting, and applying sporicidal disinfectants and include the frequency, methods, locations of cleaning, and documentation requirements.		SOP 407 Cleaning and Disinfection of the Cleanroom Complex	7, 7.2 Box 7, Box 8
2.8	**Equipment:** Description of procedures for the calibration, maintenance, cleaning, use of the equipment, and documentation requirements.		SOP 405 PEC Maintenance; SOP 415 Baxa Repeater Pump; SOP 416 Pinnacle Compounder; SOP 417 Apex Compounder	9.1, 10, 20
2.9	**Components:** Description of procedures that address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and container closures.		SOP 408 Sterile Compounded Preparations; SOP409 Aseptic Preparation; SOP 411 Parenteral Nutrition; SOP 413 Control and Monitoring of Cleanroom Storage; SOP 414 Compounding and Verification of CSP	9.3
2.10	**Master Formulation and Compounding Records:** Description of procedures for developing and maintaining MFRs and required information, documentation, and record-keeping requirements for MFRs and CRs.		SOP 414 Compounding and Verification of CSP	11.1, 11.2, 20
2.11	**Release Inspections and Testing:** Description of release testing procedures (eg, visual inspections and/or sterility and endotoxin testing), out-of-specification procedures, corrective action procedures, and documentation requirements.		SOP 606 Visual Inspection of a Finished Product	12, 18, 20

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		Observation	Inspector Notes	USP Reference(s)
2.12	**Labeling:** Procedures for labeling and label verification (confirming against the prescription or medication order, the MFR, and the CR) in order to prevent errors, CSP mix-ups, and required displayed information.		SOP 412 Labeling of Compounded Products	13
2.13	**CSP handling, storage, packaging, shipping, and transport:** Processes and techniques for handling, storing, packaging, and transporting CSPs that include temperature monitoring, excursions, shipping containers, packaging requirements, and selected transportation modes.		SOP 413 Control and Monitoring of the Cleanroom; SOP 414 Compounding and Verification of CSP; SOP 418 LAFW Cleaning and Disinfection; SOP 9.3 Distribution Process Criteria and Testing	19
2.14	**Documentation:** Record keeping requirements and procedures for documentation maintenance and storage. ***Inspector note: USP requires readily retrievable records for two years; however, it is acknowledged that state or accreditation organizations may require records for a longer period of time.***		SOP 9.6 Standardized Documentation; SOP Use of Simplifi 797; SOP 7.9 Patient Records Accuracy	20
2.15	**Sterilization and Depyrogenation:** Description of methods used for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment. ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	10

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		Observation	Inspector Notes	USP Reference(s)
2.16	**Immediate Use CSPs:** Description of processes followed to meet all conditions of exemption from the requirements for Category 1, Category 2, and Category 3 CSPs. ***If not applicable to their business practices, inspector should answer statement as N/A.***		SOP 402 Establishing Categories	1.3
2.17	**Blood/Biological Handling:** Description of processes used to avoid cross-contamination and meet applicable regulatory requirements. ***If not applicable to their business practices, inspector should answer statement as N/A.***		SOP Infection Control and Prevention Program	1.1.2
2.18	**Allergenic Extracts:** Description of procedures for training, competency assessments, personnel hygiene and garbing, facility requirements, cleaning and disinfecting, beyond use dates (BUDs), labeling, storage, shipping and transporting, and documentation. ***If applicable to their business practices, please complete the Allergenic Extracts module.*** ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	21

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		Observation	Inspector Notes	USP Reference(s)
	CSPs - Immediate Use, Proprietary Vial/Bag Systems, and Blood-Derived			1
3.0	Does the pharmacy prepare and dispense compounded sterile preparations for direct and immediate use? ***If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.***	N/A		1.3
4.0	Does the pharmacy meet all conditions specified in USP <797> for CSPs compounded for direct and immediate use? ***Inspector note: Per USP <797>, all conditions must be met to qualify for exemptions of the requirements for Category 1, Category 2, and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.***	N/A		1.3
4.1	Aseptic techniques, processes, and procedures are followed. ***Inspector note: Per USP <797>, facility SOPs must describe procedures followed "to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs."***	N/A		1.3

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		Observation	Inspector Notes	USP Reference(s)
4.2	Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. ***Review personnel records to verify.***	N/A		1.3
4.3	Preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs. ***Inspector note: Examples of this include approved labeling and/or published or unpublished stability and compatibility studies.***	N/A		1.3
4.4	Preparation involves not more than three (3) different sterile products (eg, ingredients and/or components in a single container).	N/A		1.3
4.5	Unused components from a single-use container are discarded after the preparation for one individual patient is complete (ie, single-dose containers are not used for more than one patient).	N/A		1.3
4.6	Administration begins within four hours of the start of the preparation, and if not, the preparation is discarded. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3

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		Observation	Inspector Notes	USP Reference(s)
4.7	Unless the person preparing the preparation is administering or witnessing administration, the preparation is labeled with names and amounts of all active ingredients, name or initials of preparer, and exact four-hour time period in which administration must begin. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3
5.0	Does the pharmacy prepare proprietary bag and vial systems (ex. addEASE, ADD-Vantage, Mini Bag Plus, Vial2Bag) in compliance with USP <797> standards? ***Inspector note: Docking and activation of proprietary bag and vial systems for immediate administration to an individual patient is out of scope of USP <797> and may be performed outside of an ISO Class 5 environment.*** ***If no, go to compliance statements.*** ***If the pharmacy does not stock, prepare, and/or dispense any proprietary vial and bag systems, inspector should answer statement as N/A.***	Yes		1.4
5.1	Docking for *future activation* and administration is performed in an ISO Class 5 environment and in accordance with requirements of USP <797>, with the exception of BUD assignment.	Yes		1.4
5.2	BUD assignment is not longer than specified in the manufacturer's labeling.	Yes		1.4

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6.0	Does the pharmacy meet the conditions specified in USP <797> for CSPs to be prepared per approved labeling? ***Inspector note: Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is considered outside the scope of the USP chapter.*** ***If no, go to compliance statements.*** ***If the pharmacy only <u>compounds</u> sterile preparations (eg, does <u>not</u> prepare sterile preparations that strictly adheres to the conventionally manufactured approved labeling for preparation), inspector should answer statement as N/A.***	Yes		1.4
6.1	The product is prepared as a single dose for an individual patient.	Yes		1.4
6.2	The approved labeling includes information for the diluent, the resultant strength, the container closure system, and the storage time.	Yes		1.4
7.0	Does the pharmacy perform compounding activities that require the manipulation of a patient's blood-derived or other biological material (eg, autologous serum)?	No		1.1.2

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		Observation	Inspector Notes	USP Reference(s)
8.0	For compounding activities that require the manipulation of a patient's blood-derived or other biological material, does the pharmacy perform manipulations that are clearly separated from other compounding activities and equipment used in CSP preparation activities and are controlled by specific SOPs to avoid any cross-contamination? ***Inspector note: Per USP, a separate cart could be used for blood-derived or other biological materials (a separate area is not required by the chapter). Pharmacy should change garb. Pharmacy to have cleaning processes as part of SOPs to avoid cross-contamination.*** ***If the pharmacy does not compound with blood products or other biological materials, inspector should answer statement as N/A. If the inspector answers the compliance question as "no", please describe your observations.***	N/A		1.1.2
	Facility Design and Engineering Controls			**4**
9.0	**Segregated Compounding Area (SCA):** Does the pharmacy use an SCA as an SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP, only Category 1 CSPs may be compounded in a SCA.*** ***If no, go to compliance statements.*** ***If pharmacy only uses a cleanroom suite for sterile compounding preparations, inspector should answer question as N/A.***	N/A		4.1, 4.1.1, 4.1.2, 4.2.1 Table 5
9.1	The facility is designed to afford a well-lighted and comfortable working environment.	N/A		4.2, 4.2.1

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		Observation	Inspector Notes	USP Reference(s)
9.2	Only Category 1 CSPS are prepared in a SCA. ***If pharmacy is compounding Category 2 or Category 3 CSPs in a SCA, inspector should answer this statement as no and collect photographs and copies of the MFR, CR, and provide a description of their observations in the Inspector Notes.***	N/A		4.2.1, 4.2.3 Table 5
9.3	The SCA is located away from unsealed windows, doors that connect to outdoors, and traffic flow. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	N/A		4.2.1
9.4	The SCA is located away from environmental control challenges and separate from areas not related to compounding (ie, restrooms, warehouses, food preparation areas).	N/A		4.2.1
9.5	A visible perimeter establishes the boundaries of the SCA. ***Inspector note: Per USP, the SCA is defined as "a designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only." USP further defines a perimeter as "a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA." The perimeter will be defined in the pharmacy's SOPs. Tape or an alternative method may be used to define this visible perimeter, since this is not a classified space.***	N/A		4.2.1 Glossary

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Infucare RX LLC dba Infucare RX

e-Profile ID: 1309782

Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Inspector Notes	USP Reference(s)
9.6	Access to the SCA is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning.***	N/A		4.2.1
9.7	Free-standing humidifiers/dehumidifiers and air conditioners are not located within the perimeter of the SCA.	N/A		4.2
9.8	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the compounding area. ***Inspector note: Per USP, these items should be low-shedding, easily cleaned, and disinfected. This applies to items within the perimeter around the Primary Engineering Control (PEC).***	N/A		4.5
9.9	Shipping cartons or other corrugated or uncoated cardboard are not allowed in the SCA.	N/A		4.5
9.10	The SCA and all surfaces (walls, floors, counters, equipment) are clean, uncluttered, and dedicated to compounding.	N/A		4.2.1, 4.3.2
9.11	The sink is located inside the SCA or in close proximity and is located at least one meter away from the PEC.	N/A		4.4
9.12	The area within one meter of the PEC is dedicated only for sterile compounding (eg, not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities, such as patient care).	N/A		4, 4.2.1

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9.13	If overhangs or ledges are present in the SCA, are they easily cleanable? ***If no, describe observations in Inspector Notes.***	N/A		4.2.1, 4.3.2
10.0	Are surfaces smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments Inspector Notes (eg, peeling of Formica countertops)***	Yes		4.3.2
11.0	Are surfaces resistant to damage from cleaning, sanitizing, and sporicidal agents used? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments inspector observations (ie observed rust on preparation cart or flaking of particle board on shelving).***	Yes		4.2.1, 4.3.2
12.0	**Cleanroom Suite:** Does the pharmacy use a Cleanroom Suite (ISO-classified anteroom and buffer room) as a SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP <797>, a cleanroom suite is required if compounding any Category 2 and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If pharmacy only uses an SCA for Category 1 CSPs, inspector should answer question as N/A.***	Yes		4.1, 4.1.1, 4.1.2, 4.2.1, 4.3.1 Table 5

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		Observation	Inspector Notes	USP Reference(s)
12.1	Access to the cleanroom suite is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning. Some examples pharmacies may use to demonstrate compliance with this statement (but are not specifically required by the chapter) include posting a sign or creating a badge access point for authorized personnel to enter the cleanroom suite.***	Yes		4.2.1
12.2	The facility is designed to afford a well-lit environment.	Yes		4.2, 4.2.1
12.3	The facility provides a comfortable working environment (eg, temperature and humidity settings so appropriate garb can be donned).	Yes		4.2.1
12.4	The anteroom and buffer room are separated from surrounding unclassified areas by fixed walls and doors.	Yes		4, 4.2.1
12.5	Controls are in place to minimize the flow of lower-quality air into the more-controlled areas. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	Yes		4.2.1
12.6	Anterooms providing access to only positive pressure buffer rooms meet at least ISO Class 8 specifications. ***If the pharmacy has a negative pressure room, inspector should answer statement as N/A.***	Yes		4.1.2, 4.2.1

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		Observation	Inspector Notes	USP Reference(s)
12.7	The anteroom provides access to a negative pressure room and meets at least ISO Class 7 specifications. ***If the pharmacy does not compound hazardous drugs, inspector should answer statement as N/A.***	N/A		4.1.2, 4.2.1
12.8	The buffer room, where the PEC is placed, meets ISO Class 7 or better air quality specifications. ***Inspector note: If the PEC is a pharmaceutical isolator, the buffer room must be at least ISO Class 8 air quality or better and an anteroom is not required. Per USP <797>, a pharmaceutical isolator is defined as an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. A CAI or CACI is not a pharmaceutical isolator.***	Yes		4.1.2, 4.2.1, 4.2.3
12.9	Air supply to the anteroom and buffer room is introduced through HEPA filters in the ceiling.	Yes		4.2.1
12.10	Air returns are located low on the wall. ***If the pharmacy has a visual smoke study (as described in the USP chapter and compliance statement below), inspector should answer statement as N/A.***	Yes		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
12.11	A visual smoke study demonstrates an absence of stagnant air where particles can accumulate and is repeated if any equipment/placement changes when air returns are not located low on the wall. ***Inspector note: Per USP, "the smoke study, along with environmental monitoring, must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (eg, HVAC alterations, chapter of HEPA filter units)."*** ***If air returns are low on the wall, inspector should answer statement as N/A.***	N/A		4.2.1
12.12	The anteroom has a line of demarcation to separate the dirty side from the clean side or has two separate anterooms, a dirty anteroom and a clean anteroom. ***Describe observations for the type of line of demarcation in the Inspector Notes.***	Yes	The line of demarcation is a black and yellow tape.	4.2.1
12.13	Personnel enter the dirty side/room first from the unclassified area and the clean side/room is located closest to the buffer room.	Yes		4.2.1
12.14	All surfaces (ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets) are smooth, impervious, free from cracks and crevices, and non-shedding.	Yes		4.2.1, 4.3.1
12.15	Junctures between ceilings and walls and between the walls and floors are sealed.	Yes		4.2.1, 4.3.1

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		Observation	Inspector Notes	USP Reference(s)
12.16	If the ceiling consists of inlaid panels, the panels are caulked to seal them to the support frame. *If the ceiling does not consist of inlaid panels, inspector should answer statement as N/A.*	Yes		4.2.1, 4.3.1
12.17	Walls are constructed of, or covered with, a durable material (eg, epoxy paint, heavy gauge polymer) and integrity of surface maintained.	Yes		4.2.1, 4.3.1
12.18	Walls, if paneled, are joined together and sealed to the support structure. *If walls are not paneled, inspector should answer statement as N/A.*	Yes		4.2.1, 4.3.1
12.19	Floors include coving to the sidewall or the juncture between floor and wall is caulked.	Yes		4.2.1, 4.3.1
12.20	If overhangs or ledges are present, they are easily cleanable. *If there are no overhangs, ledges, utility pipes, windowsills, etc, inspector should answer statement as N/A.*	Yes		4.2.1, 4.3.1
12.21	Exterior lens surfaces of the ceiling light fixtures are smooth, mounted flush, and sealed.	Yes		4.2.1, 4.3.1
12.22	All other penetrations through the ceiling or walls (eg, camera domes) are sealed.	Yes		4.2.1, 4.3.1
12.23	The buffer room does not contain plumbed water sources (eg, sinks, eyewashes, showers, or floor drains).	Yes		4.4

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		Observation	Inspector Notes	USP Reference(s)
12.24	The anteroom does not contain floor drains.	Yes		4.4
13.0	Are **PECs** used to prepare CSPs located in the appropriate space (eg, buffer room or SCA) for category types prepared in compliance with USP <797> standards? ***Inspector to review certification reports and observe compounding area(s) to evaluate.*** ***If no, go to compliance statements.***	Yes		4.2.1, 4.2.2, 4.2.3 Table 4, Table 5
13.1	All compounded sterile preparations (that are not for immediate use) are compounded in a PEC.	Yes		1.3, 4, 4.1.2
13.2	PEC is certified to maintain ISO 5 classification or better conditions during dynamic operating conditions. ***The inspector should only answer yes if the PEC has been certified within the past six months.***	Yes		4.2.2, 4.2.3, 5
13.3	The PEC is located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC. ***Review certification report.***	Yes		4, 4.2.2, 4.2.3
13.4	Placement of the PEC allows for cleaning around the PEC.	Yes		4.2.3
13.5	**Category 2 and Category 3:** PEC(s) are located in a cleanroom suite. ***If pharmacy only compounds Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.2.3 Table 5

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		Observation	Inspector Notes	USP Reference(s)
14.0	Does the pharmacy have any CAIs/CACIs used for sterile compounded preparations? ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3 Table 5
15.0	Are **CAIs/CACIs** (RABS) used for compounding sterile preparations operated in compliance with manufacturer specifications **and** USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3
15.1	The documented recovery time is followed after opening the CAI/CACI transfer chamber to maintain ISO Class 5 air quality. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.2	Staff ensures that adequate recovery time is allowed after closing the CAI/CACI during compounding operations. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.3	Sterile gloves are worn over the gloves attached to the CAI/CACI sleeve. ***Inspector note: Per USP, if using a RABS (ie, a CAI or CACI), disposable gloves should be (not required) worn inside the gloves attached to the RABS sleeves.***	N/A		3.3

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		Observation	Inspector Notes	USP Reference(s)
16.0	Are there controls in place to minimize the influx of contaminants from materials (supplies and equipment) and personnel as they move from areas of lower quality to those of higher quality in compliance with USP <797> standards? ***Inspector note: An example of material movement from lower quality air to higher quality air includes movement from a non-classified area to an ISO Class 8 anteroom, ISO Class 8 anteroom to an ISO Class 7 buffer room, or from an ISO Class 7 buffer room to an ISO Class 5 PEC.*** *If no, go to compliance statements.*	Yes		4.5
16.1	Before any item is introduced into the SEC, placed into the pass-through chamber, or brought into the SCA (providing that packaging integrity will not be compromised), it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (IPA) using low-lint wipers by personnel wearing gloves.	Yes		4.5
16.2	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.	Yes		4.5
17.0	Does the pharmacy have the appropriate facility design and controls (including the fixtures, types of equipment, materials, and supplies that are stored) in the classified areas in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		4, 9.1, 19.1

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		Observation	Inspector Notes	USP Reference(s)
17.1	The sink used for hand hygiene, located outside of the anteroom, is placed in an appropriate area and clean space to minimize the risk of bringing contaminants into the anteroom. ***Inspector note: Inspector should evaluate the sink location in relation to the activities that occur where the sink is located as well as the distance between the sink and the entrance to the compounding suite/SCA. Examples that may not be considered appropriate include but are not limited to: sink is located in the bathroom, an adjacent suite or property, or in an employee breakroom where food is prepared.*** ***If the sink is located in the anteroom, inspector should answer statement as N/A.***	N/A		4.4
17.2	The sink used for hand hygiene, located inside of the anteroom, is placed in an appropriate area to minimize the risk of bringing contaminants into the buffer room. ***Inspector note: Inspector should evaluate the sink location in relation to the doors and compounding activities. For example, the sink is where compounders perform hand hygiene close to where garb is stored (where it can easily get wet/splashed).*** ***If the sink is located outside the anteroom, inspector should answer statement as N/A.***	Yes		4.4
17.3	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes		4.2.1
17.4	The inside and outside doors of a pass-through are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes		4.2.1

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17.5	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. ***Inspector note: Per USP, items necessary for performing compounding activities are low-shedding and can be easily cleaned and disinfected. If no, describe the types of items that are observed. If appropriate, submit a photograph with inspection report.***	Yes		4.5, 9.1
17.6	Tacky mats are not used in the classified areas. ***Inspector note: Per USP <797>, "Tacky mats must not be placed within ISO-classified areas."***	Yes		4.2.1
17.7	Shipping cartons or other corrugated or uncoated cardboard are not permitted in the classified areas.	Yes		4.5
17.8	Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels.	Yes		4.5
17.9	Carts (including casters) are cleaned and disinfected prior to moving from the dirty side to the clean side of the anteroom.	Yes		4.5

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		Observation	Inspector Notes	USP Reference(s)
18.0	Does the pharmacy's facility design for maintaining (eg, recording, monitoring, and controlling) temperature and humidity (eg, HVAC) comply with USP <797> standards? ***Inspector note: Compounded preparations that are finished and stored will be addressed in the general pharmacy module. Inspector should be aware that USP cleanroom temperature recommendations may not be harmonized with USP, FDA, or manufacturer/supplier temperature requirements for drug storage.*** ***If no, go to compliance statements.***	Yes		4.2, 19.1 USP <659>
18.1	The compounding area temperature and humidity is maintained by a heating, ventilation, and air conditioning (HVAC) system. ***If inspector finds a free-standing air conditioner, humidifier, or dehumidifier within the classified area or the SCA, the inspector should answer statement as "No." Additionally, inspector should describe what they observed, where the equipment was located, and collect/submit photographs.***	Yes		4.2, 9.3.4, 19.1
18.2	The pharmacy records the temperature of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes		4.2, 9.3.4, 19.1
18.3	The pharmacy records the humidity of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of humidity recording in the notes.***	Yes		4.2, 9.3.4, 19.1

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18.4	The pharmacy maintains records of temperature and humidity that are specific to the cleanroom suite. ***Temperature and humidity for drug storage areas will be documented in the general pharmacy module.*** ***If the pharmacy only uses an SCA, inspector should answer statement as N/A.***	Yes		4.2, 9.3.4, 19.1
18.5	The pharmacy can readily retrieve temperature and humidity records. ***If the electronic monitoring system is only capable of providing text message alerts for excursions alone (eg, a report cannot be generated for ongoing temperature conditions), inspector should answer statement as "No."***	Yes		4.2, 9.3.4, 19.1
18.6	The pharmacy controls temperature and humidity to maintain appropriate working conditions if no overnight drug storage occurs and/or is following the most restrictive drug label. ***Inspector note: Per USP <797>, the cleanroom suite should be maintained at a temperature of 20°C or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb. CRT is defined as 20°C-25°C per USP <659>.***	Yes		4.2, 9.3.4, 19.1
18.7	The placement of the HVAC unit does not cause cross contamination or interfere with the functioning of the classified area. ***Inspector note: Air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open faced PEC such as a laminar airflow workbench (LAFW).***	Yes		4, 4.2

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18.8	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes		4.2, 9.3.4
18.9	Humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes		4.2, 9.3.4
19.0	Does the pharmacy store drugs in the cleanroom suite overnight and/or for long periods of time? ***Inspector note: Long periods of time is not defined as pre-compounding preparation right before compounding activities are commenced.***	No		4.2, 9.3.4, 19.1
20.0	If the pharmacy is storing drugs inside the cleanroom suite overnight and/or long periods of time, are any of the drugs stored unable to tolerate temperature excursions?	N/A		4.2, 9.3.4, 19.1
21.0	What is the current temperature of the cleanroom suite/SCA? ***Record in the Inspector Notes.***		Cleanroom #1: 65.6°F; Cleanroom #2: 65.5°F	4.2, 9.3.4, 19.1
22.0	What is the current relative humidity percentage of the cleanroom suite/SCA? ***Record in the Inspector Notes.***		Cleanroom #1: 49.1%; Cleanroom #2: 50.0%	4.2, 9.3.4, 19.1
23.0	Is the humidity maintained at less than 60% relative humidity (RH) in the compounding area to minimize risk of microbial proliferation?	Yes		4.2, 9.3.4, 19.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Infucare RX LLC dba Infucare RX
e-Profile ID: 1309782
Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Inspector Notes	USP Reference(s)
24.0	Is differential positive pressure maintained in compliance with USP <797> standards? ***Inspector note: Per USP <797>, no pressure differential is required between the SCA and the surrounding area.*** *If no, go to compliance statements.* *Inspector should view logs and current status (while observing compounding) to verify.* *If the pharmacy uses an SCA for sterile compounding environment, inspector should answer statement as N/A.*	Yes		4.2.1, 4.2.5, 5
24.1	The facility design creates room separation to allow positive pressure differentials between spaces (rooms) for movement of air from higher quality air to lower quality air. ***Inspector should review a graphic of the airflow contained in the certification report.***	Yes		4.2.1, 4.2.5, 5
24.2	The facility has a system in place to continuously monitor pressure differentials (eg, magnehelic gauge). ***Per USP, pressure differentials need to be monitored continuously, but personnel are not specifically required to visually monitor pressure during compounding activities.***	Yes		4.2.1, 4.2.5, 5
24.3	The facility has a record system to record pressure differentials on days when compounding occurs. ***Inspector note: Per USP, the quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurs.***	Yes		4.2.1, 4.2.5, 5

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24.4	The differential positive pressure between unclassified and the first space in the compounding suite is at least 0.020 inch water column. ***Inspector note: Per USP, certifiers should confirm (this is a USP recommendation) positive pressure around doorways, pass-throughs and any opening in the cleanroom suite with smoke testing (to confirm positive pressure is maintained) with initial certification of the cleanroom suite.*** ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the general pharmacy area).***	Yes		4.2.1, 4.2.5, 5
24.5	The differential positive pressure between adjacent classified areas is at least 0.020 inch water column. ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the ISO Class 7 buffer room).***	Yes		4.2.1, 4.2.5, 5
24.6	Pressure differential monitoring and quantitative results are reviewed and documented at least daily on days when compounding occurs.	Yes		4.2.1, 4.2.5, 5
25.0	Does the pharmacy have a policy in place to cease compounding when the pharmacy is unable to maintain positive pressure differentials (outside of anticipated variations due to opening and closing of doors)?	Yes		4.2.1, 4.2.5, 5
26.0	Are pressure differential monitoring procedures in place that include an alarm or alert when there is an excursion? ***Inspector note: USP <797> does not require there to be an alarm or an alert.***	No		4.2.5
27.0	Does the facility perform both sterile and nonsterile compounding?	No		4.2.1

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28.0	If the pharmacy performs nonsterile compounding and sterile compounding, are the designated areas separate and distinct from each other?	N/A		4.2.1
29.0	If PECs are placed into the same room that are used for both sterile and nonsterile compounding, is the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP <797>, PECs used for both sterile and nonsterile compounding may be placed in the same room only if the PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification.*** ***If no, go to compliance statements.*** ***If the pharmacy does not perform nonsterile compounding in the same room as sterile compounding, inspector should answer this question as N/A.***	N/A		4.2.1, 4.2.6
29.1	PECs used for nonsterile compounding are placed at least one meter away from PECs used for sterile compounding.	N/A		4.2.1
29.2	Particle-generating activity must not be performed while sterile compounding is in process.	N/A		4.2.1
* 29.3	PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification air quality during nonsterile compounding.	Yes		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
30.0	Does the pharmacy prepare Category 2 and Category 3 CSPs from nonsterile components? ***Inspector note: Category 1 CSPs can be made from nonsterile components. If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	No		4.2.1, 4.2.6
31.0	Does the pharmacy's presterilization procedures comply with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	N/A		4.2.6
31.1	Presterilization procedures, such as weighing and mixing, are completed in an ISO Class 8 or better environment (eg, anteroom or buffer room). ***Inspector note: This statement only applies for Category 2 and Category 3.***	N/A		4.2.6
31.2	Presterilization procedures, such as weighing and mixing, are performed in a single-use containment glove bag, CVE, BSC, or CACI to minimize the risk of airborne contamination. ***Inspector note: This statement only applies for Category 2 and Category 3. CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every six months.***	N/A		4.2.6

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		Observation	Inspector Notes	USP Reference(s)
	Certification and Environmental Monitoring Inspector to review past two (2) Certification reports for the SEC and all PECs.			5
32.0	Does the pharmacy ensure that each area related to CSP preparation is certified to meet the classified air quality standard appropriate for the activities conducted in that area in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***Inspector is to review current certification reports.***	Yes		5
32.1	The most recent PEC and SEC certification reports are available for review.	Yes		4.2, 5, 20
32.2	Certification of all classified areas, including PECs, is performed at least every six months.	Yes		4.2.3, 5
32.3	Certification of all classified areas, including PECs, is performed whenever a device is relocated or a major service to the facility is performed. ***Inspector note: Classified areas must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.***	Yes		5
32.4	Certification reports are reviewed by the designated person(s). ***Inspector note: If the designated person(s) review is not documented, describe how it is ensured that the review occurred.***	Yes		4.2, 5

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		Observation	Inspector Notes	USP Reference(s)
32.5	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, pharmaceutical isolators, IVLFZ, and robotic enclosures) have been certified within the last six months. ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.2.3, 5
32.6	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. ***Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.*** ***If no, describe what occurred and the pharmacy's response to total airborne particle sampling results, data evaluation, and action level (eg, pharmacy took PEC out of service, pharmacy ordered new HEPA filter, PEC was repaired and re-certified).***	Yes		4.1.1, 5.1 Table 4
32.7	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last six months. ***Inspector note: Per ISO definition, ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air under dynamic operating conditions and ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air under dynamic operating conditions.*** ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.1.1, 4.1.2, 5.1 Table 4

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		Observation	Inspector Notes	USP Reference(s)
32.8	All SECs meet ISO Class 7 air quality requirements and ISO Class 8 air quality requirements where permitted, with particle counts documented within the report. ***If no, describe what occurred and the pharmacy's response (eg, pharmacy reduced BUD, pharmacy used an alternative facility, pharmacy followed mitigation strategies, and/or disaster planning processes).***	Yes		4.1.1, 5.1 Table 4
33.0	Does the certification report received by the pharmacy have all required elements documented for the pharmacy's designated person(s) to make an informed decision related to functionality of PEC and SEC environments in compliance with USP <797> standards? ***Inspector note: It is recommended that the designated person review the certification report in its entirety.*** *If no, go to compliance statements.*	No		5, 20
33.1	The certification report includes information about the equipment used for performing each test including last calibration date (or date when next calibration is due). ***Inspector note: Per USP, "total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment" and "all impaction air samplers must be serviced and calibrated as recommended by the manufacturer."***	Yes		5.1, 6.1, 20

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		Observation	Inspector Notes	USP Reference(s)
33.2	The certification report includes the name of the certifier. ***Inspector note: Per USP <797>, a qualified certifier may have received training and education from professional organizations such as the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) and Controlled Environment Testing Association (CETA). Both organizations provide certification (Registered Certification Professional – Sterile Compounding Facilities), education, and resources.***	Yes		5
33.3	The certification report describes the "dynamic conditions" including the number of personnel in the cleanroom suite. ***Inspector note: Compounders can perform mock compounding activities and/or performing media-fill while the certifier is conducting testing. Number of personnel present in the SEC must be documented.***	Yes		5, 20
33.4	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **air volume and room air exchange rate (ACPH).** ***Inspector note: Per USP <797>, unclassified SCAs have no ACPH requirement.*** ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5 Table 6
33.5	**SEC:** All of the following ACPH required elements were documented on the certification report: the ACPH from HVAC, the ACPH contributed from the PEC, and the total ACPH. ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5

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		Observation	Inspector Notes	USP Reference(s)
33.6	**The ISO Class 8 anteroom** is certified and documented as having a minimum of 20 ACPH with at least 15 ACPH of the total air change rate coming from HVAC through HEPA filters located in the ceiling. ***If the pharmacy has an ISO Class 7 anteroom, inspector should mark as N/A.***	Yes		4.2.4, 5 Table 6
33.7	**The ISO Class 7 buffer room and ISO Class 7 anteroom (if required)** is certified and documented as having a minimum of 30 ACPH with at least 15 ACPH of the total air change rate in a room coming from the HVAC through HEPA filters located in the ceiling. ***Inspector note: If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off, except for maintenance.***	No	The certification report does not show the separate room and PEC contributions for total ACPH.	4.2.4, 5 Table 6
33.8	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **room pressure differential** in doorways between adjacent rooms.	Yes		4.2.5, 5
33.9	**SEC:** The differential pressure measured was at least 0.020 inch water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed. ***Inspector note: No pressure differential is required between the SCA and the surrounding area.***	Yes		4.2.1, 4.2.5, 5
33.10	**SEC:** All SEC HEPA filters were leak tested (to confirm **HEPA filter integrity**).	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
33.11	**SEC:** All SEC HEPA filters with leaks were repaired. ***If leaks were not repaired, describe what actions pharmacy took (eg, pharmacy implemented mitigation strategies such as reduced BUD or used alternative pharmacy location).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A		5
33.12	**PEC: (Dynamic airflow) Smoke pattern tests** are performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the CSPs. ***Inspector note: Per USP, "HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design, control, and use minimizes turbulence and creation of eddies or stagnant air in the PEC." Describe if smoke pattern testing of PEC was documented thoroughly in the report or through video.***	Yes	Airflow visualization studies using smoke were performed within the laminar flow hoods using visible smoke. The studies were recorded and noted to be under 'operational conditions'.	4.2.2, 4.2.3, 5
33.13	**PEC: Dynamic airflow smoke pattern** confirms equipment and supplies necessary for performing compounding activities in the PEC do not disrupt unidirectional airflow. ***Inspector note: Per USP, "Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location."***	Yes		4.2.2, 4.2.3, 4.5, 5, 9.1

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33.14	**PEC: Total (nonviable) particle count** testing was performed under dynamic operating conditions using calibrated electronic equipment. ***Inspector note: Per USP, "Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures...Measurements of total airborne particles in other classified areas, including the buffer room(s) and anteroom(s), should be taken at representative locations that reflect the quality of air in the room(s)."***	Yes		5, 5.1
33.15	**PEC:** All PEC HEPA filters were leak tested (to confirm **HEPA filter integrity**). ***Inspector note: The certification report for each PEC should show air velocities within the PEC.***	Yes		5
33.16	**PEC:** All PEC HEPA filters with leaks identified were repaired. ***If leaks were not repaired, describe what actions pharmacy took (example: PEC taken out of service until HEPA filter could be replaced).*** ***If no repairs were needed, inspector should answer statement as N/A.***	Yes	On the March 5, 2025 certification report conducted by Cleanroom Consulting Services, ISO 5 laminar flow hood serial number HLF000536 HEPA filter was patched and rechallenged with passing results.	5

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33.17	**PEC-IVLFZ**: Pharmacy's integrated vertical laminar flow zone (IVLFZ) meets design, functional requirements, and certification requirements under USP <797>. ***Inspector note: Per USP <797>, "Strategic location of air returns in addition to full coverage of HEPA-filters above the work surface is required. Both static and dynamic smoke studies of air returns in addition to full coverage of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (eg, with video)."*** ***If pharmacy does not use an IVLFZ, inspector should answer statement as N/A.***	N/A		4.2.3
33.18	If a **robotic enclosure is used as the PEC**, or placed within the PEC, a dynamic airflow smoke pattern test must be performed initially and at least every 6 months thereafter to ensure that: 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the direct compounding area(s). ***If pharmacy does not use a robotic enclosure, inspector should answer statement as N/A.***	N/A		4.2.3

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34.0	Was smoke testing performed in SEC to confirm all particle generating equipment (eg, computers, printers, refrigerators, PECs) do not disrupt airflow? ***Inspector note: This question will be N/A unless the pharmacy is new, has recently completed construction, or equipment has been moved within SEC since last certification.***	N/A		5
35.0	Does the pharmacy have an established environmental monitoring (eg, microbiological air and surface monitoring) program in compliance with USP <797> standards? ***Inspector note: Per USP, "The goals of a microbiological air and surface monitoring program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained."*** *If no, go to compliance statements.*	Yes		6, 6.1, 6.2
35.1	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed initially in the selected sampling sites to establish a baseline level of environmental quality for each classified area, ie, each ISO Class 5 PEC, each ISO Class 7, and ISO Class 8 room.	Yes		6, 6.1, 6.2
35.2	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in conjunction with the certification of new facilities and equipment.	Yes		6, 6.1, 6.2

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35.3	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed after any servicing of facilities or equipment.	Yes		6, 6.1, 6.2
35.4	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified problems (eg, positive growth in sterility tests of sterile compounded preparation).	Yes		6, 6.1, 6.2
35.5	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified trends (eg, repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination).	Yes		6, 6.1, 6.2
35.6	Results from the environmental monitoring program (eg, viable air and/or surface monitoring) are reviewed in response to changes that could impact the sterile compounding environment (eg, change in cleaning agents) and in conjunction with personnel data (ie, training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination. ***Inspector note: Per USP, the program is reviewed to "assess risks for contamination, potential routes of contamination, and the adequacy of cleaning and disinfecting agents and procedures. Regular review of the sampling data must be performed to detect trends and the results of the review must be documented."***	Yes		6, 6.1, 6.2, 20 Table 4, Table 7, Table 8

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35.7	The pharmacy ensures that viable air and surface sampling is performed by a trained and competent individual who is familiar with the methods and procedures for air sampling and surface testing. ***If sampling is conducted by internal personnel, inspector should verify that documented training and competencies are located in the employee file.***	Yes		6, 6.1, 6.2
35.8	Environmental monitoring program (eg, viable air and/or surface monitoring) describes/identifies corrective actions to minimize the risk of CSP contamination and that these corrective actions are documented.	Yes		6, 20
36.0	Is surface sampling performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected (to obtain a sample that is representative of the typical compounding conditions at the pharmacy)? ***Inspector note: this is a USP recommendation.***	Yes		6.1, 6.3
37.0	Does the pharmacy send out all air quality for viable airborne samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	Yes	The third party certification company sends their samples to the third party external lab Focus Laboratories of Allentown, PA. All samples collected by the pharmacy are internally incubated to USP standards.	6.2.2

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		Observation	Inspector Notes	USP Reference(s)
38.0	Does the pharmacy send out all surfaces for viable particle samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	N/A	The third party certification company sends their samples to the third party external lab Focus Laboratories of Allentown, PA. All samples collected by the pharmacy are internally incubated to USP standards.	6.3
39.0	For any samples that are sent to an external lab (third party), does the pharmacy receive a report from the third party confirming incubation parameters meet USP <797> requirements (eg, the correct temperature and the correct length of incubation time are documented in the report)? ***Inspector note: Incubation parameters are the same as seen in statements 40.6-40.7 and 41.4-41.5.*** ***This question applies for any air or surface sample sent to an external lab. If no, describe observations.***	Yes	The third party certification company sends their samples to the third party external lab Focus Laboratories of Allentown, PA. All samples collected by the pharmacy are internally incubated to USP standards.	6.2.2
40.0	Are processes for sampling and monitoring **air quality for viable airborne** particles in compliance with USP <797> standards? ***Inspector note: Per USP <797>, facilities performing any Category 3 compounding must adhere to the increased environmental monitoring requirements for all classified areas where Category 3 CSPs are compounded and increased environmental monitoring requirements apply at all times regardless of whether Category 3 CSPs are being compounded on a given day.*** ***Review six months of air sampling data to verify. If no, go to compliance statements.***	Yes		6.2, 6.2.1, 6.2.2, 6.2.3, 14.4.2 Box 5, Table 7

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Infucare RX LLC dba Infucare RX
e-Profile ID: 1309782
Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Inspector Notes	USP Reference(s)
40.1	All classified areas are sampled using a volumetric active air sampling device (impaction air sampler). ***Inspector note: This sampling must be performed during dynamic operating conditions (to obtain a sample that is representative of the typical compounding conditions at the pharmacy).***	Yes		6.1, 6.2.1
40.2	All classified areas are sampled at the **frequencies** specified by USP for volumetric active air sampling. ***Inspector note: Per USP <797>, Category 1 and Category 2 compounding frequency is every six months and Category 3 compounding frequency is monthly.*** ***For facilities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.***	Yes		6.2.1, 14.4.2
40.3	At least one cubic meter (1000 L) of air is tested using the volumetric active air sampling device from each sample location.	Yes		6.2.2 Box 5
40.4	All impaction air samplers are serviced and calibrated as recommended by the manufacturer.	Yes		6.1

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		Observation	Inspector Notes	USP Reference(s)
40.5	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a media that supports the growth of bacteria and fungi (eg, TSA), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements.***	Yes		6.2.2 Box 5
40.6	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797> (Box 5), when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C–35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C–25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.2.2 Box 5
40.7	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797> (Box 5), two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, malt extract agar [MEA] or sabouraud dextrose agar [SDA]). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.2.2 Box 6

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		Observation	Inspector Notes	USP Reference(s)
40.8	Results for all plates are recorded for each sample and did not exceed USP <797> Table 7 action levels (or internal action levels if more restrictive). **ISO Class 5: >1 cfu/m^3/device** **ISO Class 7: >10 cfu/m^3/device** **ISO Class 8: > 100 cfu/m^3/device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media separately.***	Yes		6.2.3 Table 7
40.9	For any air sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes		6.2.3
40.10	For any areas that exceed action levels, an investigation is conducted to attempt to determine cause and a corrective action plan is implemented.	Yes		6.2.3
41.0	Are processes for sampling and monitoring **surfaces for viable particles** in compliance with USP <797> standards? ***Review six months of surface sampling data to verify. If no, go to compliance statements.***	Yes		6.3

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		Observation	Inspector Notes	USP Reference(s)
41.1	**Surfaces** and pass-through chambers in the cleanroom suite and SCA are sampled for microbial contamination for each classified area. ***Inspector note: Sampling locations must include work surfaces in each classified room, the interior of each ISO Class 5 PEC, and all pass-through chambers connecting to classified areas. USP recommends samples be taken from: equipment contained within the PEC, staging or working area near the PEC, and frequently touched surfaces.***	Yes		6.3, 6.3.1
41.2	**Surfaces** within the cleanroom suite and SCA are sampled at the **frequencies** specified by USP for viable particle surface sampling. ***Inspector note: Category 1 and Category 2 CSP surface sampling frequency is monthly and Category 3 compounding is weekly, regardless of the frequency of compounding Category 3 CSPs. Additionally, surface sampling is to be performed within the PEC used to prepare Category 3 CSPs, at the end of each batch, before cleaning and disinfection occurs unless a self-enclosed robot is used. If a self-enclosed robot is used, frequency is at least once daily at the end of compounding operations.*** ***For facilities compounding any Category 3 CSPs, a surface sampling must be completed prior to assigning BUDs longer than the limits established in Table 13.***	Yes		6.3, 6.3.1, 14.4.2

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		Observation	Inspector Notes	USP Reference(s)
41.3	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a surface sampling device with a raised convex surface for sampling flat surfaces is used that contain general microbial growth media that supports the growth of bacteria and fungi (eg, TSA supplemented with additives that neutralize effects of any disinfecting agent, eg, lecithin and polysorbate 80), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements. Per USP, "sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations such as crevices, corners, and spaces between surfaces."***	Yes		6.3.2 Box 6
41.4	The pharmacy incubates all surface samples in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797>, when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C-35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C-25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.3.2 Box 6

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		Observation	Inspector Notes	USP Reference(s)
41.5	The pharmacy incubates all surface samples in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797>, two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, MEA or SDA). Media must be supplemented with neutralizing additives (eg, lecithin and polysorbate 80). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** *If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.*	N/A		6.3.2 Box 7
41.6	Results for all plates are recorded for each sample and did not exceed USP <797> Table 8 action levels (or internal action levels if more restrictive). **ISO Class 5: >3 cfu/media device** **ISO Class 7: >5 cfu/media device** **ISO Class 8: > 50 cfu/media device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately.***	Yes		6.3.3 Table 8

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		Observation	Inspector Notes	USP Reference(s)
41.7	For any surface sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes		6.3.3
41.8	For any areas that exceed action levels, an investigation is conducted to determine cause, and a corrective action plan is implemented.	Yes		6.3.3
	Compounding Personal Hygiene and Garbing			
42.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1
42.1	Compounding personnel are required to report conditions that may contaminate the sterile preparation and environment to the designated person(s). ***Inspector note: Per USP <797>, examples of conditions that have a higher risk of contaminating the CSP and sterile environment includes: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.***	Yes		3, 3.1
42.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in compounding areas before their conditions have been resolved. ***Inspector note: Per USP <797>, the designated person(s) may permit accommodations as long as the quality of the CSP and environment will not be affected.***	Yes		3, 3.1

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		Observation	Inspector Notes	USP Reference(s)
42.3	Any accommodations permitted by the designated person(s) are documented.	N/A		3.1
42.4	Food (including mints, gum, etc) and drinks are not permitted in anterooms, buffer rooms, or segregated compounding areas.	Yes		3.1
43.0	Does the pharmacy stock the necessary garb to ensure minimum garbing requirements are continuously met in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		3.3
43.1	The pharmacy stocks gowns and/or coveralls that are low-lint with sleeves that fit snugly around the wrists and an enclosed neck.	Yes		3.3
43.2	The pharmacy stocks shoe covers that are low lint.	Yes		3.3
43.3	The pharmacy stocks head covers that are low lint and cover the hair and ears.	Yes		3.3
43.4	The pharmacy stocks facial hair covers (not masks) that are low-lint. *If the pharmacy does not have personnel with beards, inspector should answer this statement as N/A.*	Yes		3.3
43.5	The pharmacy stocks masks that are low lint.	Yes		3.3
43.6	The pharmacy stocks sterile, powder-free gloves.	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
43.7	**Category 1 and Category 2:** All non-disposable garb used to prepare Category 1 and Category 2 CSPs is laundered before reuse. ***If only disposable items are used, inspector should mark as N/A.***	Yes		3.3
43.8	**Category 3 only:** The pharmacy stocks low lint face and neck coverings that ensure no skin is exposed. ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2
43.9	**Category 3 only:** The pharmacy stocks sterile, low lint outer garb (including sterile sleeves over gauntlet sleeves when a RABS is used). ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3
43.10	**Category 3 only:** All non-disposable garb used to prepare Category 3 CSPs is **laundered and resterilized** with a validated cycle before each use. ***Document whether laundering and sterilization is performed in-house or by an outside vendor.*** ***If only disposable items are used, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2

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		Observation	Inspector Notes	USP Reference(s)
	Media-Fill			
44.0	Is the media-fill testing simulation performed by the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP, "When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean-casein digest media. The simulation must capture elements that could potentially affect the sterility of the CSP."*** ***If no, go to compliance statements.***	Yes		2.3
44.1	The simulation captures factors associated with the length of the process that can pose contamination risk (eg, operator fatigue, quality of equipment).	Yes		2.3
44.2	The simulation captures number of aseptic additions or transfers.	Yes		2.3
44.3	The simulation captures number, type, and complexity of manipulations.	Yes		2.3
44.4	The simulation captures number of personnel in the buffer room or SCA.	Yes		2.3

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		Observation	Inspector Notes	USP Reference(s)
44.5	Does the facility define "the most difficult and challenging procedures" and the rationale for how they are the most challenging? ***Inspector note: Best practice is for this to be documented in an SOP. Inspectors may also find this information documented on a training/competency assessment checklist. For complex/variety of compounding practices, inspectors may find additional media fills are completed (more than what is required by the USP chapters).***	Yes	The compounding pharmacy staff perform an aseptic media fill for Category 2 CSPs and a TPN media fill every 6 months.	2.3, 20
45.0	Are the pharmacy's media-fill storage, review, and preparation processes in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		2.3
45.1	If pharmacy uses commercial sterile microbial growth media, a COA was obtained. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.2	The COA for the commercial sterile microbial growth media includes statements from the supplier that the lot of the growth media will support the growth of microorganisms. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3

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		Observation	Inspector Notes	USP Reference(s)
45.3	Storage of commercial sterile microbial growth media is in accordance with manufacturer instructions. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.4	Commercial sterile microbial growth media is stored and used before its expiration date. ***Inspector note: Media is to be inoculated by the expiration date, meaning that the test needs to be started (not that incubation needs to be completed before the expiration date).*** ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.5	Sterile-to-sterile media-fill testing microbial growth media (non-commercial) was prepared and growth promotion capability was demonstrated prior to use, following USP <71>. ***If pharmacy only uses commercial sterile microbial growth media, inspector should answer statement as N/A.***	N/A		2.3
45.6	Nonsterile starting components (commercially available nonsterile soybean-casein digest powder) are dissolved to make a 3% nonsterile solution, manipulated in a manner that simulates nonsterile-to-sterile compounding activities, with a minimum of one positive control container. ***If pharmacy does not perform sterile compounding using nonsterile ingredients, inspector should answer statement as N/A.***	N/A		Box 2

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		Observation	Inspector Notes	USP Reference(s)
	Cleaning and Disinfection			7
46.0	Is the pharmacy equipped with the necessary cleaning and disinfecting equipment and supplies that comply with USP <797> standards? *If no, go to compliance statements.*	Yes	TB1-3300 sterile, PeridoxRTU sterile, Sterile 70% IPA	7, 7.1.1, 7.1.2 <1072>
46.1	All cleaning and disinfecting supplies (eg, wipers, sponges, pads, and mop heads), with the exception of tool handles and holders, are low lint (and sterile if used within PEC).	Yes		7.1.2
46.2	Reusable cleaning tools are made of cleanable materials (no wood handles or any other porous material).	Yes		7.1.2
46.3	Reusable cleaning tools are dedicated for use in the classified areas or SCA and are not removed from these areas except for disposal.	Yes		7.1.2
46.4	The pharmacy has the appropriate cleaners **EPA-registered disinfecting agent(s)** to adequately perform cleaning and disinfection. ***Inspector note: Examples of EPA-registered disinfectants include, but are not limited to: phenolics; oxidizers, such as peroxyacetic acid and sodium hypochlorite; quaternary ammonium; and hydrogen peroxide. If the agent is EPA-registered, a registration number will be on the label. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 7, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.***	Yes		7.1.1 Box 7 <1072>

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46.5	The pharmacy has the appropriate **EPA-registered sporicidal agent(s)** to adequately perform sporicidal disinfection. ***Inspector notes: Examples of EPA-registered agents include but are not limited to: oxidizers such as peroxyacetic acid, sodium hypochlorite, and hydrogen peroxide.*** ***Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 8, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.*** ***Per USP, Inspector should check to see if agent is effective against Clostridium difficile.***	Yes		7.1.1 Box 7 <1072>
46.6	All cleaning and disinfectant agents are appropriately labeled including expiration dates. ***Inspector should verify that no expired agents are present.***	Yes		7.1.1
46.7	When used in the PEC, any cleaning and disinfecting agents that are not "ready-to-use" sterile formulations are diluted using sterile water. ***If only ready-to-use sterile formulations are used, inspector should answer statement as N/A.***	N/A		7.1.1
47.0	Does the pharmacy's documented **cleaning and disinfection** activities for surfaces in the classified areas and/or SCA comply with the **frequencies** specified in USP <797> Table 10? ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.1	All interior surfaces of the PEC are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.2	All interior surfaces of the PEC are cleaned and disinfected when surface contamination is known or suspected.	Yes		7.2 Table 10
47.3	The removable work tray inside the PEC is cleaned and disinfected on days when compounding occurs. ***If the PEC is not equipped with a removeable work tray, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.4	All equipment inside the PEC is cleaned and disinfected on days when compounding occurs.	Yes		7.2, 9.1 Table 10
47.5	All work surfaces outside of the PEC (eg, counters, work tables) are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.6	All pass-through chambers are cleaned and disinfected on days when compounding occurs. ***If the pharmacy is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.7	Floors in the buffer room, anteroom, and/or SCA are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Infucare RX LLC dba Infucare RX

e-Profile ID: 1309782

Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Inspector Notes	USP Reference(s)
47.8	Sinks used for hand hygiene are cleaned and disinfected on each day of use.	Yes		4.4, 7.2, Table 10
47.9	Walls, doors, and door frames are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.10	Storage and shelving bins are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.11	All equipment outside the PEC are cleaned and disinfected monthly. ***Inspector note: Equipment in the SEC/SCA may include, but is not limited to: carts, refrigerators, computers, barcode readers, and label printers.***	Yes		7.2 Table 10
47.12	Ceilings in the buffer room and anteroom are cleaned and disinfected monthly. ***If the pharmacy performs compounding only in a SCA, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.13	Ceilings in the SCA are required to be cleaned and disinfected only when visibly soiled and when surface contamination is suspected. ***If the pharmacy performs compounding only in a cleanroom suite, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.14	The surface of the removable work tray and the area underneath the removable work tray of the PEC is cleaned and disinfected monthly. ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.0	Does the pharmacy's documented application of **sporicidal disinfectant** on surfaces comply with the **frequencies** specified for each CSP category in USP <797> Table 10? ***Inspector note: Per USP <797>, if the pharmacy prepares any Category 3 CSPs, the cleaning requirements for Category 3 must be followed at all times regardless of whether a Category 3 CSPs is prepared on any given day. Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2, 14.4.2 Table 10
48.1	**Sporicidal disinfectant** is applied to all interior surfaces of the **PEC** at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2, Table 10
48.2	Sporicidal disinfectant is applied to equipment inside the PEC at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10
48.3	Sporicidal disinfectant is applied to work surfaces outside the PEC (eg, counters, work tables) at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, application frequency is monthly. For any Category 3 compounding, application frequency is weekly.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.4	Sporicidal disinfectant is applied to surfaces in the pass-through chambers at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.*** ***If the facility is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10
48.5	Sporicidal disinfectant is applied to the floors in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10
48.6	Sporicidal disinfectant is applied to walls, doors, and door frames at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.7	Sporicidal disinfectant is applied to storage shelving and bins at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.8	Sporicidal disinfectant is applied to equipment stored outside the PEC at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.9	Sporicidal disinfectant is applied to ceilings in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: Per USP <797>, Table 10, the application frequency is monthly for all category types. Per USP, ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is suspected. The SCA may not have an accessible ceiling.***	Yes		7.2 Table 10
48.10	Sporicidal disinfectant is applied to sinks used for hand hygiene at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		4.4, 7.2 Table 10
48.11	Sporicidal disinfectant is applied to the work surface of the removable tray in the PEC and area underneath the removable work tray at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*** ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
	Components FDA defines manufacturer... as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes the activities of relabelers, repackers, and salvagers. When not modified by "domestic" or "foreign," the term includes both domestic manufacturers and foreign manufacturers.			9
49.0	Does the pharmacy compound CSPs using active pharmaceutical ingredients (APIs) and non-API components? ***Inspector note: Per USP <797>, non-API components may include pharmaceutical excipients, sterile containers, and container closure systems. If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	N/A		9.3
50.0	Is the pharmacy's selection of active API and non-API components in compliance with USP <797> standards? ***Verify by selecting products from the shelf of different suppliers and ask to see the COAs for those products. If no, go to compliance statements. If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	N/A		9.3
50.1	**APIs**: APIs used are compliant with the criteria in the USP–NF monograph, if one exists. ***If pharmacy does not compound CSPs that have a USP monograph, inspector should answer this statement as N/A.***	N/A		9.3.1

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		Observation	Inspector Notes	USP Reference(s)
50.2	**APIs:** All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that test results for the component show that the API meets expected quality.	N/A		9.3.1
50.3	**APIs:** All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. Inspector should verify the pharmacy looks up the name of the manufacturer listed on the COA to determine if they are registered as an FDA drug establishment https://dps.fda.gov/decrs.***	N/A		9.3.1
50.4	All **non-API components** comply with the criteria in the USP–NF monograph, if one exists.	N/A		9.3.1
50.5	All **non-API components** are accompanied by documentation (eg, COA, labeling) that include the specifications and test results and shows that the component meets the specifications.	N/A		9.3.1

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		Observation	Inspector Notes	USP Reference(s)
50.6	All **non-API components** used are manufactured by an FDA-registered facility. ***Inspector note: Per USP <797>, "If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see USP <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications."***	N/A		9.3.1
51.0	Does the pharmacy have processes in place to evaluate API and non-API components upon receipt and before use in compliance with USP <797> standards? ***Inspector note: Non-API components may be defined as excipients, containers, and container closure systems.*** ***If no, go to compliance statements.*** ***If the pharmacy does not compound with API or other non-API components, inspector should answer question as N/A.***	N/A		9.3.2, 9.3.3
51.1	APIs or other components have been evaluated for use in sterile drug preparation. ***Inspector note: Per USP <797>, "Components labeled with 'not for pharmaceutical use,' 'not for injectable use,' 'not for human use' or an equivalent statement must not be used to compound for these purposes."*** ***If no, photograph and describe in the notes column. Request copies of the invoices for products with these types of labels.***	N/A		9.3.2, 9.3.3

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		Observation	Inspector Notes	USP Reference(s)
51.2	Upon receipt of each lot of a component, personnel verify the labeling and condition of each component and examine the external packaging for evidence of deterioration and other aspects of unacceptable quality (eg, outer packaging is damaged, temperature-sensing indicators show that the component has been exposed to excessive temperatures).	N/A		9.3.2, 9.3.3
51.3	Each lot of commercially available sterile, depyrogenated containers and container-closure systems are accompanied by a COA or other documentation showing conformance with established specifications for sterility and depyrogenation requirements.	N/A		9.3.1, 9.3.2, 9.3.3
51.4	The date of receipt by the pharmacy is clearly marked on each API or component package that lacks a vendor expiration date and are assigned and labeled with an expiration date not to exceed one year after receipt by the pharmacy.	N/A		9.3.2, 9.3.3
51.5	All components are reinspected before use. ***Inspector note: Per USP <797>, all packages must be inspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures are visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use.***	N/A		9.3.2, 9.3.3

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		Observation	Inspector Notes	USP Reference(s)
51.6	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	N/A		9.3.2, 9.3.3
51.7	Any other lots of that component from that vendor are examined to determine whether other lots have the same defect.	N/A		9.3.2, 9.3.3
	Equipment and Supplies			9
52.0	Is the pharmacy equipped with the appropriate supplies and equipment used for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		9, 9.1, 9.2
52.1	Supplies (eg, beakers, utensils, needles, syringes, filters, and tubing sets) that contact components are not reactive, additive, sorptive, and do not alter the quality of sterile compounded preparation. ***Inspector note: The appropriate supplies are available as applicable to the type of CSPs prepared (eg, non-PVC, silicone-free, able to withstand high heat, able to be sterilized).***	Yes		9.2
52.2	Any supplies that are in direct contact with CSPs are sterile and/or depyrogenated.	Yes		9.2
52.3	The equipment must be able to be cleaned using the required agents and tools without damaging the equipment and/or contaminating the compounded preparation. ***Inspector note: Equipment used in compounding are of suitable composition and the surfaces that contact components are not reactive or sorptive.***	Yes		9.1

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		Observation	Inspector Notes	USP Reference(s)
52.4	When nonsterile ingredients, products, components, or devices (eg, non-sterile APIs and nonsterile vials and closures) are used for compounding, the pharmacy has the appropriate equipment to sterilize the finished product. Per USP, "Injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure must be sterilized within 6 hours after completing the preparation to minimize the generation of bacterial endotoxins in CSPs." ***If the pharmacy does not perform compounding that requires sterilization, inspector should answer statement as N/A.***	N/A		9.1, 9.3.1, 10
53.0	Does the pharmacy operate and maintain records for all equipment used for compounding in accordance with manufacturer specifications and USP <797> standards? ***If no, go to compliance statements.***	Yes		9.1, 20
53.1	Automated, mechanical, or electronic equipment (monitoring equipment, autoclaves, ovens, etc) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines.	Yes		9.1, 9.3.4
53.2	Automated compounding devices (ACDs) and other similar equipment (single channel or multi-channel) are assessed for accuracy and calibrated daily, prior to initial use, and a daily record is maintained. ***Inspector note: Per USP, "The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification."***	Yes		9.1

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53.3	Incubators used for environmental and personnel monitoring are placed in a location outside of the sterile compounding area and calibrated in accordance with manufacturer's instructions. ***If the pharmacy does not incubate samples and or/media-fills in-house, inspector should answer statement as N/A.***	Yes		6.1, 6.2.2, 6.3.2
53.4	Incubators used for environmental and personnel monitoring are monitored for temperature during incubation periods either manually or by use of a continuous recording device. ***Inspector note: Incubators store media at 20˚C-25˚C and 30˚C-35˚C. If the pharmacy has more than one incubator, review records for both incubators. View incubator temperature records to verify. Evaluate the size of the incubator and volume of media it can store. If the pharmacy does not incubate samples and/or media-fills in-house, inspector should answer statement as N/A.***	Yes		6.2.2, 6.3.2 Box 5
	Compounding Personnel Observation - Inspector ***must*** observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. If the inspector is unable to view activities from a window or other observation area, it is expected they will gown/garb into compounding area. It is acceptable for pharmacy staff to perform mock compounding activities (with sterile saline or other drug) as long as all observations can be viewed.			
54.0	**Personnel Preparation Observation:** Before entering the compounding area, do compounding personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1

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54.1	All outer garments such as hats, scarves, sweaters, bandanas, vests, coats, and jackets are removed.	Yes		3.1
54.2	Makeup and/or cosmetics are removed.	Yes		3.1
54.3	All hand, wrist, and other exposed jewelry, including piercings such as earrings, lip or eyebrow piercings, etc, are removed and any jewelry that cannot be removed is covered.	Yes		3.1
54.4	Earbuds or headphones are removed.	Yes		3.1
54.5	Electronic devices that are not necessary for compounding or other required tasks are prohibited from entering the compounding areas.	Yes		3.1
54.6	Nails are kept clean and neatly trimmed.	Yes		3.1
54.7	Any nail polish, artificial nails, or extenders are removed.	Yes		3.1
54.8	If worn, eyeglasses are wiped. *If none of the pharmacy staff wear glasses, inspector should answer statement as N/A.*	Yes		3.1

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54.9	Any accommodations permitted by the designated person(s) have been documented. ***Inspector note: Per USP <797>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	N/A		3.1
55.0	**Hand Hygiene Observation:** Were compounding personnel entering the compounding area observed performing the appropriate hand washing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.2 Box 3
55.1	All personnel entering the compounding area performed hand hygiene.	Yes		3.2 Box 3
55.2	The order of hand washing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2 Box 3
55.3	Fingernails are cleaned under warm running water using a disposable nail cleaner (eg, nail pick). ***Inspector note: During observations, inspect whether nail picks are available for use when performing hand hygiene.***	Yes		3.2 Box 3
55.4	Brushes are not used for hand hygiene.	Yes		3.2 Box 3

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55.5	Hands and forearms are washed up to the elbows with soap and warm water for at least 30 seconds. ***Inspector note: Compounding personnel describe method for ensuring they have washed for 30 seconds (example: clock or timer is available near the sink).***	Yes		3.2 Box 3
55.6	Soap containers are not refilled or topped off.	Yes		3.2
55.7	Hands and forearms are completely dried up to the elbows with low-lint disposable towels or wipers.	Yes		3.2 Box 3
55.8	Hand dryers are not used for hand hygiene.	Yes		3.2 Box 3
56.0	**Garbing Observation:** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3
56.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3

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56.2	Compounding personnel entering the cleanroom suite and/or SCA adhere to the minimum garbing requirements in USP <797>. ***Inspector note: Per USP <797>, additional garbing requirements must be continuously met in the buffer room where Category 3 CSPs are prepared, regardless of whether Category 3 CSPs are compounded on a given day.***	Yes		3.3
56.3	Donning procedures are performed in an order that reduces the risk of contamination. ***Inspector note: USP recommends (not requires) the donning procedure to be performed in the anteroom.*** ***If no, inspector must describe in the notes column why a risk of contamination is a concern.***	Yes		3.3
56.4	Doffing procedures are performed in an order that reduces the risk of contamination.	Yes		3.3
56.5	The order of garbing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2, 3.3
56.6	Sterile gloves are donned in a classified room or SCA. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb and again before sterile gloves are donned, see USP <797> FAQ #97.***	Yes		3.2

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		Observation	Inspector Notes	USP Reference(s)
56.7	Skin is not exposed inside the ISO Class 5 PEC.	Yes		3.3
56.8	Garb is replaced immediately if it becomes visibly soiled or if its integrity is compromised.	Yes		3.3
56.9	**Category 1 and Category 2 only:** Upon exit of the compounding area, all garb (except for gowns) is discarded or laundered prior to reuse. ***Inspector note: Gowns (disposable and non-disposable) may be reused within the same shift by the same person only if stored appropriately.*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused, inspector should answer statement as N/A.***	Yes		3.3
56.10	**Category 1 and Category 2 only:** Gowns reused within the same shift and by the same person are maintained in a manner that prevents contamination. ***Inspector note: Per USP <797>, gowns stored for reuse must be maintained in a classified area or adjacent to or within the SCA in a manner that prevents contamination (eg, away from sinks to avoid splashing).*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused; inspector should answer statement as N/A.***	N/A	Gowns are not allowed to be reused.	3.3
57.0	List the name(s) of the CSPs observed by the inspector as part of live compounding demonstration.		Magnesium Sulfate 2 grams in sodium chloride 0.9% 500mL IVPB #8; and Ceftriaxone 2 g/20mL syringe SWFI #15	

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Infucare RX LLC dba Infucare RX

e-Profile ID: 1309782

Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Inspector Notes	USP Reference(s)
58.0	**Compounding Observation:** Are compounding personnel observed using the appropriate aseptic technique that ensures the quality of the CSP and the environment is maintained in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		1, 2.1, 2.3
58.1	All sterile compounding is performed in a PEC with ISO Class 5 conditions or better. ***If the pharmacy only performs immediate use compounding, inspector should answer this statement as N/A.***	Yes		4.1.2
58.2	**Category 2 and Category 3 only:** All PECs are placed in a cleanroom suite. ***Inspector note: Per USP, "If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA." If the pharmacy only prepares Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.1.2
58.3	Compounding personnel ascertain before use that components are of the correct identity, appropriate quality, within the expiration date, and have been stored under the proper conditions.	Yes		9.3.3

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		Observation	Inspector Notes	USP Reference(s)
58.4	All items are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA prior to being introduced into the clean side of the anteroom, placed into a pass-through chamber, and/or brought into the SCA. ***Inspector note: The wiping procedure or agents used should not compromise the packaging integrity or render the product label unreadable. Disinfectant dwell time minimums, as specified by the manufacturer, are to be followed.***	Yes		8.1
58.5	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. ***Inspector note: Per USP, "When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable."***	Yes		8.2
58.6	Aseptic processes and manipulations are performed in a manner intended to minimize the risk of contamination. ***Inspector note: Observe the compounder's technique to ensure proper aseptic technique is utilized such as: preparation occurs in the direct compounding area (DCA); the compounder does not interrupt first air during the compounding process; proper set up of equipment, supplies, and components that ensure first air is not interrupted; the compounder handles the syringe in a manner that does not introduce contaminates (touch contamination on the plunger rod); proper entry and exit of materials in ISO Class 5 PEC; and frequent sanitization of gloves.***	Yes		2.3

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		Observation	Inspector Notes	USP Reference(s)
58.7	All critical sites (eg, vial stoppers, ampule necks, and IV bag septums) are wiped with sterile 70% IPA in the PEC and allowed to dry before puncturing.	Yes		7, 8.3
58.8	Gloves are disinfected with sterile 70% IPA immediately before compounding and regularly throughout the compounding process. ***Inspector note: Per USP, best practice is to re-sanitize each time hands re-enter the PEC. This may not occur when compounder is staging the next batch.***	Yes		3.3
58.9	Gloves are regularly inspected for holes, punctures, or tears, and are replaced immediately if such defects are detected.	Yes		3.3
59.0	Do compounding personnel adhere to the USP established time limits for components after initial puncture or entry in compliance with USP <797> standards? ***Look at punctured, stored containers and confirm if puncture time or BUD is noted on the container and stored within time limits. If no, go to the compliance statements.***	Yes		15

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		Observation	Inspector Notes	USP Reference(s)
59.1	Single dose containers (entered or punctured only in an ISO Class 5 air or cleaner air) are not used beyond 12 hours after initial puncture or entry or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured single-dose vials, compounded single-dose CSPs used as components, and CSP stock solutions. The labeled storage requirements during that 12-hour period must be maintained. Additionally, per USP, "This time limit for entering or puncturing (a single-dose CSP or CSP stock solution) is not intended to restrict the BUD of the final CSP."***	Yes		15.1, 16.2
59.2	Multiple-use containers are not used for more than 28 days after initial puncture or entry, manufacturer specifications, or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured multiple-dose vials and compounded multiple-dose CSPs used as components. Multiple-dose CSPs are required to meet the criteria for antimicrobial effectiveness testing (USP <51>) and must be stored under the conditions upon which its BUD is based (eg, refrigerator or controlled room temperature).***	Yes		14.5, 15.2, 16.1
59.3	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. ***Inspector note: Ampules or vials where the container closure system has been removed must not be stored for any time period.***	Yes		15.1

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		Observation	Inspector Notes	USP Reference(s)
59.4	Pharmacy bulk package containers of sterile drugs for parenteral use are only entered or punctured in an ISO Class 5 PEC. ***Inspector note: Per USP, the pharmacy bulk package system must be used according to the manufacturer's labeling.***	Yes		15.3
60.0	**Inspect several different finished compounded sterile preparations.** Are all the finished compounded sterile preparations free from any evidence of particulates, filaments, floaters, or signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately. Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, filament or floater); number of preparations affected (eg, two of the five vials on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12
61.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes or high risk drugs or high risk populations (eg, neonates).*** ***These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product.*** ***Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage. Some checks may be done retrospectively and with the assistance of technology.***	Yes		2 Table 2, Table 3

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		Observation	Inspector Notes	USP Reference(s)
62.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and disinfection activities in compliance with USP <797> standards? ***If inspector is unable to observe cleaning activities (due to timing of compounding activities observed), inspector should interview compounder(s) to have them walk through their normal process. If this occurs, inspector should record in notes column "process only."*** ***If no, go to compliance statements.***	Yes		7
62.1	All cleaning and disinfection activities are performed by appropriately garbed personnel.	Yes		7
62.2	Cleaning and disinfection are performed on all surfaces in the classified area and SCA.	Yes		7
62.3	Cleaning is performed in the direction of clean to dirty areas.	Yes		7
62.4	Reusable cleaning tools are disinfected prior to and after each use.	Yes		7.1.2
62.5	Only sterile cleaning, disinfecting, and sporicidal agents are permitted for use in the PEC. ***Inspector note: If pharmacy utilizes non-ready to use (RTU) agents, they must be diluted with sterile water. Per USP, "Once opened, sterile cleaning and disinfecting agents and supplies (eg, closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs."***	Yes		7.1.1, 7.1.2

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		Observation	Inspector Notes	USP Reference(s)
62.6	Only sterile supplies and equipment are permitted for use in the PEC. ***Inspector notes: Non-disposable cleaning tools or handles must be properly disinfected prior to entering the PEC and prior to use.***	Yes		7.1.1, 7.1.2
62.7	Compounding personnel are using the appropriate sterile cleaning, disinfecting, and sporicidal agents within the PEC.	Yes		7.1.1
62.8	Compounding personnel are using the appropriate cleaning and disinfecting procedures and techniques within the PEC. ***Inspector note: Per USP, "All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs"; "Cleaning must be performed in the direction of clean to dirty areas"; and when 70% sterile IPA is used, it is used last and allowed to dry. There are differing opinions on the best order of cleaning. Procedure includes using a sterile low-lint wiper to all surfaces. Allow surfaces to dry completely before beginning compounding.***	Yes		7.1.2 Box 7, Box 8
62.9	The manufacturer's directions or published data for the minimum contact time is followed for each of the cleaning, disinfecting, and sporicidal disinfectant used. ***Per USP, contact times should be included in the SOP based on the agent used.***	Yes		7.1.1 Box 7, Box 8

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		Observation	Inspector Notes	USP Reference(s)
62.10	Sterile 70% IPA is applied to all surfaces in the ISO Class 5 PEC at the frequencies specified by USP during active compounding. ***Inspector note: Per USP <797>, sterile 70% IPA must be applied: immediately before initiating compounding procedures, to the work surface of the PEC at least every 30 minutes (if the compounding process takes 30 minutes or less), to the work surface of the PEC immediately after compounding (when the compounding process takes more than 30 minutes), after each batch or lot is completed, and after cleaning and disinfecting.***	Yes		7
	Sterilization and Depyrogenation			**10**
63.0	Does the pharmacy compound preparations with any nonsterile starting components? ***If the pharmacy does not compound preparations with any nonsterile starting components, inspector should answer question as N/A.***	N/A		10
64.0	Are injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure, sterilized within six hours after completing the preparation? ***If no, describe observations and collect a copy of the master formulation record, a copy of the compounding record, and a copy of the process for sterilization.*** ***If the pharmacy does not compound with nonsterile components or devices, or they only compound sterile ophthalmic and/or sterile drugs administered by inhalation, inspector should answer question as N/A.***	N/A		10

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		Observation	Inspector Notes	USP Reference(s)
65.0	**Filter Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***View compounding records for CSPs sterilized by filtration to verify.*** ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.2 USP <1229.4>
65.1	Sterilization by filtration is performed in an ISO 5 environment.	N/A		4.1.2, 10.2
65.2	Filters used have enough capacity to filter the required volumes. ***Inspector note: Per USP, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process."***	N/A		10.2
65.3	The 0.2 micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP. Inspector note: Per USP <797>, sterilizing filters must be appropriate for pharmaceutical use. Sterilizing filters labeled "for laboratory use" or equivalent must not be used. "Sterilizing filters must be certified by the manufacturer to retain at least 107 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (ie, pressure, flow rate, and volume filtered)."	N/A		10.2

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		Observation	Inspector Notes	USP Reference(s)
65.4	Confirmation of filter integrity (bubble testing) is performed and documented for each filter used with each batch sterilized by filtration. ***Inspector note: If multiple filters are required for the compounding process, each of the filters must be tested.*** ***If no, collect a copy of the master formulation record and compounding record.***	N/A		10.2
65.5	A prefiltration step is performed for any CSPs that are known to contain excessive particulate matter. ***Inspector note: The prefiltration step consists of using a filter with a larger nominal pore size (eg, 1.2 micron) or a separate filter of larger nominal pore size should be placed upstream of (ie, prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter.***	N/A		10.2
65.6	CSPs that are prepared using a filter that failed integrity tests are either discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time. ***If no, collect a copy of the master formulation record and compounding record.***	N/A		10.2
65.7	Single-use filters are only used once.	N/A		4.1.2, 10.2

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		Observation	Inspector Notes	USP Reference(s)
66.0	**Steam Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment (autoclave), documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***View documentation on compounding records for CSPs sterilized by steam to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.3 USP <1229.1>
66.1	The pharmacy has evaluated if steam sterilization would cause degradation of the drug. ***Inspector note: Per USP, compounded preparations that are degraded by moisture, pressure, or temperatures used may not be sterilized by steam heat.***	N/A		10.3
66.2	Steam supplied is free of contaminants and generated using water per manufacturer's specifications.	N/A		10.3
66.3	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.3

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66.4	Items are placed in the autoclave in a manner that allows steam to reach them without entrapment of air. ***Inspector note: The pharmacy should have the autoclave cycle validated for the size of the batch, sterilization temperature, and sterilization time to ensure the load will be sterile.***	N/A		10.3 USP <1229.1>
66.5	Sealed containers used are able to generate steam internally (eg, small amount of water in empty crimped vials).	N/A		10.3
66.6	The appropriate biological indicators (USP <1229>) are used to verify the effectiveness of each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent; see Biological Indicators for Sterilization USP <1229.5>), and other confirmation methods such as physicochemical indicators (see Physicochemical Integrators and Indicators for Sterilization USP <1229.9>). The date, run, and load numbers of the steam sterilizer used to sterilize a CSP is documented in the compounding record."***	N/A		10.3 USP <1229.5> USP <1229.9>

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66.7	All items are directly exposed to steam under adequate pressure for the length of time necessary as determined by use of appropriate biological indicators to render the items sterile. ***Inspector note: Per USP <797>, the duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period (an example provided in the chapter is 20-60 minutes at 121°C saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized).*** ***Any parameters for the autoclave must be set through validation.***	N/A		10.3 USP <1229.1>
66.8	A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (eg, deviations in temperature or pressure) and results documented on the CR.	N/A		10.3, 20
67.0	**Dry Heat Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity. USP <1229.8> also applies.*** ***View documentation on compounding records for CSPs sterilized by dry heat to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.4 USP <1229.8>

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		Observation	Inspector Notes	USP Reference(s)
67.1	The pharmacy has the appropriate dry heat sterilization equipment. ***Inspector note: Dry heat sterilization is usually performed in an oven designed for sterilization at 160°C or higher. The dry heat oven should be able to get to the appropriate temperature and pressure, for example, not be a toaster oven.***	N/A		10.4
67.2	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.4
67.3	During sterilization, sufficient space is left between materials to allow for circulation of hot air.	N/A		10.4
67.4	CSPs and other items are exposed to dry heat for the length of time necessary for all items to reach sterilizing temperature of 160°C or higher. ***Inspector note: Per USP <797>, if lower temperatures are used, they are validated by biological indicators (see USP <1229.8>, Validation of Dry Heat Sterilization, Biological Indicators). The calibrated oven must be equipped with temperature controls and a timer.***	N/A		10.4

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67.5	The appropriate biological indicators are used to verify the effectiveness each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of dry heat sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus atrophaeus (ATCC 9372; see Biological Indicators for Sterilization USP <1229.5>) and other confirmation methods (e.g., temperature-sensing devices). The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR."***	N/A		10.4 USP <1229.5>
67.6	A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (eg, deviations in temperature or exposure time) and results documented on the CR.	N/A		10.4, 20
68.0	**Dry Heat Depyrogenation:** Is the appropriate depyrogenation method used and documented in compliance with USP <797> standards? ***View documentation records of items depyrogenated to confirm.*** ***If the pharmacy does not use this method, inspector should answer question as N/A.***	N/A		10.1 USP <1228.1>
68.1	Glassware, metal, and other thermostable containers are exposed to dry heat for the length of time necessary for all items to be rendered pyrogen free.	N/A		10.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Infucare RX LLC dba Infucare RX
e-Profile ID: 1309782
Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Inspector Notes	USP Reference(s)
68.2	The effectiveness of the dry heat depyrogenation cycle is established and documented. ***Inspector note: Per USP <797>, this must be done initially, re-established any time there are changes made to the cycle (eg, load conditions, duration, temperature), and verified at least annually by using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥ 3-log reduction in endotoxins (see Bacterial Endotoxins Test USP <85>). The verification must be documented.***	N/A		10.1 USP <1228.1> USP <85>
68.3	Items that are not thermostable are depyrogenated by multiple rinses with sterile, nonpyrogenic water (eg, sterile water for injection or sterile water for irrigation) and then thoroughly drained or dried immediately before use in compounding. ***Inspector note: USP <1228.4> Depyrogenation by Rinsing also applies.***	N/A		10.1 USP <1228.4>
	Master Formulation and Compounding Records **Inspector should review a minimum of five (5) master formulation records and five (5) compounding records.**			**11**
69.0	Are **Master Formulation Records (MFRs)** created and maintained in compliance with USP <797> standards? ***If no, go to the compliance statements.***	No		11.1
69.1	The pharmacy creates and maintains MFRs for CSPs that are prepared for more than one patient.	Yes		11.1, 20
69.2	MFR changes and alterations are approved and documented according to the pharmacy's SOPs.	Yes		11.1

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		Observation	Inspector Notes	USP Reference(s)
69.3	The pharmacy creates and maintains MFRs for CSPs that are prepared from nonsterile ingredients.	Yes		11.1, 20
69.4	The MFR includes the name, strength or activity, and dosage form of the sterile compounded preparation.	Yes		11.1, 20
69.5	The MFR includes the identities and amounts of all ingredients.	Yes		11.1, 20
69.6	The MFR includes the type and size of container closure.	Yes		11.1, 20
69.7	The MFR includes complete instructions for preparing the sterile compounded preparation, including equipment, supplies, a description of the compounding steps, and any special precautions.	Yes		11.1, 20
69.8	The MFR includes a physical description of the final CSP.	No	The integrated MFR to CR does not have a physical description for the compounding personnel to review.	11.1, 20
69.9	The MFR includes the BUD and storage requirements.	Yes		11.1, 14.2, 20
69.10	The MFR includes the reference source to support the stability of the CSP.	No	References for BUDs on MFRs were inconsistently documented.	11.1, 20
69.11	The MFR includes quality control procedures (eg, pH testing, filter integrity testing).	Yes		11.1, 20

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		Observation	Inspector Notes	USP Reference(s)
69.12	The MFR includes other information as needed to describe the compounding process and ensure repeatability (eg, adjusting pH and tonicity, sterilization method).	Yes		11.1, 20
69.13	The MFR includes all required release tests, and if applicable, sterility test methods, process, number and endotoxin test and limits.	Yes		11.1, 12, 20
70.0	Are **Compounding Records (CR)** created and maintained in compliance with USP <797> standards? ***Inspector note: Per USP, a prescription or medication order or label may serve as the CR. Also, a copy of the MFR can be made that contains spaces for recording the information needed to complete the CR (eg, both the MFR and CR are on the same document/form). A CR may be kept electronically, if readily retrievable, as long as it contains all required information.*** *If no, go to compliance statements.*	No		11.2 Box 10
70.1	The pharmacy creates and maintains CRs for all for immediate-use CSPs prepared for more than one patient. ***Inspector note: if pharmacy does not prepare any CSPs for immediate-use, inspector should answer compliance statement as N/A.***	N/A		11.2 Box 10
70.2	The pharmacy creates and maintains CRs for all Category 1, Category 2, and Category 3 CSPs.	Yes		11.2 Box 10
70.3	The CR includes the name, strength or activity, dosage form of the CSP, and (if applicable) the MFR reference.	Yes		11.2 Box 10

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		Observation	Inspector Notes	USP Reference(s)
70.4	The CR includes the date and time of preparation.	Yes		11.2 Box 10
70.5	The CR includes an assigned internal identification number (eg, prescription, order, or lot number).	Yes		11.2 Box 10
70.6	The CR includes the identity of the individual(s) involved in the compounding process.	Yes		11.2 Box 10
70.7	The CR includes identity of the individual(s) verifying the final CSP.	Yes		11.2 Box 10
70.8	The CR includes the name of each component.	Yes		11.2 Box 10
70.9	The CR includes the vendor/manufacturer, lot number, and expiration date for each component. ***Inspector note: this is required for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).***	Yes		11.2 Box 10
70.10	The CR includes the weight or volume of each component.	Yes		11.2 Box 10
70.11	The CR includes the strength or activity of each component.	Yes		11.2 Box 10
70.12	The CR includes the total quantity compounded.	Yes		11.2 Box 10
70.13	The CR includes the final yield (eg, quantity, containers, number of units).	Yes		11.2 Box 10

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		Observation	Inspector Notes	USP Reference(s)
70.14	The CR includes the assigned BUD and storage requirements.	Yes		11.2 Box 10
70.15	The CR includes results of quality-control procedures (eg, visual inspection, filter integrity testing, pH testing).	No	The CR for ceftriaxone and daptomycin do not have visual inspection criteria.	11.2, 12 Box 10
70.16	The CR includes calculations made to determine and verify quantities and/or concentrations of components. ***Inspector note: Per USP, "If applicable, the CR must also include...Calculations."***	Yes		11.2 Box 10
70.17	The CR is verified by the pharmacist for appropriateness and accuracy with in-process and final checks. ***Inspector note: "Documentation must comply with all laws and regulations of the applicable regulatory jurisdiction."***	Yes		2, 11.2, 12.1, 13, 20 Box 10
71.0	Are the pharmacy's labels for CSPs in compliance with USP <797> standards and display all required information? ***If no, go to compliance statements.***	Yes		13 USP <7>
71.1	Information on the label is prominently and legibly displayed. ***Inspector note: Definition of labeling includes other accompanying materials with the CSP, which includes, "written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed." The shipping container is not included in the definition of the "label."***	Yes		13

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		Observation	Inspector Notes	USP Reference(s)
71.2	Labeling meets any state or federal regulatory requirements.	Yes		13
71.3	Labeling on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		13
71.4	Labeling on the immediate container includes the active ingredients and their amounts, activity, or concentration.	Yes		13
71.5	Labeling on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		13
71.6	Labeling on the immediate container includes the BUD. Per USP, "Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded (ie, the BUD)."	Yes		13, 14.1
71.7	The compounded CSP label does not use the term "expiration date" or equivalent.	Yes		13, 14.1 USP <7>
71.8	Labeling on the immediate container includes the dosage form.	Yes		13
71.9	Labeling on the immediate container includes the total amount or volume when not obvious from the container.	Yes		13

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		Observation	Inspector Notes	USP Reference(s)
71.10	Labeling on the immediate container states that the CSP is a single-dose container (when space permits).	Yes		13
71.11	Labeling on the immediate container states that the CSP is a multiple-dose container.	Yes		13
71.12	Labeling includes the route of administration, as applicable.	Yes		13
71.13	Labeling includes any special handling instructions and/or warning statements, as applicable.	Yes		13
71.14	Labeling includes the compounding facility name and contact information if the CSP is to be sent outside of the facility or health care system in which it was compounded.	Yes		13
72.0	Does the label contain information identifying the CSP is a compounded preparation? ***Inspector note: Per USP, this is a recommendation/should.***	Yes		13 USP <7>
	Establishing BUDs			**14**
73.0	**Category 1 and Category 2 CSPs:** Does the pharmacy assign BUDs for Category 1 and Category 2 CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		14, 14.1, 14.2
73.1	The assigned BUD does not exceed the shortest expiration date of any of the individual commercially available starting components.	Yes		14.3

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		Observation	Inspector Notes	USP Reference(s)
73.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and that its packaging maintains its integrity for the duration of the assigned BUD.	Yes		14.3
73.3	**Category 1 CSPs:** BUDs for **Category 1 CSPs** prepared in an SCA do not exceed the limits established in Table 12. ***Inspector note: Per USP <797> Table 12, BUD maximum limits for Category 1 CSPs are defined as 12 hours at controlled room temperature (CRT 20°C-25°C) or 24 hours refrigerated (2°C-8°C).*** ***If no Category 1 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, Table 12
73.4	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs using one or more nonsterile starting components are defined as: one day CRT; four days refrigerator; and 45 days freezer. Aseptically processed Category 2 CSPs using only sterile starting components are defined as: four days CRT; 10 days refrigerator; and 45 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, Table 13

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		Observation	Inspector Notes	USP Reference(s)
73.5	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs, that were steriiity tested and passed, regardless of starting components being sterile or nonsteriie, are defined as: 30 days CRT; 45 days refrigerator; and 60 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, 14.2.1, 14.2.3, Table 13
73.6	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to probability of nonsterile unit (PNSU) of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 14 days CRT; 28 days refrigerator; and 45 days freezer.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, 14.2.1, Table 13

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		Observation	Inspector Notes	USP Reference(s)
73.7	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to PNSU of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 45 days CRT; 60 days refrigerator; and 90 days freezer. Endotoxin testing is required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing. USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components are also endotoxin tested.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, 14.2.1, 14.2.3, Table 13
74.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest beyond use date of any individual compounded components? ***Inspector note: Per USP, "the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (eg, pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted." Other examples where this may occur: formula within a formula, preservative-free compounded component used in a preserved final CSP, "in-use" times for pharmacy bulk packages, and cyclosporine ophthalmic stock solution.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		14.3

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		Observation	Inspector Notes	USP Reference(s)
75.0	Are BUDs for **Category 3 CSPs** assigned in compliance with all conditions outlined in USP <797> standards and do not exceed the maximum limits established in Table 14? ***Inspector note: If all of the conditions described for Category 3 CSPs are not met, the applicable BUD must not exceed the established maximum limits in Table 13 for Category 2 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer question as N/A.***	N/A		14.3, 14.4., 14.4.1, 14.4.2, 14.4.3, 14.4.4, Table 14
75.1	The assigned BUD does not exceed the shortest expiration date of any of the individual starting components.	N/A		14.3 Table 14
75.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and its packaging maintains its integrity for the duration of the assigned BUD.	N/A		14.3 Table 15
75.3	BUDs for **Category 3 CSPs** do not exceed the maximum limits for aseptically processed (eg, filtered) established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits for aseptically processed Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 60 days CRT; 90 days refrigerator; and 120 days frozen.***	N/A		14.4.1 Table 14

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		Observation	Inspector Notes	USP Reference(s)
75.4	BUDs for **Category 3 CSPs** do not exceed the maximum limits for terminally sterilized established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits terminally sterilized Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 90 days CRT; 120 days refrigerator; and 180 days frozen.***	N/A		14.4.1 Table 14
75.5	**Category 3 CSPs** are supported by stability data obtained using methods described in USP <1225> or a validated noninferior stability-indicating analytical method. ***Inspector note: Per USP <797>, Category 3 CSPs must prepared according to the EXACT formulation (API and other ingredients of identical grade and procedures) from which the stability data is derived. Category 3 CSPs must be packaged and stored in container closure of the same materials of composition as used in study and the facility must have documentation of the stability study.*** ***View records to verify the preparation exactly matches the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.***	N/A		14.4.3 Table 14 USP <1225>
75.6	**Category 3 CSPs** undergo sterility testing. ***Inspector note: Sterility testing is performed on all Category 3 CSPs.***	N/A		14.4.4 Table 14 USP <71>

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		Observation	Inspector Notes	USP Reference(s)
75.7	**Category 3 CSPs** undergo bacterial endotoxin testing. ***If all compounds prepared are ophthalmics and/or drug administered by inhalation, bacterial endotoxin is not required, inspector should answer statement as N/A.***	N/A		12.3, 14.4.4 Table 14 USP <85>
75.8	**Category 3 CSPs** undergo particulate matter testing. ***Inspector note: If the Category 3 CSP is an injection or an ophthalmic solution, particulate matter testing is also conducted once per formulation with acceptable results (See USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions).***	N/A		14.4.3 Table 14 USP <788>, <789>
75.9	**Category 3 CSPs** undergo an evaluation for the container closure system. ***Inspector note: The container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD (see USP <1207> Package Integrity Evaluation— Sterile Products). Evaluation must be done once for each formulation and for each container closure system in which it will be packaged.***	N/A		14.4.3 Table 14 USP <1207>
76.0	Are **multiple-dose CSPs prepared** in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not prepare multiple-dose CSPs, inspector should answer question as N/A.***	N/A		14.5
76.1	Multiple-dose CSPs are prepared as a Category 2 or Category 3 CSP only.	N/A		14.5

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		Observation	Inspector Notes	USP Reference(s)
76.2	When preservatives are used, they are appropriate for the CSP formulation and the route of administration. Inspector note: Per USP <797>, "The preservative must not be inactivated by any ingredients in the CSP, and some preservatives are not always appropriate for the patient (eg, neonates) or route of administration (eg, intrathecal or ophthalmic injection)."	N/A		14.5
76.3	Aqueous multiple-dose CSPs pass antimicrobial effectiveness testing in accordance with USP <51>. ***Inspector note: Per USP <797>, a test can be one test done for each formulation in the particular container-closure system in which it will be packaged, or test results provided by an FDA-registered facility or in appropriate peer-reviewed literature,, provided the sterile compounded preparation formulation and container-closure system used are exactly the same as those tested, unless a bracketing study is performed. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.*** ***Additionally, multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs prepared as a Category 2 or Category 3 CSP are not required to pass antimicrobial effectiveness testing if the preparation is: For use by a single patient, labeled (in the label or labeling) to indicate that, once opened, it must be discarded after 24 hours when stored at controlled room temperature and/or that, once opened, it must be discarded after 72 hours when stored under refrigeration.***	N/A		14.5 USP <51>

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		Observation	Inspector Notes	USP Reference(s)
76.4	Multiple-dose CSPs are labeled to indicate the beyond use date of the CSP once it is opened or punctured. ***Inspector note: Labeling on the CSP should indicate that once the CSP container is entered or punctured, it must not be used for longer than the assigned BUD or 28 days (if supported by antimicrobial effectiveness testing results), whichever is shorter.*** ***Inspector should review the CR or final compounded preparation to verify the label contains this information.***	N/A		14.5
76.5	Container-closure systems used are evaluated for maintaining integrity (USP <1207>) for each formulation and fill volume. ***Inspector note: Per USP <797>, the container closure integrity test needs to be conducted only once on each formulation and on fill volume in the particular container closure system in which the multiple-dose CSP will be packaged.***	N/A		14.5 USP <1207>
	Finished Preparation Release Checks and Tests			**12**
77.0	Are all CSPs visually inspected for quality prior to release or dispensing in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		12.1
77.1	The CSP label is visually inspected to confirm that the CSP and its labeling match the prescription or medication order.	Yes		12.1
77.2	CSPs are visually inspected for quality characteristics such as discoloration, visible particulates, or cloudiness.	Yes		12.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Infucare RX LLC dba Infucare RX
e-Profile ID: 1309782
Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Inspector Notes	USP Reference(s)
77.3	CSPs are visually inspected to verify container closure integrity (eg, checking for leakage, cracks in the container, or improper seals).	Yes		12.1
77.4	A visual inspection is also repeated prior to release or dispense for CSPs that have been stored in the pharmacy and not released or dispensed on the day of preparation.	Yes		12.1
77.5	Any CSPs found to be of unacceptable quality (eg, observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		12.1
78.0	For any CSPs assigned beyond use dates that require sterility testing, does the pharmacy ensure that all testing is performed, evaluated, and documented in accordance with USP <71> or a validated alternative method that is noninferior to USP <71> testing and USP <797> standards? ***Inspector note: Alternative testing methods may not be accepted in all regulatory jurisdictions that the pharmacy conducts business.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare any CSPs that require sterility testing, inspector should mark as N/A.***	N/A		12.2

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Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Inspector Notes	USP Reference(s)
78.1	The required number of sterile compounded preparation units, as described in USP <71> and USP <797>, are tested. ***Inspector note: Per USP <71> Table 3, the minimum number of items to be tested for each medium is:*** ***<u>Parenterals</u>*** ***Not more than 100 containers = 10% or four containers, whichever is greater*** ***More than 100, but not more than 250 containers = 10 containers*** ***<u>Large-volume parenterals</u>*** ***2% or 10 containers, whichever is less*** ***<u>Non-parenterals (eye drops, inhalation, pellets, etc.)</u>*** ***Not more than 200 containers = 5% or two containers, whichever is greater*** ***More than 200, but not more than 250 containers = 10 containers*** ***Per USP <797>, if the number of CSPs compounded in a single batch is less than what is needed for testing as specified in USP <71> Table 3, additional units must be compounded to be able to perform testing as follows:*** ****<u>If 1-39 CSPs</u> are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number.*** ****<u>If more than 40 CSPs</u> are prepared in a single batch, the sample sizes specified in USP <71> Table 3 must be used.***	N/A		12.2, 14.2.3 USP <71>
78.2	Batch sizes of sterile CSPs do not exceed 250. ***Inspector Note: Per USP <797>, the maximum batch size for all sterile compounded preparation requiring sterility testing is limited to 250 final yield units.***	N/A		12.2, 14.2.3

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Inspection Date: 09/15/2025 & 09/16/2025

		Observation	Inspector Notes	USP Reference(s)
78.3	Pharmacy is utilizing an alternative method for sterility assurance testing (other than USP <71>). ***Inspector note: Per USP, "If an alternative method is used for sterility testing, the method must be validated (see USP <1223>) and demonstrated to be suitable for that CSP formulation."*** ***If an alternative method is used, describe the method used and how the pharmacy ensures they are compliant with state-specific regulations.***	N/A		12.2 USP <71>, <1223>
78.4	When sterility testing identifies a failure, the pharmacy has processes to investigate and identify any contributing factors. ***Inspector note: Per USP, "Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented."*** ***Additionally, some rapid sterility test methods do not allow for the identification of the recovered microorganisms. If one of these methods is used, the pharmacy is not in compliance with the chapter, as the investigation must include identification of the recovered microorganism.***	N/A		12.2

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		Observation	Inspector Notes	USP Reference(s)
79.0	For any CSPs assigned BUDs that require **bacterial endotoxin testing**, does the pharmacy ensure that all testing is performed and documented in compliance with USP <85> and USP <797> standards? ***Inspector note: Endotoxin limits reflect limits in an official monograph, or calculated as described in USP Chapter <85> for the route of administration for humans, and for animals based on weight.*** ***Although USP <797> refers to USP <85> Bacterial Endotoxins Test for calculating endotoxin limits for the appropriate route of administration, it does not address products administered epidurally or administered directly into the central nervous system. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare CSPs that require bacterial endotoxin testing, inspector should answer question as N/A.***	N/A		12.3 USP <85>
79.1	The pharmacy has an appropriate procedure for calculating/determining endotoxin limits. ***Per USP, there are endotoxin limits listed in USP product and compounded preparation monographs. The laboratory may be performing the calculation rather than the pharmacy; however, if done in house, this should be included in the pharmacy SOPs.*** ***If the dosage form does not require, inspector should answer statement as N/A.***	N/A		12.3

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		Observation	Inspector Notes	USP Reference(s)
79.2	The pharmacy collects patient weight to make bacterial endotoxin calculation for an animal patient. ***If the dosage form does not require or the pharmacy does not compound sterile preparations for animals, inspector should answer statement as N/A.***	N/A		12.3
79.3	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 2 CSPs** compounded from one or more nonsterile components that are assigned a BUD requiring sterility testing per Table 13. ***Inspector note: USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components is also endotoxin tested.***	N/A		12.3 Table 13 USP <85>
79.4	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 3 CSPs** compounded from one or more nonsterile components.	N/A		12.3 Table 13 USP <85>
79.5	Any CSPs with failed endotoxin testing are quarantined, not further released, and action is taken for any product released prior to receipt of failed test results. ***View testing records and note any products with failed results and actions taken.***	N/A		12.2, 12.3

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		Observation	Inspector Notes	USP Reference(s)
	CSP Packaging, Shipping and Transport			19
80.0	Are processes and techniques for packaging and transporting CSPs in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes	Shipping integrity test are performed at the pharmacy and is conducted two times a year; once in the summer and once in the winter.	19.1, 19.2, 19.3
80.1	The pharmacy uses the appropriate shipping containers and packaging materials (eg, coolers and light-resistant packaging) based on the product specifications.	Yes		19.2
80.2	CSPs are appropriately packaged to protect against damage, leakage, contamination, degradation, and adsorption during storage and transport. ***Inspector should look at packaging materials used to ensure cushioning to prevent breakage of glass vials and ensure that container is generally clean without non-microbial growth that would come in direct contact with CSPs.***	Yes		19.2
80.3	Specific handling instructions when applicable, are included on the exterior of the container.	Yes		19.3
80.4	The pharmacy selects transport modes that ensure CSPs are delivered properly in undamaged, sterile, and stable conditions (eg, no undue exposure to heat, cold, or light). ***Inspector note: Transport modes include pneumatic tube transport systems and should not be used if the CSP is sensitive to shaking.***	Yes		19.3

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		Observation	Inspector Notes	USP Reference(s)
	Quality Assurance and Quality Control			18
81.0	**Quality Assurance and Quality Control (QA/QC):** Does the pharmacy's SOP on quality assurance and quality control meet the requirements in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		18 USP <1163>
81.1	Description of procedures for complaint handling, adverse events, and recalls that include corrective action, investigation, reporting, and documentation requirements.	Yes		18.1, 18.2
81.2	**QA/QC Out-Of-Specification (OOS) SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the severity of the problem and the urgency for implementation and completion of the recall.	Yes		18.1
81.3	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the distribution of any affected CSP, including the date and quantity of distribution.	Yes		18.1
81.4	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to identify patients who have received the CSP.	Yes		18.1

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		Observation	Inspector Notes	USP Reference(s)
81.5	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process for the disposal and documentation of the recalled CSP.	Yes		18.1
81.6	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to investigate and document the reason for failure.	Yes		18.1
82.0	Does the pharmacy ensure that QA and QC programs are conducted in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		18, 20
82.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of: adherence to procedures; prevention and detection of errors and other quality problems; evaluation of complaints and adverse events; and appropriate investigations and corrective actions."***	Yes		18
82.2	The pharmacy's QA/QC program is reviewed at least once every 12 months by the designated person(s) and the results of the review are documented.	Yes		18

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		Observation	Inspector Notes	USP Reference(s)
82.3	The designated person(s) reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.	Yes		18.2, 20
82.4	All complaints and adverse events are thoroughly investigated. ***Inspector note: Per USP <797>, the timeframe is specified in the facility SOP. Additionally, USP states, "The investigation must consider whether the quality problem extends to other CSPs."*** ***If facility SOP permits a long investigation period, include in the inspector notes the SOP's expected time frame to complete an investigation. State may have a more aggressive time frame to complete an investigation and report quality events to the state.***	Yes		18.2, 18.3, 20
82.5	The record of each complaint is maintained by the pharmacy regardless of the source of the complaint (eg, email, telephone, or mail) and includes the minimum required information. ***Inspector note: Per USP <797>, the complaint record must contain the following information:*** ***-Name of the complainant or other unique identifier;*** ***-Date the complaint was received;*** ***-Nature of the complaint;*** ***-The response to the complaint; and*** ***-Results of any investigation and any follow-up.*** ***In addition, to the extent that the information is known, the following should be recorded:*** ***-The name and strength of the CSP and the assigned internal identification number (eg, prescription, order, or lot number).*** ***If no, inspector should document what is missing in the notes column.***	Yes		18.2, 20

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		Observation	Inspector Notes	USP Reference(s)
82.6	The pharmacy's QA/QC program includes documentation of steps necessary for completing a recall, including reporting the recall to appropriate regulatory agencies. ***Inspector note: Per USP, "The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction."***	Yes		18.1, 18.2
83.0	If a CSP is dispensed or administered **before the results of release testing are known**, does the pharmacy ensure procedures for recalls and out-of-specification notifications are conducted and documented in compliance with USP <797> standards? ***Inspector note: Per USP <797>, if a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to notify, recall, and investigate.*** ***If no, go to the compliance statements.***	N/A		18.1, 20
83.1	The pharmacy has a process in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, sterility, strength, purity, bacterial endotoxin, or other quality attributes).	N/A		18.1
83.2	The pharmacy has a process in place to recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy.	N/A		18.1
83.3	The pharmacy has a process in place to investigate if other lots are affected and recall if necessary.	N/A		18.1

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		Observation	Inspector Notes	USP Reference(s)
	Personnel Training and Evaluation - Verify records of all compounding personnel (up to 10). **Use the records tab to document records reviewed.**			2
84.0	Is the pharmacy's documented hand hygiene and garbing competency evaluations compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** *If no, refer to the records review worksheet for details.*	Yes		2.2, 20 Box 1, Table 1
85.0	Is the pharmacy's documented aseptic manipulation competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** *If no, refer to the records review worksheet for details.*	Yes		2.3, 20 Box 2, Table 1
86.0	Is the pharmacy's documented training program and ongoing competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** *If no, refer to the records review worksheet for details.*	Yes		2, 2.1, 17 Table 2, Table 3

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Sterile Compounding Personnel Records Review

Select personnel with compounding responsibilities for your records review; preferably select staff performing compounding duties at time of inspection or staff identified during CR review.
- Recommend also pulling supervising personnel file.
- Inspector can consider pulling non-compounder employee file ("Other") who cleans and stocks compounding area but who does not compound (Note: frequency of competency assessment will be defined by pharmacy SOPs).
Review five (5) personnel files and document your observations. (For applicants seeking a Class E-S Non-Resident Sterile Compounding Inspection (Texas Sampling), review a total of 10 personnel records.)
- *Note: long-term employees may not have initial training available. If this is the case, you may select an alternative file. If an alternate file is not available, document length of service of long-term employee.
Inspector Note: soybean casein digest medium and trypticase soy broth are the same media.

Inspector Instructions

1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position.
2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.
3. Select the appropriate response for each item reviewed:
-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.
-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.
-Select "Missing" if the document is not present in the file.
-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.
4. Use the notes column to document any pertinent information.

Demonstrating Knowledge and Competency of Core Skills (Section 2.1)

USP requirements:
1. Personnel who perform or oversee compounding *or support activities* must be trained in the SOPs and trained on maintaining the quality of the environment (See Table 2).
2. Compounding personnel and supervising personnel must complete training needed to demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions (See Table 2 and Table 3). This must be completed initially and every 12 months in at least the following areas:
-Hand hygiene
-Garbing
-Cleaning and disinfection
-Calculations, measuring, and mixing
-Aseptic technique
-Achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components)
-Use of equipment
-Documentation of the compounding process (eg, master formulation and compounding records)
-Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area
-Proper use of PECs
-Principles of movement of materials and personnel within the compounding area
3. Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control (PEC) must complete ongoing training as required by the facility's SOPs (See Table 3).
4. Personnel compounding only immediate-use CSPs must complete training as required by the facility's SOPs (See Table 3).
5. All training and evaluations must be documented.

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Compounding SOPs	*Initial Training and Competency in Maintaining the Quality of the Environment	*Initial Training and Competency in Sterile Compounding Principles and Practices	Ongoing Training and Competency in Sterile Compounding Principles and Practices	Notes
				Compounders and Supervising Personnel: Initially and at least every 12 months Other Personnel (examples: persons who do not compound but clean/disinfect and restock or who perform in-process checks; persons who only compound immediate use): Initially and as defined by pharmacy SOPs				
#1	Pharmacist	Designated Person	Category 2 only	Yes	Yes	Yes	Yes	

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#2	Pharmacy Technician	Designated Person	Category 2 only	Yes	Yes	Yes	Yes	
#3	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	
#4	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	
#5	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	
#6								
#7								
#8								
#9								
#10								

Inspector Instructions

1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position.
2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.
3. Select the appropriate response for each item reviewed.
-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.
-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.
-Select "Missing" if the document is not present in the file.
-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.
4. Use the notes column to document any pertinent information.

Hand Hygiene and Garbing Competency Evaluation (Section 2.2)

USP requirements:
1. The garbing and hand hygiene competency evaluation consists of a visual observation and gloved fingertip and thumb sampling (GFT) of both hands.
2. The initial competency evaluation consists of three (3) separate and complete hand hygiene observation, followed by a full garbing procedure and a GFT after garbing. The initial three (3) successful completions must be in succession—failure of any of the three (3) initial garbing competency evaluations requires repeat testing until personnel successfully complete three (3) evaluations in a row.
3. The pharmacy uses a microbiological growth media device (eg, plates, paddles, or slides) containing general microbial growth agar (eg, trypticase soy agar [TSA]) supplemented with neutralizing additives (eg, lecithin and polysorbate 80) that supports both bacterial and fungal growth.
4. The media device is incubated at 30°C-35°C for no less than 48h and then at 20°C-25°C for no less than an additional five days.
5. Failure is indicated by visual observation of improper hand hygiene and garbing procedures and/or GFT results that exceed the defined action levels. Action level after garbing: >0 cfu/total from both hands.
6. Documentation includes, at minimum:
-Name of the person evaluated
-Evaluation date and time
-Media and components used including manufacturer, expiration date, and lot number
-Starting temperature for each interval of incubation
-Dates of incubation
-Results (the number of cfu per hand must be recorded; microbial identification of the cfu is not required by the chapter for GFT)
-Results of the evaluation and any corrective actions
-Name of the observer and personnel reading and documenting the results

Hand Hygiene and Garbing Visual Observation	*Initial GFT x 3 (Post hand washing and garbing)	Subsequent GFT (Post handwashing and garbing)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes

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Employee Record #	Employee Title	Personnel Function	CSP Category Type	Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially at least every 3 months Supervising Personnel: Initially and at least every 12 months				
#1	Pharmacist	Designated Person	Category 2 only	Yes	Yes	Yes	N/A	
#2	Pharmacy Technician	Designated Person	Category 2 only	Yes	Yes	Yes	N/A	
#3	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	N/A	
#4	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	N/A	
#5	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	N/A	
#6								
#7								
#8								
#9								
#10								

Inspector Instructions

1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position.
2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.
3. Select the appropriate response for each item reviewed.
-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.
-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.
-Select "Missing" if the document is not present in the file.
-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.
4. Use the notes column to document any pertinent information.
5. Document in notes if initial aseptic manipulation competencies are present in files (*unless long-term employee).

Aseptic Manipulation Competency (Section 2.3)

USP requirements:
1. Media-fill testing procedures simulate the most difficult compounding procedures encountered by personnel.
2. The pharmacy conducts media-fill testing as described in Box 2.
3. The final containers are incubated at 20°C-25°C and 30°C-35°C for a minimum of seven days at each temperature band.
4. Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container closure unit(s) on or before 14 days.
5. Immediately following the media-fill test, GFT is performed on both hands and inside of an ISO Class 5 PEC. Failure is indicated by visual observation of GFT results that exceed defined action levels. Action level after media-fill testing: >3 cfu/total from both hands.
6. Immediately following the GFT, a surface sample of the direct compounding area inside the PEC is performed in accordance with USP standards for surface sample monitoring and action levels. Action level ISO Class 5: >3 cfu/media device.
7. Failure in the media fill, GFT, or surface sampling constitutes an overall failure of the aseptic manipulation competency.
8. Documentation includes, at minimum:
-Name of the person evaluated
-Evaluation date and time
-Media and components used including manufacturer, expiration date, and lot number
-Starting temperature for each interval of incubation
-Dates of incubation
-Results (for GFT, the number of cfu per hand must be recorded and for surface samples, the number of cfu per sample must be recorded. Note: microbial identification of the cfu is not required for media-fill testing)
-Results of the evaluation and any corrective actions
-Name of the observer and personnel reading and documenting the results

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				Aseptic Manipulation Visual Observation	Media-fill	GFT (post media-fill)	Surface Sampling (post media-fill)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
Employee Record #	Employee Title	Personnel Function	CSP Category Type	Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially and at least every 3 months Supervising Personnel: Initially and at least every 12 months					
#1	Pharmacist	Designated Person	Category 2 only	Yes	Yes	Yes	Yes	N/A	
#2	Pharmacy Technician	Designated Person	Category 2 only	Yes	Yes	Yes	Yes	N/A	
#3	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	N/A	
#4	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	N/A	
#5	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	N/A	
#6									
#7									
#8									
#9									
#10									

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GLOSSARY USP <797>
ACD: Automated compounding device.
ACPH: Air changes per hour.
Active pharmaceutical ingredient (API): Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as *Bulk drug substance*. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added substance: An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms *inactive ingredient, excipient, and pharmaceutical ingredient.*
Administration: The direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise providing a sterile product or preparation in its final form.
Airlock: A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas (generally with different air cleanliness standards). The intent of an airlock is to prevent ingress of particulate matter and microbial contamination from a lesser-controlled area.
Alcohol-based hand rub: An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Allergenic extract compounding area (AECA): A designated space, area, or room that is not required to be classified, with a visible perimeter that is suitable for preparation of allergenic extract prescription sets.
Allergenic extract prescription set: Combinations of licensed allergenic extracts that would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved BLAs for the licensed biological products.
Allergenic extract: A biological substance used for the diagnosis and/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy.
Anteroom: An ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The anteroom is the transition room between the unclassified area of the facility and the buffer room.
Aseptic processing: A method by which separate, sterile components (eg, drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (eg, by membrane filtration or by autoclave).

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GLOSSARY USP <797>
Aseptic technique: A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.
Assigned trainer: One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CSPs.
Batch: More than one CSP prepared as described in the MFR in a single, discrete process, and expected to have uniform character and quality, within specified limits.
Beyond-use date (BUD): The date, or the hour and date, after which a CSP must not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
Biological safety cabinet (BSC), Class II: A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare a CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.
Biological safety cabinet (BSC): A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
BLA: Biological license application.
Blood components: Any therapeutic constituent of blood separated by physical or mechanical means (eg, white cells, red cells, platelets, plasma, serum). It is not intended to include plasma-derived products (eg, albumin, coagulation factors, immunoglobulins) manufactured under an approved BLA or equivalent.
BMBL: Biosafety in Microbiological and Biomedical Laboratories.
Buffer room: An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.
Bulk drug substance: See the entry for *Active pharmaceutical ingredient*.
Category 1 CSP: A CSP that is assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in this chapter.
Category 2 CSP: A CSP that may be assigned a BUD of greater than 12 hours at controlled room temperature or greater than 24 hours refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in this chapter.

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GLOSSARY USP<797>
Category 3 CSP: A CSP that may be assigned a BUD exceeding the limits in *Table 13* for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter.
CDC: Centers for Disease Control and Prevention.
Certificate of analysis (COA): A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
CFU: Colony-forming units.
Classified area: An area that maintains an air quality classification based on the ISO standards required in this chapter (see also the definition for *ISO class).*
Cleaning agent: An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Cleaning: The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleanroom suite: A classified area that consists of both an anteroom and buffer room.
Component: Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.
Compounded sterile preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.
Compounded stock solution: A sterile mixture of components that is used to compound additional CSPs.
Compounding area: The area where compounding is occurring (ie, a cleanroom suite, inside the perimeter of the SCA, or AECA).
Compounding aseptic containment isolator (CACI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for the compounding of sterile HDs.
Compounding aseptic isolator (CAI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile non-HDs.

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GLOSSARY USP <797>
Compounding record (CR): Documents the compounding of each CSP.
Compounding: The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation.
Container closure system: Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection.
Containment glove bag: A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE): A non-ISO classified full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.
Conventionally manufactured product: A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Critical site: A location that includes any component or fluid pathway surfaces (eg, vial septa, injection ports, and beakers) or openings (eg, opened ampules and needle hubs) that are exposed and at risk of direct contact with air (eg, ambient room or HEPA filtered), moisture (eg, oral and mucosal secretions), or touch contamination.
Designated person(s): One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CSPs.
Direct compounding area (DCA): A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
Disinfectant: A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that also are effective against bacterial and fungal spores.
Dynamic airflow smoke pattern test: A PEC test in which a visible source of smoke, which is neutrally buoyant, is used to observe air patterns within the unidirectional space (i.e., the DCA) under dynamic operating conditions (see the entry for *Dynamic operating conditions).* This test is not appropriate for ISO Class 7 or ISO Class 8 cleanrooms that do not have unidirectional airflow (see the entry for *Visual smoke study).*
Dynamic operating conditions: Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).

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GLOSSARY USP<797>
ECV: Endotoxin challenge vial.
EPA: US Environmental Protection Agency.
Excipient: See the entry for *Added substance.*
FDA: US Food and Drug Administration.
Filter integrity test: A test (eg, bubble point test) of the integrity of a sterilizing-grade filter performed after the filtration process to detect whether the integrity of the filter has been compromised.
Final yield: The total number of containers prepared at the end of the compounding process prior to release testing.
First air: The air exiting the HEPA filter in a unidirectional air stream.
Formulation: The specific qualitative and quantitative composition of the final CSP.
Garb: Items such as gloves, garments (eg, gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle shedding from personnel and minimize the risk of contamination of CSP(s).
GFT: Gloved fingertip and thumb testing.
Hazardous drug (HD): Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.
High-efficiency particulate air (HEPA) filtration: Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.
HVAC: Heating, ventilation, and air conditioning.
Integrated vertical laminar flow zone (IVLFZ): A designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room. In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the worktables and by effective placement of air returns.
IPA: Isopropyl alcohol.

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GLOSSARY USP <797>
ISO class: An air-quality classification from the International Organization for Standardization.
ISO: International Organization for Standardization.
Label: The part of the labeling on the immediate container.
Labeling: All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except any outer shipping container.
Laminar airflow system (LAFS): A device or zone within a buffer room that provides an ISO Class 5 or better air quality environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow.
Laminar airflow workbench (LAFW): A device that is a type of LAFS that provides an ISO Class 5 or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.
Line of demarcation: A visible line on the floor that separates the clean and dirty sides of the anteroom.
Low-lint wiper: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from or easily removed from the wiper material in a dry condition.
Master formulation record (MFR): A detailed record of procedures that describes how the CSP is to be prepared.
MEA: Malt extract agar.
Media-fill test: A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.
Monograph: A quality documentary standard within *USP–NF* that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Multiple-dose container: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed to contain more than one dose of the sterile product. A multiple-dose container is usually required to meet the antimicrobial effectiveness testing criteria. See <659>Injection Packaging Systems, Multiple-dose container.

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GLOSSARY USP<797>
One-step disinfectant cleaner: A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.
Oversight: The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available for consultation if and when needed, even if not physically present.
Pass-through chamber: An enclosure with sealed doors on both sides that should be interlocked. The pass-through chamber is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.
Perimeter: A visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA.
Pharmaceutical isolator: An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. [Note—A CAI or CACI is not a pharmaceutical isolator.]
Pharmacy bulk package: A conventionally manufactured sterile product for parenteral use that contains many single doses intended for use in a pharmacy admixture program. A pharmacy bulk package may either be used to prepare admixtures for infusion or, through a sterile transfer device, for filling sterile containers. See <659>*Injection Packaging Systems, Pharmacy bulk package.*
Positive-pressure room: A room that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the room.
PPE: Personal protective equipment.
Preservative: A substance added to inhibit microbial growth.
Primary engineering control (PEC): A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
Probability of a nonsterile unit (PNSU): The probability of an item being nonsterile after it has been exposed to a verified sterilization process. A PNSU value can only be applied to terminal sterilization. [Note—This is also called the sterility assurance level (SAL).]
Pyrogen: A substance that induces a febrile reaction in a patient.
Quality assurance (QA): A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

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GLOSSARY USP <797>
Quality control (QC): The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.
Reconstitution: The process of adding a diluent to a conventionally manufactured product to prepare a sterile solution or suspension.
Release inspection and testing: Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Repackaging: The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation.
Restricted-access barrier system (RABS): An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.
SDA: Sabouraud dextrose agar.
Secondary engineering control (SEC): The area where the PEC is placed (eg, a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
Segregated compounding area (SCA): A designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only.
Single-dose containers: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed for use with a single patient as a single injection/infusion. A single-dose container usually does not contain a preservative. See <659> Injection Packaging Systems, Single-dose container.
SOP: Standard operating procedure.
Specification: The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.
Sporicidal disinfectant: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.

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GLOSSARY USP <797>
Stability: The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Sterility assurance level (SAL): See the entry for *Probability of a nonsterile unit* (PNSU).
Sterility: The absence of viable microorganisms.
Sterilization by filtration: Passage of a gas or liquid through a sterilizing-grade membrane to yield filtrates that are sterile.
Sterilizing-grade filter: Filter membranes that are documented to retain 100% of a culture of 10^7 microorganisms of a strain of *Brevundimonas diminuta* per square centimeters of membrane surface under a pressure of not less than 30 psi. Such filter membranes are nominally 0.22- or 0.2-µm pore size.
Terminal sterilization: The application of a lethal process (eg, steam, dry heat, irradiation) to sealed containers for the purpose of achieving a predetermined PNSU of greater than 10−6 or a probability of less than one in one million of a nonsterile unit.
TSA: Trypticase soy agar.
Unclassified space: A space not required to meet any air cleanliness classification based on the ISO.
Unidirectional airflow: Air within a PEC moving in a single direction in a uniform manner and at sufficient velocity to sweep particles away from the DCA.
Verify: To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Visual smoke study: A test, used in ISO Class 7 and ISO Class 8 rooms that do not have unidirectional airflow, in which a visible source of smoke, which is neutrally buoyant, is used to verify an absence of stagnant airflow. This test does not need to be performed under dynamic operating conditions and is not appropriate for PECs (see the entry for *Dynamic airflow smoke pattern test*).
Workflow management system: Technology comprised of hardware and/or software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes.

4SS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	■ Service Modification*	☐ Nuclear	DEA #: [redacted]
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	■ Non-sterile Compounding
			■ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 04469		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	■ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: RxCompoundStore.com

Physical Address: 8950 SW 74th Ct Ste 101

City: Miami State: FL Zip: 33156

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 786-803-8947 Toll Free # (NAC 639.708, NRS 639.23286): 833-792-6673

Fax: 844-875-0009 Contact Email: shibu.john@rxcs.net

Website: https://rxcompoundstore.com/

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Shibu John

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 14862

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Shibu John	NV Pharmacist Registration #: 14862
Name: Hong-Chun Yeh	NV Pharmacist Registration #: 23334
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Mario Tabraue

Business Name: RxCompoundStore.com, LLC

Business Address: 8950 SW 74th Ct Ste 101

City: Miami State: FL Zip: 33156

Telephone: 786-803-8947 Email: mario.tabraue@rxcs.net

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Shibu John (title) for RxCompoundStore.ocm (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Shibu John

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

11/3/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shibu John

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

11/3/2025

Date

Board Use Only	Date Received: 11/17/25	Amount: $500 CK 1171

State of Florida
Department of State

I certify from the records of this office that RXCOMPOUNDSTORE.COM, LLC is a limited liability company organized under the laws of the State of Florida, filed on May 2, 2016, effective May 1, 2016.

The document number of this limited liability company is L16000086389.

I further certify that said limited liability company has paid all fees due this office through December 31, 2025, that its most recent annual report was filed on March 13, 2025, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Thirty-first day of October, 2025



Secretary of State

Tracking Number: 6119613158CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

RxCompoundStore.com
8950 Southwest 74th Court
Suite 101, Miami, FL 33156
PH: 786.803.8947
FAX: 844.875.0009
Email: orders@rxcompoundstore.com

Nevada State Board of Pharmacy,

11/3/2025

This letter serves to formally authorize Shibu John, holding the position of Pharmacist-in-Charge at RxCompoundSotre.com, LLC, to appear and act on behalf of RxCompoundStore.com, LLC before Nevada State Board of Pharmacy during any meeting, hearing, or proceeding where representation may be required.

He is hereby granted full authority to present information, respond to inquiries, and sign any necessary documents related to the corporation's application, compliance, or other matters under review.

Should further verification be needed, please feel free to contact the undersigned at 786-803-8947 or mario.tabraue@rxcs.net.

Sincerely,

Mario Tabraue, Owner

Rxcompoundstore.com

8950 SW 74th Court

Suite 101

Miami, FL 33156

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler RXCOMPOUNDSTORE.COM

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 8950 SW 74TH COURT, SUITE #101

City MIAMI State FL Zip 33156

Mailing Address (if different from physical address) SAME AS PHYSICAL ADDRESS

City _____ State _____ Zip _____

Telephone 786-803-8947 Website RXCOMPOUNDSTORE.COM

Licensing Company Email _____

Section 2: Personal Information

First SHIBU Middle N Last JOHN

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
BISHOP MOORE COLLEGE		06/87 -06/89	
Address	City	State	Zip
KERALA STATE INDIA			
Diploma/Degree obtained, if any			
PRE-DEGREE DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
ST JOHNS PHARMACY COLLEGE / BANGALORE UNIVERSITY		06/90 -05-94	
Address	City	State	Zip
BANGALORE INDIA			
Diploma/Degree obtained, if any			
BS PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/24-CURREN	[redacted]			
06/23- 11/24				
06/19 - 06/23				
06/17-06/19				
06/16-06/17				
04/08-05/16				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
RXCOMPOUNDSTORE.COM			09/23-CURRENT	
Business Address		**City**	**State**	**Zip**
8950 SW 74TH CT ,UNIT #101		MIAMI	FL	33156
Phone	**Title**		**Number of Employed Hours**	
786-803-8947	PHARMACIST		4000 HOURS	
Description of Duties				
DUR , VERIFICATION OF RXS, INVENTORY AND PURCHASE,PRODUCT VERIFICATION,COUNSELLING,MAKING COMPOUND FORMULAS				

Business Name			From - To (MM/YY – MM/YY)	
MARCO DRUGS			11/20-09/23	
Business Address		**City**	**State**	**Zip**
6420 SW 62ND AVE		MIAMI	FL	33143
Phone	**Title**		**Number of Employed Hours**	
305-665-4411	PHARMACIST		3800	
Description of Duties				
DUR , VERIFICATION OF RXS, INVENTORY AND PURCHASE,PRODUCT VERIFICATION,COUNSELLING,MAKING COMPOUND FORMULAS,IMMUNIZATION				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, SHIBU JOHN, **certify that as the designated representative for**

RXCOMPOUNDSTORE.COM,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SNJ I am at least 21 years of age;
3. SNJ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SNJ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SNJ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SNJ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SNJ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

SHIBU JOHN

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/03/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SHIBU JOHN

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/03/2025

Date

Please have this section completed in the presence of a Notary Public.

State of FLORIDA, ss. County of MIAMI-DADE

I, SHIBU JOHN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/03/2025

Date

Subscribed and Sworn to before me this 03rd day of November.

Notary Public Signature

Cindy Basso
Comm.: HH 289930
Expires: Jul. 20, 2026
Notary Public - State of Florida

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site RxCompoundStore.com

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04469

Physical Address 8950 SW 74th Ct Ste 101

City Miami State FL Zip 33156

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 786-792-6673 Website https://rxcompoundstore.com/

Licensing Company Email shubi.john@rxcs.net

Section 2: Personal Information

First Mario Middle Guillermo Last Tabraue

Alias(es, nicknames, name changes, etc.) [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✔	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✔	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Immaculate La Salle High School			08/93-06/97	
Address		City	State	Zip
3601 S Miami Ave		Miami	FL	33133
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)				
04/24-current	[redacted]			
From - To (MM/YY – MM/YY)				
04/20-03/24				
From - To (MM/YY – MM/YY)				
04/19-03/20				
From - To (MM/YY – MM/YY)				
08/18-03/19				
From - To (MM/YY – MM/YY)				
08/16-07/18				
From - To (MM/YY – MM/YY)				
02/14-07/16				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
RxCompoundStore.com LLC			06/23-current
Business Address	**City**	**State**	**Zip**
8950 SW 74th Court Ste 101	Miami	FL	33156
Phone	**Title**		
786-803-8947	Manager		

Description of Duties

Manage all pharmacy operations

Business Name			From - To (MM/YY – MM/YY)
JCR Medical Equipment Corp			12/19-03/24
Business Address	**City**	**State**	**Zip**
10650 NW 29th Terr	Doral	FL	33172
Phone	**Title**		
305-262-7004	Controller		

Description of Duties

Manage company cash flow and financing

Business Name			From - To (MM/YY – MM/YY)
Eller-ITO Stevedoring Company, LLC			09/01-06/23
Business Address	**City**	**State**	**Zip**
1007 N America Wy Ste 501	Miami	FL	33132
Phone	**Title**		
305-379-3700	Special Projects Manager		

Description of Duties

Oversee process implementation

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mario Tabraue

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/3/25

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Miami Dade

I, Mario Tabraue, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/3/25

Date

Subscribed and Sworn to before me this 11 day of 3.

Notary Public Signature

Cindy Basso
Comm.: HH 289930
Expires: Jul. 20, 2028
Notary Public - State of Florida

(Seal)

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 23985
Insp # 192043

NAME	PERMIT NUMBER	DATE OF INSPECTION
RXCompoundStore.com LLC	30412	06/18/2024
DOING BUSINESS AS		
RX COMPOUND STORE		
STREET ADDRESS	**TELEPHONE #**	**EXT**
8950 SW 74TH CT, SUITE 101		
CITY	**COUNTY**	**STATE/ZIP**
MIAMI	MIAMI-DADE	FL/33156

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 10:00 AM - 6:00 PM
Monday N	Monday Hours 10:00 AM - 6:00 PM
Tuesday N	Tuesday Hours 10:00 AM - 6:00 PM
Wednesday N	Wednesday Hours 10:00 AM - 6:00 PM
Thursday N	Thursday Hours 10:00 AM - 6:00 PM
Friday N	Friday Hours 10:00 AM - 6:00 PM
Saturday N	Saturday Hours Closed
Sunday N	Sunday Hours Closed

Registered Pharmacist / Intern / Tech

License # PS 60454	Licensee Name Shibu John PDM
License Type Registered Pharmacists	
License # RPT 93153	Licensee Name Yanet Cruz
License Type Pharmacy Tech	
License # RPT 70110	Licensee Name Kevin Vargas
License Type Pharmacy Tech	
License # RPT 120250	Licensee Name Giselle Canas
License Type Pharmacy Tech	
License # RPT 119349	Licensee Name Elizabeth Rodriguez
License Type Pharmacy Tech	
License # RPT 65485	Licensee Name Dania Grana
License Type Pharmacy Tech	
License # RPT 108363	Licensee Name Alan Cender
License Type Pharmacy Tech	
License # RPT 118978	Licensee Name Mildrey Sobrino
License Type Pharmacy Tech	
License # PS 61464	Licensee Name Hong-Chun Yeh
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # [redacted]	

License Relations

Pharmacy Affiliate

TABRAUE, MARIO	License #

RX DPT MGR/COR/POR

JOHN, SHIBU N	License # 60454

Special Sterile Compounding

RXCOMPOUNDSTORE.COM LLC	License # 34603

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081(2), F.A.C.]	Yes
"Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109, F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] [64B16-28.1035, F.A.C.]	Yes

Community Requirements General Section

Outdated medications removed from active stock. [64B16-28.110, F.A.C.] [64B16-28.1191, F.A.C.]	Yes
Prescription Department is open for a minimum of 20 hours per week. [64B16-28.1081(1), F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c), F.S.] [21CFR1306.05]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d), F.A.C.]	Yes
Prescription department has current copy of laws and rules, references end equipment necessary to the professional practice of pharmacy. [64B16-28.102(5)(a), F.A.C.]	Yes
Technicians properly identified. [64B16-27.100(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.410, F.A.C.] [64B16-27.420, F.A.C.]	Yes
Legend drugs properly stored within confines of pharmacy department and maintained at eppropriate temperature to preserve therapeutic activity. [64B16-28.118, F.A.C.]; [64B16-28.120, F.A.C.]; [64B16-28.102, F.A.C.]	Yes
Documentation of destruction or return of controlled substances. [64B16-28.303, F.A.C.]	Yes
Generic equivalent sign is posted. [465.025(7), F.S.]	Yes

Additional Community Requirements

Prescription department is operating under clean, sanitary, and uncrowded health conditions. [64B16-28.102, F.A.C.]	Yes
Prescription department has a sink with running water easily accessible to the prescription counter. [64B16-28.102, F.A.C.]	Yes
Pharmacist is on the premises and on duty when the prescription department is open. [64B16-28.109, F.A.C.]	Yes
Pharmacy maintains a written policy and procedure manual regarding the number of registered pharmacy technician positions and the pharmacy operates within the established ratio es defined by rule. [64B16-27.410(2)(a), F.A.C.]	Yes
Pharmacists, technicians, and interns are licensed in the State of Florida. [465.015(1)(a), F.S.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication is properly labeled for dispensing to patient. [64B16-28.108, F.A.C.]	Yes
Unclaimed prescriptions are maintained in stock for no more than one year past dispensing date. [64B16-28.1191, F.A.C.]	Yes
Manufacturer containers are properly labeled. [499.003(26), F.S.]	Yes
Customized medication packages are labeled properly with beyond use date of not more than 120 days from the date of preparation but not later than the beyond use date for any of the medications in the package. [64B16-28.108(6)9., F.A.C.]	N/A
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality-Related Events are available for inspection. [64B16-27.300, F.A.C.] [766.101(1)(a)(l), F.S.]	Yes
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	Yes
Compounding records include compounding date, lot number, expiration date, name and manufacturer of ingredients, peckage size, number of units, technician compounding and pharmacist verifying the final compound. [64B16-28.140(4), F.A.C.]	Yes
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005, F.S.] [61N-1.012, F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005(14), F.S.]	Yes
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility. [64B16-27.700(3)(g), F.A.C.]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek follow-up care from his or her primary care physician. [465.1895(9), F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S.]	N/A

Requirements for Dispensing Controlled Substances

Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11]	Yes
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2), F.S.] [21CFR 1305.13(e)] [21CFR1305.22(g)]	N/A

INV359 - Community Requirements

Insp # 192043

RXCompoundStore.com LLC

File # 23995

Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [465.022(12)(a), F.S.] [64B16-28.140, F.A.C.] [21CFR1306.22] [21CFR1304.04]	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	Yes
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b), F.S.] [465.022(11)(b), F.A.C.]	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4)(3)(a), F.S.]	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	Yes
Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	Yes

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Pharmacy engages in Centralized Prescription Filling [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of tha originating pharmacy's employee accepting delivery.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197(3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

Remarks:

Last CQI meeting conducted on: 04/10/2024. Biennial Inventory of controlled substances completed on: 04/01/2024, No CII on stock. Pharmacy keeps a non-sterile compounding Log (Troches, Creams, suspensions, capsules, gels). Wholesaler: Smith, PCCA & Medisca. Medicinal Drugs ships thru an internal employee, Fedex & UPS.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

CASTILLO, ELIZABETH

Date:6/18/2024

Representative:

Hong-Chun Yeh PS

Date:6/18/2024

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797 USP Sterile Compounding

File # 29154
Insp # 192044

NAME	PERMIT NUMBER	DATE OF INSPECTION
RXCOMPOUNDSTORE.COM LLC	34603	06/18/2025
DOING BUSINESS AS RXCOMPOUNDSTORE.COM		
STREET ADDRESS 8950 SW 74TH COURT, SUITE # 101	**TELEPHONE #** 786-803-8947	**EXT**
CITY MIAMI	**COUNTY** MIAMI-DADE	**STATE/ZIP** FL/33156

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 9 AM TO 5 PM
Monday Y	Tuesday Y
Wednesday Y	Thursday Y
Friday Y	Saturday N
Sunday N	

Registered Pharmacist / Intern / Tech

License # PS 60454	Licensee Name Shibu John
License Type Registered Pharmacists	
License # RPT 93106	Licensee Name Mario Tabraue
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # [redacted]	

License Relations

Pharmacy Affiliate

TABRAUE, MARIO	License #

RX DPT MGR/COR/POR

JOHN, SHIBU N	License # 60454

Special Sterile Compounding

RXCOMPOUNDSTORE.COM LLC	License # 30412

INV797 - USP Sterile Compounding
(Revision 1, USP 797 2022. August 2024)
A. INTRODUCTION & SCOPE – ALL CATEGORIES

DESIGNATED PERSON: A designated person(s) is identified who is responsible and accountable for the performance and operation of the facility and personnel involved in the preparation of CSPs. [USP 797 Section 1.1.3]	Yes
IMMEDIATE USE COMPOUNDING: When preparing immediate use preparations, written SOPs are in place for all requirements and all criteria are met including 1. aseptic technique, processes, and procedures; and, 2. personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and SOP's, 3. the preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs, 4. the preparation involves not more than 3 different sterile products, 5. Any unused starting component from a single-dose container is discarded, 6. Administration begins within 4 hours following the start of preparation and, 7. Unless directly administered by the preparer or administration is witnessed by the preparer, the CSP is labeled with the names and amounts of all active ingredients, the name or initials of the preparer and the 4 hour period within which administration must begin. [USP 797 Section 1.3]	N/A

BAG & VIAL SYSTEM: Docking of vial and bag systems for future activation and administration is performed in an ISO 5 environment and BUDs are not longer than those specified in the manufacturer's labeling. [USP 797 Section 1.4]	Yes
REPACKAGING: Repackaging of sterile products or preparations from its original container into another container are prepared according to all applicable USP 797 requirements. [USP 797 Section 1.1.2]	Yes

B. COMPONENT BUDs (Single and Multi-dose Containers) – ALL CATEGORIES

SINGLE DOSE CONTAINERS (SDCs): SDCs are entered or punctured only in an ISO Class 5 or cleaner air and are used up to 12 hours after initial entry or puncture if the labeled storage requirements during that 12-hour period are maintained. [USP 797 Section 15.1]	N/A
AMPULES: Opened SINGLE DOSE AMPULES are used immediately and not stored for any time period. [USP 797 Section 15.1]	N/A
MULTIDOSE CONTAINERS (MDCs): Upon initially entering or puncturing a conventionally manufactured MDC, the MDC is not used for more than 28 days unless otherwise specified by the manufacturer on the labeling. [USP 797 Section 15.2] *BUD 3 months, no Exp date on multi-dose vial. No other BUD assigned*	No
PHARMACY BULK PACKAGES: Conventionally manufactured pharmacy bulk packages are entered or punctured only in an ISO Class 5 PEC and must be used according to the manufacturer's labeling. [USP 797 Section 15.3]	N/A
SINGLE DOSE COMPONENT CSPs & STOCK SOLUTIONS: When single-dose CSPs or CSP stock solutions are used as a component to compound additional CSPs, the original compounded single-dose component CSP or CSP stock solution is entered or punctured in ISO Class 5 or cleaner air and is stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). Once punctured, the component CSP is used for sterile compounding for up to 12 hours or its assigned BUD, whichever is shorter, and any remainder is discarded. [USP 797 Section 16.2]	Yes

C. CSP LABELING – ALL CATEGORIES

CSP LABEL REQUIREMENTS: CSP Immediate container label prominently and legibly displays 1) assigned internal identification number; 2) active ingredient(s) and their amount(s), or concentration(s); 3) storage conditions if other than controlled room temperature; 4) BUD; 5) dosage form; 6) total amount or volume; 7) statement if CSP is a single dose container (when space permits) or multi-dose container. Labeling of CSP displays 1) route of administration, 2) special handling instructions, 3) warning statements, and the compounding facility name and contact information if the CSP is sent outside of the facility in which it was compounded. [USP 797 Section 13]	Yes
ADDITIONAL REQUIREMENTS FOR A CLASS II OR III FACILITY: 1) Identification of responsible compounding personnel and/or dispensing pharmacist;2) labels for batch-prepared CSPs must also include: Control or lot number, auxiliary labeling (including precautions); and device-specific instructions. Patient specific medications must also include patient's name, location the medication is to be delivered to and directions for use. [USP 797 Section 13] [F.A.C.64B16-28.108(10)]	Yes
LABELING SOP: SOPs describe labeling procedures and are followed to prevent labeling errors and CSP mix-ups. [USP 797 Section 13]	Yes
LABEL VERIFICATION: CSP labels are verified to ensure that they conform with the prescription or medication order, MFR (if required), and the CR. [USP 797 Section 13]	Yes

D. PERSONNEL PREPARATION & OBSERVATION – ALL CATEGORIES

UNNECESSARY ITEMS: Personnel remove outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests); cosmetics, and all hand, wrist, and other exposed jewelry, including piercings that may interfere with effectiveness of garbing. Items not necessary for compounding (e.g., food, drinks, mints, gum, earbuds, headphones) are not introduced into the compounding environment. Accommodations are documented. [USP 797 Section 3.1]	Yes
NAILS: Nails are clean and trimmed. Nail products (e.g., polish, artificial nails, and extenders) are not worn. Personnel clean under nails under warm running water with a disposable nail cleaner. Hands and forearms are washed with soap and water for at least 30 seconds prior to entering a compounding area. [USP 797 Section 3.2]	Yes
REQUIRED PPE GARBING ORDER & STORAGE: Personnel garb (don and doff) in an order that reduces risk of contamination per SOP. Required garb, manner of storage, and order or garbing is documented in SOP's. The minimum required PPE when preparing CSPs includes a garment with sleeves that fit around wrists and enclosed neck, shoe covers, head/facial hair cover, face mask, and sterile powder-free gloves. All PPE is low lint for Category 1 & 2 compounding or sterile if Category 3. Gowns and other garb are stored in a manner that minimizes contamination (e.g., away from sinks) and within a classified area or SCA. [USP 797 Section 3.3]	Yes
INAPPROPRIATE HAND HYGIENE PRACTICES: Brushes and hand dryers are not used, and soap containers are not refilled or topped off. [USP 797 Section 3.2]	Yes
ALCOHOL-BASED HAND RUB: Hands are sanitized with alcohol-based hand rub prior to donning gloves. Handrub is used prior to donning garb when hand hygiene is done outside of a classified area. [USP 797 Section 3.3]	Yes
STERILE GLOVES USED: Sterile gloves are donned in classified room or SCA. Skin is not exposed inside ISO 5 PEC (e.g., gloves are not donned or doffed). [USP 797 Section 3.3]	Yes
SANITIZATION OF STERILE GLOVES: Sterile 70% IPA is applied to gloves prior to compounding and regularly throughout the compounding process. [USP 797 Section 3.3]	Yes
SANITIZATION OF ITEMS INTRODUCED INTO PEC: Items are wiped with sterile 70% IPA and sterile low-lint wipers just prior to being introduced into the PEC and allowed to dry before use. [USP 797 Section 8.2]	Yes
CRITICAL SITES (e.g., vial stoppers, ampule necks, and intravenous bag septum's) are wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA is allowed to dry before personnel enter or puncture stoppers and septum's or break the necks of ampules. [USP 797 Section 8.3]	Yes
MATERIALS AND EQUIPMENT DISINFECTION: Before any item is introduced into the clean side of anteroom(s), placed into pass-through chamber(s), or brought into the SCA, it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. Dwell time is followed. [USP 797 Section 8.1 & 9.1]	Yes

E. EQUIPMENT, SUPPLIES, & COMPONENTS – ALL CATEGORIES

DAILY ACD ACCURACY ASSESSMENT: An accuracy assessment is conducted for Automated Compounding Devices (ACDs) or similar equipment before the first use and again each day the equipment is used to compound CSPs. A daily record of accuracy measurements is maintained. Corrective actions are implemented if accuracy measurements are outside of manufacturer's specifications. [USP 797 Section 9.1]	Yes
EQUIPMENT SOPs: Written SOPs for the calibration, maintenance, cleaning, and use of equipment are established and are based on the manufacturer's recommendations. Procedures are followed and records are maintained. [USP 797 Section 9.1] *no SOP at time of inspection*	No

F. SEGREGATED COMPOUNDING AREA: Category 1

CATEGORY 1 MAXIMUM BUDs & COMPOUNDING AREA REQUIREMENTS: Category 1 CSPs are compounded in an ISO class 5 PEC located within a SCA and are assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less when refrigerated. [USP 797 Section 1.5, 4.2.1]	
DEDICATED AREA FOR SCA: The SCA is separated from areas not directly related to compounding, and all surfaces (walls, floors, counters, and equipment) are clean, uncluttered, and dedicated to compounding. [USP 797 Section 4.2.1]	
SCA LOCATION: The SCA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC. SCA is not located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality of the PEC within the SCA. A sink is not located within 1 meter of PEC. [USP 797 Section 4.2.1]	
ITEMS WITHIN SCA: Only furniture, equipment, and other materials necessary for performing compounding activities are located within the SCA. [USP 797 Section 4.2.1]	

G. FACILITIES & SECONDARY ENGINEERING CONTROLS – Categories 2 and 3

STERILE SUITE CONSTRUCTION: The ISO-classified anteroom and buffer room are separated from the surrounding unclassified areas of the facility by fixed walls and doors, and controls are in place. [USP 797 Section 4.2.1]	Yes
HEPA FILTERED AIR: Air supplied to the cleanroom suite is introduced through HEPA filters located in the ceiling of the buffer room and anteroom. [USP 797 Section 4.2.1]	Yes
AIR RETURNS: Air returns in the cleanroom suite are low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow. [USP 797 Section 4.2.1] *smoke study available*	Yes
LINE OF DEMARCATION: The anteroom has a line of demarcation to separate the clean side from the dirty side. [USP 797 Section 4.2.1]	Yes
SURFACES & WALLS: The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area are smooth, impervious, free from cracks and crevices, and non-shedding. Walls are constructed of/or covered with durable material. [USP 797 Section 4.3.1]	Yes
CEILINGS & FLOORS: Inlaid panels of ceilings are caulked around each panel to seal them to the support frame. Junctures between the ceiling and the walls and between the walls and the floor are sealed to eliminate cracks and crevices where dirt can accumulate. Floors include coving to the sidewall, or the juncture between the floor and the wall are caulked. [USP 797 Section 4.3.1]	Yes
LEDGES & OVERHANGS: Overhangs and ledges are easily cleanable, and the exterior lens surface of ceiling light fixtures are smooth, mounted flush, and sealed. [USP 797 Sections 4.3.1]	Yes
FURNITURE, EQUIPMENT, & MATERIALS: Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. Tacky mats are not placed within ISO-classified areas. Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels. [USP 797 Sections 4.2.1 & 4.5]	Yes
TEMPERATURE & HUMIDITY MONITORING: Temperature and humidity in the cleanroom suite are controlled through a heating, ventilation, and air conditioning (HVAC) system. The temperature and humidity are monitored in each room of the cleanroom suite each day that compounding is performed, either manually or by a continuous recording device. They are documented at least once daily or stored in the continuous recording device and are retrievable and are reviewed as described in the facility's SOP. [USP 797 Section 4.2]	Yes
PRESSURE DIFFERENTIATION MONITORING & DOCUMENTATION: Facility maintains a minimum differential positive pressure of 0.020-inch water column between the nonhazardous buffer room to anteroom and anteroom to unclassified area. A pressure differential monitoring device is used to continuously monitor the pressure differentials. Quantitative results from the pressure monitoring device are reviewed and documented at least daily on the days when compounding is occurring. [USP 797 Sections 4.2.5]	Yes
PEC LOCATION: PECs are located in a buffer room in a manner that minimizes conditions that could increase the risk of microbial contamination (strong air currents, personnel traffic, or air streams from HVAC system(s)) and allows for cleaning around the PEC. [USP 797 Sections 4.2.2 & 4.2.3]	Yes
INTEGRATED VERTICAL LAMINAR FLOW ZONES: IVLFZ is separated from ISO Class 7 area with a physical barrier and there is full coverage of HEPA filters above the work surface. [USP 797 Section 4.2.3]	Yes

H. CERTIFICATION AND RECERTIFICATION – ALL CATEGORIES

PEC & SEC CERTIFICATION: PECs are certified initially and every 6 months to meet ISO Class 5 or better conditions, during dynamic operating conditions. SECs are certified initially and every 6 months to meet ISO Class 7 or 8 or better conditions, during dynamic operating conditions (including presterilization activities if applicable). Anterooms providing access to positive-pressure buffer rooms are at least ISO 8 and at least ISO 7 for anterooms providing access to negative-pressure buffer rooms. ISO Class 7 rooms maintain a minimum of 30 total HEPA-filtered ACPH during dynamic operating conditions, at least 15 ACPH come from the HVAC through HEPA filters located in the ceiling. ISO Class 8 rooms maintain a minimum of 20 total HEPA-filtered ACPH during dynamic operating conditions; 15 ACPH must come from the SEC. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH are documented on the certification report. HEPA filter integrity testing for both SECs & PECs is conducted initially and every 6 months as part of total particle testing. Classified areas are recertified when changes occur that could affect airflow or air quality [USP 797 Sections 4.1, 4.2.4, 4.2.6, & 5.0]	Yes
DOCUMENTATION OF PERSONNEL PRESENT DURING CERTIFICATION: The number of personnel present in each PEC and SEC during total particle counts and dynamic airflow smoke-pattern tests is documented on the certification report. [USP 797 Section 5.0]	Yes
PEC DYNAMIC SMOKE PATTERN TEST: Smoke pattern tests are performed under dynamic conditions initially to demonstrate minimal disruption in airflow and repeated if equipment is placed in a different location. Smoke pattern tests are performed under dynamic conditions every 6 months to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s). [USP 797 Section 5.0]	Yes
ROBOTICS / ROBOTIC ENCLOSURES: Robotic enclosures used as a PEC or placed within a PEC have a dynamic airflow smoke pattern test is performed initially and at least every 6 months that confirms 1) the robotic device is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the DCA(s). [USP 797 Section 4.2.3]	N/A
MONITORING DEVICE CERTIFICATION: Temperature and humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. [USP 797 Section 4.2] *No SOP or documentation available at the time of inspection*	No
CONTAINMENT DEVICES USED FOR PRESTERILIZATION PROCEDURES: CVEs, BSCs, or CACIs used for presterilization procedures are certified at least once every 6 months. Presterilization procedures do not adversely affect the required air quality of the SEC as demonstrated during certification under dynamic operating conditions. [USP 797 Section 4.2.6]	Yes
CERTIFICATION REPORT REVIEW BY DESIGNATED PERSON: All certification and recertification records are reviewed by the designated person(s). A corrective action plan is implemented and documented in response to any out-of-range results on certification report and data reviewed to confirm that the actions taken have been effective. [UPS 797 Section 5.0] *no document available at the time of inspection*	No

I. RABS

LOCATION: If used to prepare Category 2 or Category 3 CSP's RABS are located in a cleanroom suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom. [USP 797 Section 4.2.3]	
RECOVERY TIME: When a RABS is used, the recovery time after opening the transfer chamber to achieve ISO Class 5 air is documented and internal procedures are developed to ensure that adequate recovery time is allowed after opening and closing the RABS. [USP 797 Section 4.2.3]	
STERILE GLOVES: are worn over gloves attached to RABS sleeves. [USP 797 Section 3.3]	

J. CATEGORY 2 CSPs WITHOUT STERILITY TESTING

CATEGORY 2 COMPOUNDING ENVIRONMENT: Category 2 CSPs are compounded in an ISO class 5 PEC located within an ISO classified anteroom and buffer room. [USP 797 Sections 4.1 & 14.3]	
CATEGORY 2 BUDs FROM STERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from all sterile starting components and in the absence of sterility testing do not exceed the following BUDs: 4 days room temperature, 10 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3]	
CATEGORY 2 BUDs FROM NONSTERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from one or more nonsterile starting components and in the absence of sterility testing do not exceed the following BUDs: 1 day room temperature, 4 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3]	

K. CATEGORY 2 EXTENDED BUD REQUIREMENTS

CATEGORY 2 BUDs FOR ASEPTICALLY PROCESSED CSPs WITH STERILITY TESTING: Category 2 CSPs compounded aseptically, and which have passed sterility testing do not exceed the following BUDs: 30 days room temperature, 45 days refrigerated, or 60 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *visual inspection of CSP vial: BUD 90 days*	No
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITHOUT STERILITY TESTING: Category 2 CSPs terminally sterilized and in the absence of sterility testing do not exceed the following BUDs: 14 days room temperature, 28 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *sterility testing performed on all batches*	N/A
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITH STERILITY TESTING: Category 2 CSPs terminally sterilized, and which have passed sterility testing do not exceed the following BUDs: 45 days room temperature, 60 days refrigerated, or 90 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *90 days BUD with refrigeration*	No
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmics) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1]	Yes
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved CSPs), container integrity testing is performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	Yes
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are assigned are prepared as a Category 2 CSP, for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	N/A
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1]	N/A
OUTSOURCED STERILITY TESTING: Sterility testing is performed for all Category 2 CSPs assigned a BUD requiring sterility testing according to USP <71> or a validated alternative and noninferior method. Membrane Filtration as described in USP <71> is the preferred method when the formulation allows. [USP 797 Section 12.2]	Yes
INHOUSE STERILITY TESTING: Sterility testing is according to USP <71> or a validated alternative and noninferior method. Membrane filtration is used if appropriate and filters are rinsed according to USP <71>. Direct inoculation is done only when membrane filtration cannot be carried out. Volume inoculated does not exceed 10% of the culture media volume. Growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP <71>. TSB or SCD is incubated at 20-25C for 14 days; FTM is incubated at 30-35C for 14 days. (2 incubators present). *testing outsourced*	N/A
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method. [USP 797 Section 12.2]	Yes
MAXIMUM BATCH SIZE: The maximum batch size for all CSPs requiring sterility testing is 250 final yield units. [USP 797 Section 12.2]	Yes
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2] *not available at the time of inspection*	No
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	Yes
ENDOTOXIN TESTING: Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing are tested for bacterial endotoxins. [USP 797 Section 12.3]	Yes
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	Yes

L. CATEGORY 3 CSPs, BUDs, & RELATED REQUIREMENTS

CATEGORY 3 REQUIREMENTS: All requirements associated with Category 3 compounding (e.g., garbing, cleaning, environmental monitoring) apply to all personnel entering the buffer room where Category 3 CSPs are compounded and always apply regardless of whether Category 3 CSPs are compounded on a given day. [USP 797 Section 14.4.2]	
STERILE/SINGLE USE GARB: When compounding Category 3 CSPs, skin is not exposed in buffer room (i.e., face and neck are covered) and all low lint outer garb is sterile, including sterile sleeves over RABS gauntlet sleeves. Disposable garb items are not reused. [USP 797 Section 3.3]	

STERILIZED/REUSABLE GARB: Non-disposable garb is not reused without being laundered and resterilized with a validated cycle. Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment. [USP 797 Section 3.3]	
CATEGORY 3 BUDs FOR ASEPTICALLY PROCESSED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 60 days room temperature, 90 days refrigerated, or 120 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for aseptically processed CSPs. [USP 797 Section 14.4.3]	
CATEGORY 3 BUDs FOR TERMINALLY STERILIZED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 90 days room temperature, 120 days refrigerated, or 180 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for terminally sterilized CSPs. [USP 797 Section 14.4.3]	
MAXIMUM BATCH SIZE: Category 3 CSP batch sizes do not exceed 250 final yield units. [USP 797 Section 12.2]	
STABILITY INDICATING ASSAYS: All Category 3 CSP formulations are supported by data obtained using a validated stability-indicating analytical method that can distinguish active ingredients from degradants and impurities and quantify the amount of active ingredient. CSPs are prepared according to the exact formulation, components, and packaged in a container closure system of the same materials of composition. Facilities have documentation of the stability study, its results, and the method validation available for review. [USP 797 Section 14.3.3]	
STERILITY TESTING: All category 3 CSPs and batches undergo sterility testing performed according to USP <71> or a validated alternative and noninferior method. [USP 797 Sections 12.2 & 14.4.4]	
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method for each formulation. [USP 797 Section 12.2]	
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	
ENDOTOXIN TESTING: Category 3 injectable CSPs compounded from one or more nonsterile component(s) are tested for bacterial endotoxins. [USP 797 Section 12.3]	
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	
PARTICULATE MATTER TESTING: Category 3 injectable CSPs undergo USP <788> (Particulate Matter in Injections) and ophthalmic solutions undergo USP <789> (Particulate Matter in Ophthalmic Solutions) test once per formulation with acceptable results. [USP 797 Section 14.3.3]	
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmic) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1]	
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved multi-dose CSPs), container closure integrity testing is also performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are prepared for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1]	

M. PERSONNEL TRAINING & COMPETENCIES - ALL CATEGORIES

TRAINING PROGRAM & SOP: Facility maintains a written training program and corresponding SOP which defines required trainings, frequency of training and the process for evaluating the performance of individuals who compound, have direct oversight of compounding personnel, perform in-process checks, final verification and dispensing of CSP's. The training program equips personnel with the appropriate knowledge and training in the required skills necessary to perform their assigned tasks. [USP 797 Section 2]	Yes
INITIAL DIDACTIC TRAINING & SKILLS ASSESSMENT: Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel complete training and can demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions. [USP 797 Section 2.1]	Yes
INITIAL GLOVED FINGERTIP & HAND HYGIENE/GARBING COMPETENCY: Before beginning to compound independently or have direct oversight of compounding personnel, personnel successfully complete an initial gloved fingertip (GFT) competency no fewer than 3 separate times, with a documented visual audit while performing hand hygiene and garbing procedures. GFT samples are collected before applying sterile 70% IPA to gloves. [USP 797 Section 2.2]	Yes
INITIAL MEDIA FILL & ASEPTIC TECHNIQUE ASSESSMENT: Before beginning to compound independently or have direct oversight of compounding personnel, personnel who compound or have direct oversight of compounding successfully complete an initial aseptic manipulation competency evaluation which consists of a visual observation, media-fill testing followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area. [USP 797 Section 2.3]	Yes
GFT & MEDIA FILL INCUBATION: Documentation includes the name of the person evaluated, evaluation date and time, media and components used to include their manufacturer or supplier, expiration dates and lot numbers, starting temperature for each interval of incubation, dates of incubation, the results, and the names or other identification of the observer and the person who reads and documents the results. [USP 797 Section 2.3]	Yes
ONGOING CATEGORY 1 AND 2- GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency evaluation and GFT every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2] *GFT done annually for 1 Tech 4/30/25 and 8/7/24. 3 new personnel less than 6 months*	No
ONGOING CATEGORY 1 AND 2- MEDIA FILL & ASSESSMENT: After initial aseptic manipulations competency evaluations, compounding personnel complete aseptic technique competency, media fill, GFTs, and surface sampling of DCA every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete media fill every 12 months. GFTs and surface samples are appropriately incubated. [USP 797 Section 2.3] *GFT done annually for 1 Tech 4/30/25 and 8/7/24. 3 new personnel less than 6 months*	No

ONGOING KNOWLEDGE & COMPENTENCY OF CORE SKILLS: Training and knowledge assessment of sterile compounding principles or core skills is completed at least every 12 months. [USP 797 Section 2.1]	Yes
FAILED COMPETENCY INVESTIGATION: Initial and ongoing competency assessment failures are investigated, remediated, and documented in a Corrective Action Plan. [USP 797 Sections 2.2 & 2.3] *No Competency failures documented*	N/A
STAFF TRAINING IN VIABLE AIR AND SURFACE SAMPLING: Personnel are trained and competent in air and surface sampling procedures to ensure accurate and reproducible sampling. [USP 797 Section 6.1]	Yes
CLEANING PERSONNEL: Cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures. Cleaning personnel demonstrate knowledge and competency of core skills related to cleaning, disinfection, and maintenance of environmental conditions initially and at least once every 12 months. [USP 797 Sections 7 & 2.1] *No documentation available at the time of inspection*	No

FACILITY COMPOUNDS CATEGORY 3

ONGOING CATEGORY 3 GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency and GFT every 3 months for Category 3 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2]	
ONGOING CATEGORY 3 ASEPTIC PROCESSING COMPETENCY: Aseptic competency is repeated at least one time every 3 months for personnel compounding Category 3 CSPs. The simulation must capture elements that could potentially affect the sterility of the CSP. Immediately following the media-fill test, gloved fingertip and thumb sampling is performed on both hands and surface sampling of the direct compounding area. Direct oversight personnel who do not compound must complete media fill every 12 months. [USP 797 Section 2.3]	

N. MICROBIOLOGICAL AIR AND SURFACE MONITORING: ALL CATEGORIES

ENVIRONMENTAL MONITORING PROGRAM & SOPs: The microbiological air and surface monitoring program is clearly described in the facility's SOPs, which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that trigger corrective action. [USP 797 Section 6]	Yes
VIABLE AIR SAMPLING: Volumetric active air sampling using an impaction air sampler collecting at least 1000L of air is conducted in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions and is completed at least every 6 months. [USP 797 Section 6.2]	Yes
AIR IMPACTION DEVICE: Device is serviced and calibrated according to the manufacturer's recommendations. [USP 797 Section 6.1]	Yes
SURFACE SAMPLING: Microbiological surface sampling is conducted in all classified areas and pass-through chambers under dynamic operating conditions and performed at least once monthly. [USP 797 Section 6.3]	Yes
GROWTH MEDIA: A general microbiological growth media that supports the growth of bacteria and fungi is used and a COA from the manufacturer is available. Growth media used for surface sampling contains neutralizing agents (e.g., lecithin and polysorbate 80). [USP 797 Sections 6.2 & 6.3]	Yes
MEDIA INCUBATION: Samples are incubated at 30°C - 35°C for 48 hours and 20°C - 25°C for an additional 5 days; if dual growth media are used, incubate one media device at 30°C - 35°C for 48 hours and the second media device at 20°C - 25°C for 5 days. The incubator temperature is monitored during incubation, either manually or by a continuous recording device, and results are reviewed and documented as described in the facility's SOPs. Incubators are placed in a location outside of the sterile compounding area. [USP Sections 6.2.2 (Box 5) & 6.3.2 (Box 6)]	Yes
ENVIRONMENTAL MONITORING TREND ANALYSIS: Regular review of sampling data is performed to detect trends and review of trending data is documented. [USP 797 Section 6.1]	Yes
CORRECTIVE ACTION: When microbial growth exceeds action levels, the cause is investigated, and corrective action is taken; corrective actions taken are reviewed for effectiveness. An attempt to identify microorganisms at the genus level is made. [USP Sections 6.2.3 & USP 6.3.3]	Yes

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-VIABLE AIR SAMPLING: Volumetric air sampling is completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.Air sampling sites are selected in all classified areas. [USP 797 6.2.1]	
CATEGORY 3-SURFACE SAMPLING: Surface sampling for any Category 3 CSPs, is completed in all classified areas, and pass-through chambers connecting to classified areas, prior to assigning a BUD longer than BUD limits for Category 2 CSPs (defined in Table 13 of USP 797) and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. [USP 797 6.2.2]	
CATEGORY 3-BATCH SURFACE SAMPLING: Surface sampling is conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used. When a self-enclosed robotic device is used as the PEC, surface sampling is conducted at least once daily at the end of compounding operations before cleaning and disinfection occurs. [USP 797 Section 6.3.2]	

O. CLEANING AND DISINFECTING: ALL CATEGORIES

CLEANING SOPS: The frequency, method(s), documentation requirements, and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants are described in written SOPs; use of agents is in accordance with manufacturer's instructions, procedures, and in adherence with minimum wet contact times. SOPs describe the time period during which, once opened, sterile cleaning and disinfecting agents, supplies, and sterile 70% IPA may be reused. Sterile water is used to dilute concentrated cleaning agents used inside of PECs (if applicable). Cleaning and disinfecting agents are EPA-registered. If a one-step disinfectant cleaner is not used, surfaces are cleaned prior to being disinfected. [USP 797 Section 7]	Yes
DAILY PEC CLEANING & DISINFECTION WITH STERILE AGENTS: Equipment and all interior surfaces of the PEC are cleaned and disinfected daily on days when compounding occurs and when surface contamination is known or suspected. Sterile 70% IPA is applied after cleaning, disinfecting, or after one-step disinfectant cleaner or sporicidal agent application to remove residue. [USP 797 Section 7]	Yes
CATEGORY 1 AND 2-MONTHLY PEC SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, are cleaned with a sporicidal agent monthly. [USP 797 Section 7]	Yes
DAILY SEC & SCA CLEANING & DISINFECTION: Work surfaces, floors, sink surfaces, and pass-through chambers are cleaned and disinfected daily on days when compounding occurs. [USP 797 Section 7]	Yes
CATEGORY 1 AND 2 -MONTHLY PEC, SEC & SCA SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings*, walls, doors, and doors frames at least once monthly. SCA ceilings (if applicable) are only cleaned, disinfected, and have sporicidal agents applied when visibly soiled and when surface contamination is known or suspected. [USP 797 Section 7]	Yes
PEC SANITIZATION WITH STERILE 70% IPA: Sterile 70% IPA is applied to the horizontal work surface, including removable trays, immediately before initiating compounding and at least every 30 minutes. If a compounding process takes more than 30 minutes, the work surface is disinfected immediately after the end of the compounding process. Sterile 70% IPA is allowed to dry. [USP 797 Section 7] *compounding syringes and equipment introduced to PEC prior to cleaning of surface*	No

CLEANING SUPPLIES & TOOLS: All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads), except for tool handles and holders, are low lint. Supplies used inside PECs are sterile. [USP 797 Section 7.1.2]	Yes
REUSABLE CLEANING TOOLS: Reusable cleaning tools (e.g., mop frames) are made of cleanable materials and are cleaned and disinfected before and after each use. Reusable tools are dedicated for use in the classified areas or SCA and are not removed. Mops used in HD compounding areas, are dedicated for use only in those areas. [USP 797 Section 7.1.2]	Yes

FACILITY COMPOUNDS CATEGORY 3

WEEKLY SPORICIDAL CLEANING OF PECs & SECs: Weekly cleaning using a sporicidal agent is performed on all internal surfaces of PEC and equipment in PEC's, on work surfaces outside the PEC, pass-through chambers, and floors. [USP 797 Section 7]	
MONTHLY SEC SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to storage shelving and bins, equipment outside of PEC's, sink surfaces, ceilings, walls, doors, and doors frames at least once monthly. [USP 797 Section 7]	

P. COMPOUNDING CSPs FROM NONSTERILE COMPONENTS OR SUPPLIES – CATEGORY 2 & 3

PRESTERILIZATION ACTIVITY CONTAINMENT ENCLOSURES: Pre-sterilization procedures, such as weighing and mixing of nonsterile components, occur in ISO Class 8 or better environment (e.g., anteroom or buffer room) and are performed in single-use containment glove bags, CVEs, BSCs, or CACIs. [USP 797 Section 4.2.6]	Yes
LOCATION OF STERILE & NONSTERILE PECs: PECs used for sterile and nonsterile compounding (e.g., pre-sterilization procedures) are placed in separate rooms unless the buffer room can maintain an ISO Class 7 classification during particulate generating activities. Co-located PECs are at least 1 meter apart and particle-generating activities are not performed during sterile compounding processes [USP 797 Section 4.2.1; USP 800 Section 5.3]	Yes
COMPONENT SOPs: Written SOPs address the selection, receipt, evaluation, handling, storage, and documentation of all CSP componenta including ingredients and container closures. [USP 797 Section 9.3]	Yes
COMPONENT QUALITY & COA: APIs and components comply with the criteria in the USP-NF (if one exists for inactive components) and have a COA including specifications and test results showing the API or component meets expected quality. APIs and other components labeled "not for pharmaceutical use", "not for injectable use", "not for human use", or equivalent are not used in CSPs. [USP 7 Section 9.3.1]	Yes
API MANUFACTURERS: APIs are manufactured by an FDA-registered facility in the U.S. or comply with the laws and regulations of the applicable regulatory jurisdictions outside of the U.S. [USP 797 Section 9.3.1] *manufactured in china*	No
COMPONENT STORAGE: Components are handled and stored in a menner thet preventa contamination, mix-ups, and deterioretion and under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers and/or manufacturers. [USP 797 Section 9.3.4]	Yes
STERILE, DEPYROGENATED SUPPLIES: Supplies in direct contact with CSPs are sterile and depyrogenated. A COA or similar conformance documentation is reviewed. [USP 797 Section 9.3.1] *no document available or reviewed by designated person at the time of inspection*	No
COMPONENT RECEIPT: Upon receipt, the external packaging of components is examined and components of unacceptable quality or showing deterioration are promptly labeled as rejected and segregated from active stock. APIs and components are inspected for a visible manufacturer expiration date. Components lacking expiration dates are assigned an expiration date no more than 1 year after receipt and both the date of receipt and facility assigned expiration date is clearly marked on the component packaging. [USP 797 Section 9.3.2]	Yes
STERILIZATION OF INJECTABLES WITHIN 6 HOURS OF COMPLETION: Injectable CSPs containing nonsterile components or that come into contact with nonsterile devices (e.g., conteiners, tubing) during compounding are sterilized within 6 hours of completion. [USP 797 Section 10] *CSP discarded if it comes into contact with non-sterile components.*	No

Q. STERILIZATION OF CSPs - CATEGORY 2 & 3

STERILIZING FILTERS: Sterilizing filters used are sterile, depyrogenated, have a nominal pore size of 0.22 µm or smaller, and are appropriate for pharmaceutical use. Sterilizing filters are certified by the manufacturer to retain at least 10,000,000 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area. Filters are chemically and physically compatible with all ingredients in the CSP (e.g., water-miscible alcohols may damage filter integrity); chemically stable at the pressure and temperature conditions that will be used; and have enough capacity to filter the required volumes. [USP 797 Section 10.2]	Yes
BUBBLE POINT TESTING: Sterilizing filters are subjected to the manufacturers' recommended integrity testing, such as a post-use bubble point test. If multiple filters are required for the compounding process, each of the filters passes a filter-integrity test. [USP 797 Section 10.2] For failed BP testing, CSP is discarded or, after investigating, refiltered not more than one time. [USP 797 Section 10.2]	Yes
CSP PREFILTRATION: When CSPs are known to contain excessive particulate matter, prefiltration is performed using a filter of larger nominal pore size (e.g., 1.2 µm) or a separate filter of larger nominal pore size placed upstream of (i.e., prior to) the sterilizing filter. [USP 797 Section 10.2] *refiltered CSP is done using 0.22micron filter. does not match SOP*	No
CSP TERMINAL STERILIZATION SOP includes: 1) A description of CSP terminal sterilization process(es), including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization methods and equipment. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. [USP 797 Section 10] *No personnel log available at the time of inspection*	No
STEAM OR DRY HEAT STERILIZATION CYCLES FOR CSPs: Sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of the CSP to reach and remain at the sterilizing temperature during the duration of the sterilization period. CSPs sterilized vial steam are placed in the autoclave to allow steam to reach CSPs without entrapment of air. CSPs sterilized via dry heat are placed with sufficient space between materials to allow for hot air circulation. Sterilization cycle parameters (e.g., temperature, pressure, and duration) and load configuration(s) are documented. [USP 797 Section 10.3 & 10.4]	Yes
BIOLOGICAL INDICATOR USE: The effectiveness of steam or dry heat sterilization of CSPs is verified and documented for each sterilization run or load by using appropriate biological indicators (e.g., Geobacillus stearothermophilus for steam, Bacillus atrophaeus for dry heat) and other confirmation methods. [USP 797 Section 10.3]	Yes
STEAM & DRY HEAT CSP PREFILTRATION: Immediately before filling containers that will be sterilized via steam, or dry heat, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.3]	Yes
CALIBRATED DATA RECORDER: A calibrated data recorder or chart is used to monitor each steam or dry heat sterilization cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure). The calibrated oven is equipped with temperature controls and a timer. [USP 797 Section 10.3 & 10.4] *not available at the time of inspection*	No

R. STERILIZATION & DEPYROGENATION OF SUPPLIES & CONTAINER CLOSURE SYSTEMS - CATEGORY 2 & 3

STERILIZATION & DEPYROGENATION SOP's include: 1) A description of sterilization and depyrogenation process(es) used to sterilize and/or depyrogenated compounding supplies and container closure systems, including the temperature, duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. [USP 797 Section 10] *SOP does not include personnel training or competency at the time of inspection*	No
DEPYROGENATION VIA DRY HEAT: Dry heat depyrogenation is used to render glassware, metal, and other thermostable containers and components pyrogen free. The exposure period includes sufficient time for items to reach the depyrogenation temperature; items remain at the depyrogenation temperature for the duration of the depyrogenation period. [USP 797 Section 10.1 & USP 1228.4]	Yes
DEPYROGENERATION VIA RINSING: Non-thermostable items are sterilized via a validated sterilization method and cycle: these items are also depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., Sterile Water for Injection or Sterile Water for Irrigation) and then thoroughly drained or dried immediately before use in compounding. [USP 797 Section 10 & 10.1]	N/A
DEPYROGENATION PROCESS VALIDATION: The effectiveness of the dry heat depyrogenation cycle(s) is established initially and verified annually using Endotoxin Challenge Vials (ECVs) to demonstrate the cycle achieves a greater than or equal to 3-log endotoxin reduction. The effectiveness of the depyrogenation cycle is re-established if there are changes to the cycle parameters . Cycle verifications are documented. [USP 797 Section 10.1]	Yes
STERILIZATION CYCLE VALIDATION: When performed onsite, the efficacy of sterilization cycles used for supplies or container closure systems are established and documented. Each sterilization run or load is verified and documented by using appropriate biological indicators (e.g., spores of Geobacillus stearothermophilus) and other confirmation methods. [USP 797 Section 9.3.1 & USP 1229] *no report available at the time of inspection*	No

S. MASTER FORMULATION AND COMPOUNDING RECORDS – ALL CATEGORIES

MASTER FORMULATION RECORD (MFR): A MFR is created for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more than one patient and any changes or alterations to an MFR are approved and documented per facility's SOPs. [USP 797 Section 11.1]	Yes
MFR DOCUMENTATION: An MFR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Identities, amounts of all ingredients, and, if applicable, relevant characteristics of components; 3) Type and size of container closure system(s); 4) Complete instructions for preparing the CSP including equipment, supplies, a description of the compounding steps, and any special precautions; 5) Physical description of the of the final CSP; 6) BUD and storage requirements; 6) Stability reference; 7) Quality control procedures; 8) other information as needed to describe the compounding process and ensure repeatability. [USP 797 Section 11.1 (Box 9)]	Yes
COMPOUNDING RECORD (CR): A CR is created for all Category 1, Category 2, and Category 3 CSPs. A CR is created for immediate-use CSPs prepared for more than one patient. A CR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Date and time of preparation of the CSP; 3) Assigned internal identification number (e.g., prescription, order, or lot number); 4) A method to identify the individuals involved in the compounding process and individuals verifying the final CSP; 5) Name of each component; 6) Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s); 7) Weight or volume of each component; 8) Strength or activity of each component; 9) Total quantity compounded; 10) Final yield; 11) Assigned BUD and storage requirements; 12) Results of QC procedures. And, if applicable, 13) MFR reference for the CSP; and 14) Calculations made to determine and verify quantities and/or concentrations of components. [USP 797 Section 11.2]	N/A
STERILIZATION CYCLE DOCUMENTATION: The date, run, and load numbers of the steam or dry heat sterilizer used to sterilize a CSP are documented on the CR if applicable. [USP 797 Sections 10.3 & 10.4]	N/A

T. RELEASE INSPECTION AND TESTING – ALL CATEGORIES

RELEASE TESTING PROCEDURES: All release testing procedures (e.g., visual inspections and testing) are included in facility documentation such as MFRs and SOPs. [USP 797 Section 12]	Yes
VISUAL INSPECTION: CSPs are visuelly inspected before release and dispensing to determine whether the 1) physical appearance of the CSP is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects), 2) container closure integrity is intact (e.g., checking for leakage, cracks in the container, or improper seals), 3) CSP and its labeling metch the prescription or medication order. [USP 797 Section 12.1]	Yes
DELAYED DISPENSING VISUAL INSPECTION: When CSPs are not released or dispensed on the day of preparation, a visual inspection is conducted immediately before its release to ensure the CSP is free from any defects such as precipitation, cloudiness, or leakage, which could develop during storage. [USP 797 Section 12.1]	Yes
CSP REJECTION & QUARANTINE: CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock. [USP 797 Section 12.1] *products not meeting standards are sent back into cleanroom and filtered again. If CSP does not pass inspection the second time it is discarded. No separation of stock or labeling "rejected".*	No
INVESTIGATION OF OOS RESULTS: Out-of-specifications results and defects indicating sterility or stability problems are investigeted to determine the root cause and a corrective action plan is implemented and documented per facility SOPs. [USP 797 Section 12 & 12.1]	Yes

U. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, & TRANSPORT – ALL CATEGORIES

STORAGE AREA TEMPERATURE MONITORING: Temperature in CSP & component storage areas is monitored at least once deily and recorded on a log on days when the facility is open or by a continuous temperature recording device; temperature data is readily retrievable. Monitoring equipment is calibrated or verified for accuracy as recommended by the manufacturer or every 12 months. When CSPs have been exposed to temperature excursions above or below storage temperature limits for the CSP, a Designated Person determines whether the CSP has retained its integrity or quelity. [USP 797 Sections 9.3 & 19.1]	No
CSP PACKAGING: CSP packaging and shipping materials are selected to protect CSPs from damage, leakage, contamination, degradation, adsorption and prevent inadvertent exposure to transport personnel. [USP 797 Section 19.2]	Yes
SHIPPING & TRANSPORTING: Modes of transport are selected that are expected to deliver properly packaged CSPs in an undamaged, sterile, and stable condition. Special handing instructions are provided and/or affixed to the exterior of the container when applicable. [USP 797 Section 19.2]	Yes

V. STERILE QUALITY PROGRAM, SDP's & DOCUMENTATION- ALL CATEGORIES

QA/QC PROGRAM & SOPs: A Quality Assurance (QA) and Quality Control (QC) program is documented in facility SOPs and formally establishes a system of 1) adherence to procedures, 2) prevention and detection of errors and other quality problems, 3) evaluation of complaints and adverse events, and 4) appropriate investigations and corrective actions. The QA/QC SOPs describe the roles, duties, and training of personnel responsible for each aspect of the QA program. [USP 797 Section 18]	Yes
INVESTIGATIONS & CAPAs: A designated person(s) follows up to ensure investigations are conducted and corrective actions are taken if problems, deviations, failures, or errors are identified or when complaints or adverse reactions are reported. A complete record of each reported complaint and adverse reaction is created and retained. Investigations and corrective actions are documented. [USP 797 Sections 17, 18.2, & 18.3]	Yes

ADR & COMPLAINT DOCUMENTATION: A complete record of each reported complaint and adverse reaction is created and retained per USP 797. [USP 797 Section 18.1] *no record available at the time of inspection*	No
RECALL PROCEDURES & SOP: If CSPs are dispensed or administered before the results of release testing are known, procedures are in place to immediately notify the prescriber of a failure of specifications with a potential to cause patients harm; determine the severity of the problem and urgency for implementation/completion of recall; identify patients (or other points of distribution) who have received affected CSP; recall any unused dispensed CSPs; quarantine remaining stock in the pharmacy; investigate if other lots are affected and recalled if needed; conduct investigation and document reason for the failure. Recalls are reported to the appropriate regulatory body as required by the laws and regulations of the applicable regulatory jurisdiction. [USP 797 Section 18]	Yes
ANNUAL SOP & QA/QC COMPLIANCE REVIEW: Facility sterile compounding SOPs are reviewed every 12 months by the Designated Person(s); the review is documented. Changes to SOP are made only by the Designated Person and documented. Acknowledgement of revisions to SOP's are communicated to all personnel. The overall QA/QC Program is reviewed at least once every 12 months by the Designated Person(s); the review is documented, and corrective actions are taken if needed. [USP 797 Section 17 & 18]	Yes

W. HAZARDOUS DRUG HANDLING & COMPOUNDING – ALL CATEGORIES

DESIGNATED PERSON: The entity has a Designated Person who is qualified and trained to be responsible for implementing appropriate HD procedures, overseeing compliance with USP 800 requirements, ensuring environmental control of the storage and compounding areas, monitoring HD facility operations, testing, and acting on results. [USP 800 Section 4]	
HAZARD COMMUNICATION PROGRAM (HCP): Facility has SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of HDs and use of Safety Data Sheets. The HCP and HD SOPs include a written plan describing 1) how USP 800 requirements are implemented, 2) HD chemical container labeling with the identity of the material and appropriate hazard warnings, 3) readily accessible location of HD chemical SDSs known and accessible by all personnel, 4) HD risk training and information provided to all personnel with HD exposure risk before initial HD handling work assignment and whenever hazard changes, 5) personnel of reproductive capability written acknowledgement of understanding of HD handling risks. [USP 800 Section 8]	
LIST OF HAZARDOUS DRUGS & ASSESSMENT OF RISK: Facility maintains a list of HDs that includes any items on the current NIOSH that the entity handles. The list is reviewed every 12 months and whenever a new agent or dosage form is used. All HD drugs follow the requirements of USP 800 unless an assessment of risk (AOR) is performed. If an assessment of risk approach is taken, the entity must documents what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. The AOR minimally contains the type of HD, dosage form, risk of exposure, packaging, and manipulation considerations. The HD drug list & AOR is reviewed at least every 12 months and whenever a new agent or dosage form is used. [USP 800 Section 2]	
CONTAINMENT REQUIREMENTS: All antineoplastic HDs requiring manipulation and HD active pharmaceutical ingredients (APIs) on the NIOSH list follow all the requirements of USP 800. [USP 800 Section 2, Box 1]	
HD HANDLING, RECEIPT & STORAGE SOPs: SOPs are created and followed for the safe handling of HDs used by the facility. [USP 800 Section 17]	
HD HANDLING AREAS, SIGNAGE, & ACCESS: Signage designating HD handling areas are prominently displayed and access to HD handling areas is restricted to authorized personnel. Designated areas are available for receipt, unpacking, storage, and sterile compounding of HDs. [USP 800 Section 5]	
HD STORAGE: HDs are stored to prevent spillage or breakage, off floors, and in areas appropriate for natural disasters. Antineoplastic HDs and HD API are stored separately from non-HDs to prevent contamination and personnel exposure. HD storage areas are externally ventilated and negative-pressure rooms with at least 12 ACPH. Refrigerated antineoplastic HDs are stored in a dedicated refrigerator, in a negative pressure area with at least 12 ACPH. Pass through refrigerators are not used. [USP 800 Section 5.2]	
STERILE HDs COMPOUNDED IN A C-SCA: C-SCA maintains a minimum of 12 ACPH of HEPA- filtered air and has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800, sections 5.3.2 Table 3]	
C-SEC DESIGN AND ENGINEERING CONTROLS: The C-SEC has fixed walls physically separated from other preparation areas, is externally ventilated has 30 ACPH, and negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800 Section 5.3.2 Table 3]	
C-SEC ACCESS: The Ante Room used for entry into the negative pressure buffer room has fixed walls and maintains a minimum of 30 ACPH of HEPA-filtered air, positive pressure of +0.02" w.c. to all adjacent unclassified areas, and ISO7 or better classification. Alternatively, a negative-pressure HD buffer entered exclusively through a positive pressure non-HD buffer room contains a line of demarcation (LOD) within the negative-pressure buffer room for donning/doffing HD PPE and a method a transport of HDs, HD CSPs, and HD waste into and out of the HD buffer (e.g., pass-through chamber). Pass through chambers are included in semi-annual facility certification. [USP 800 Section 5.3.2]	
C-SEC SINK & SAFETY EQUIPMENT: A sink is available for hand washing and an eyewash station and/or other emergency safety precautions meeting applicable laws and regulations are readily available and located where operation does not interfere with ISO classifications. Sinks are located at least 1 meter from the entrance into the buffer room (or at least 1 meter from the C-PEC in a C-SCA). [USP 800 Sections 5.3 & 5.3.2]	
C-PEC LOCATION, VENTING, & OPERATION: All C-PECs used for sterile HD compounding (e.g., CACIs or BSCs), are located within a C-SEC or C-SCA, externally vented, and maintain an ISO 5 or better air quality. C-PECs operate continuously if supplying some or all the negative pressure in the C-SEC or if used for sterile compounding. During power outages, repairs, or relocation, C-PEC use is suspended immediately. Once C-PEC power is restored, all PEC surfaces are decontaminated, cleaned, and disinfected, and compounding is not resumed until the manufacturer's specified recovery time has elapsed. [USP 800 Section 5.3.2]	
REQUIRED HD PPE: When compounding HDs, gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are donned per facility SOPs. Chemotherapy gloves are tested to ASTM standard D6978 (or its successor) and are powder free and two pair of chemotherapy gloves are donned per SOP. Gloves are inspected for physical defects. Gloves are changed when torn, punctured, or contaminated. Personnel wash hands with soap and water after removing gloves. HD gowns are disposable, resistant to permeability by HDs, close in back, are long sleeved, closed cuff, and seamless. Gowns are changed per manufacturer's permeation information; if no data is available, HD gowns are change every 2-3 hours or immediately after a spill or splash. Gowns are limited to HD handling areas and are donned over the sterile compounding garment. When compounding, a second pair of shoe covers is donned before entering the C-SEC and doffed when exiting the C-SEC. HD PPE is disposed of appropriately prior to exiting the C-SEC. Chemotherapy gloves and sleeve covers (if used during compounding) are carefully removed and discarded immediately into an appropriate waste container inside of the C-PEC or contained in a sealable bag for discarding outside of the C-PEC. Reusable PPE is decontaminated and cleaned after each use. [USP 800 Section 7]	
EYE AND FACE PROTECTION: Appropriate eye (goggles) and face protection (face shield) are worn when there is a risk for spills or splashes or when working outside of a C-PEC. Surgical masks are not used when respiratory protection is required per SOP and/or AOR as protection from HD exposure. [USP 800 Section 7.4]	
HD TRAINING & COMPETENCY ASSESSMENT: Personnel who handle HDs are trained and demonstrate competency initially before independently handling HDs, annually, and when a new HD medication, process, SOP, or equipment is introduced. Training minimally includes an overview of the entity's HD list and their risks; review of HD SOPs; proper use of PPE, equipment, and devices; prevention of HD exposures and spills; HD exposure and spill response; use of a spill kit, PPE, and NIOSH-certified respirators; and HD disposal. Based on job duties, personnel receive additional HD training in HD acquisition and receipt, preparation, compounding, dispensing, labeling, storage, and transport. Training and competency assessments are documented. [USP 800 Sections 8, 9, 11.1, 16, & 17]	
HD ATTESTATION: Personnel of reproductive capability have a written acknowledgement attesting to their understanding of HD handling risks. [USP 800 Section 8]	
DEDICATED HD EQUIPMENT: Disposable or cleanable equipment for compounding (e.g., mortar and pestle, graduated cylinder, spatulas) is dedicated for use with HDs. [USP 800 Section 13]	

NON-HD COMPOUNDING IN A C-PEC: Non-HDs compounded in a HD C-PEC are placed in protective outer wrapping, labeled for PPE handling precautions, and treated as an HD. The C-PEC worksurface is decontaminated between compounding of different HDs. [USP 800 Section 5.3.2 and Table 3]	
DEACTIVATION, DECONTAMINATION, CLEANING & DISINFECTION (D/D/C/D): Areas where HDs are handled and all reusable equipment and devices are deactivated/decontaminated, and cleaned. Sterile compounding areas and devices are subsequently disinfected. Written procedures for decontamination, deactivation, cleaning, and disinfection are available and followed. Procedures include agents used, dilutions (if used), frequency, and documentation requirements. Agents selected are appropriate for the type of HD contamination(s), location, and surface materials. Sterile 70% IPA is used to remove residue left on sterile surfaces and compounding areas by decontaminating agents. [USP 800 Section 15]	
D/D/C/D TRAINING & PPE REQUIREMENTS: Personnel are trained in deactivation/decontamination, cleaning, and disinfection to protect themselves and the environment from contamination. Personnel wear appropriate PPE resistant to cleaning agents used, including 2 pairs of ASTM-tested chemotherapy gloves and impermeable disposable gowns. Eye protection and face shields are worn if splashing may occur. [USP 800 Section 15]	
C-PEC D/D/C/D: C-PEC is decontaminated at least daily (when used), after as spill, before and after certification, voluntary interruption, or if ventilation tool is removed. The C-PEC worksurface is decontaminated between compounding of different HDs. The area under the work tray of a C-PEC is deactivated, decontaminated, and cleaned at least monthly. [USP 800 Section 15.2]	
HD LABELING, PACKAGING, TRANSPORT & SPILLS HANDLING: Facility follows SOP for the labeling, handling, packaging, and transport of HDs which addresses the prevention of spills/exposures, training for exposure, and spill handling. HD CSPs are identified as hazardous and labeled with special handling precautions. Labeling process for compounded HD products does not introduce contaminated materials into non-HD areas. [USP 800 Section 11 & 11.2]	
SPILL KITS, & SINGAGE: Spill kits are readily available with appropriate supplies, PPE, and signs to restrict access to affected areas. restriction posted, and documentation of spills occur when needed. [USP 800 Section 16]	

X. LYOPHILIZATION

Sterile preparations prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling, and transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	
A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times. [64B16-27.797(5) F.A.C.]	
The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.]	
The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.]	
Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]	
The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.]	
SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.]	
The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.]	
Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.]	
Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin. [64B16- 27.797(5) F.A.C.]	
Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product. [64B16- 27.797(5) F.A.C.]	
A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.]	
Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.]	
Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has vieble air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record. [64B16-27.797(5) F.A.C.]	
Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.]	
Potency, radiochemical purity, or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight-based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.]	

Y. SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

Technicians properly identified. [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16- 27.420 F.A.C.].	
Medication is properly labeled for dispensing to patient. [64B16-28.108(2) F.A.C.]	
Outdated medications removed from active stock. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	

Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality Related Events are available for inspection. [64B 16 27.300 F.A.C.]; [766.101 (1) (a)(i) F.S.]	
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	
Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] [21CFR1304.04]	
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) F.A.C]	
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]	
A special sterile products and parenteral/enteral compounding pharmacy provides telephone accessibility to its pharmacist(s) for its patients at all hours. [64B16-28.820(3)(b)]	
A special sterile products and parenteral/enteral compounding pharmacy provides special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. [64B16-28.820(3)(b)]	

Z. Miscellaneous

BLOOD-DERIVED OR BIOLOGICAL MATERIAL MANIPULATIONS: Compounding activities that require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum), are clearly separated from other compounding activities and equipment used in CSP preparation activities and controlled by specific SOPs to avoid cross-contamination. [USP 797 Section 1.1.2]	
ALLERGENIC EXTRACTS: Licensed allergenic extracts are mixed and diluted to prepare prescription sets for administration to patients. A prescriptions set is a vial or set or vials of premixed licensed allergenic extracts for subcutaneous immunotherapy that have been diluted with an appropriate diluent for an individual patient. Compounding allergenic extracts 1) minimally complies with all aspects of USP <797> Section 21; 2) involves transfer via sterile needles and syringes of conventionally manufactured sterile allergen products and appropriate conventionally manufactured sterile added substances; and 3) manipulations are limited to penetrating stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile vials. If these conditions are not met, compounding of allergenic extracts follows all aspects of USP <797>. [USP 797 Sections 1.1.2 and 21]	

Corrective Action Plan

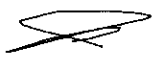
A corrective action plan is required to be submitted within 30 days for the non-compliant items listed above. [64B16-27.797(5), F.A.C.]	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

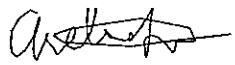
KHEIRABI, MARYAM



Date:6/18/2025

Representative:

Amelia yeh

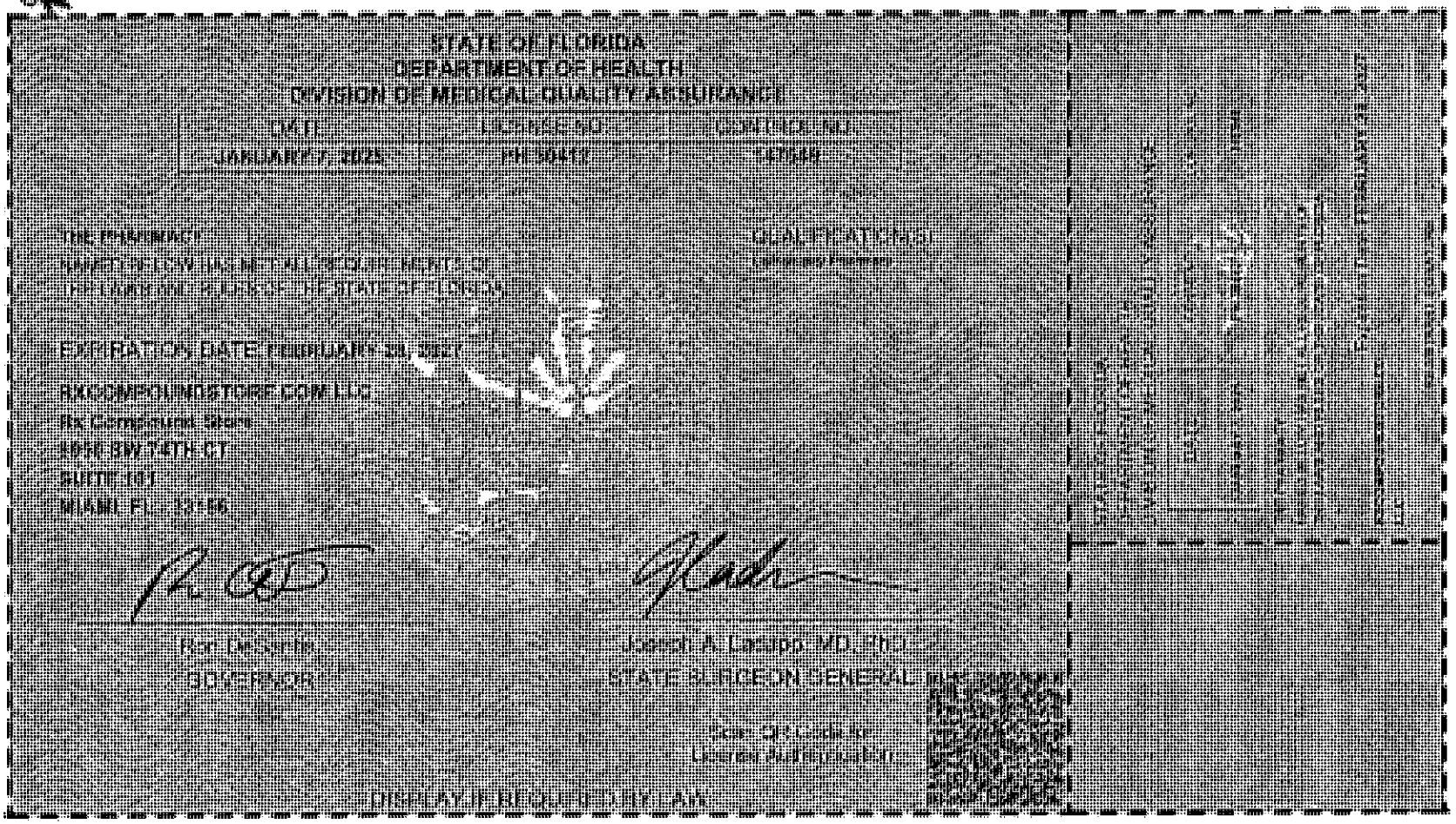


Date:6/18/2025

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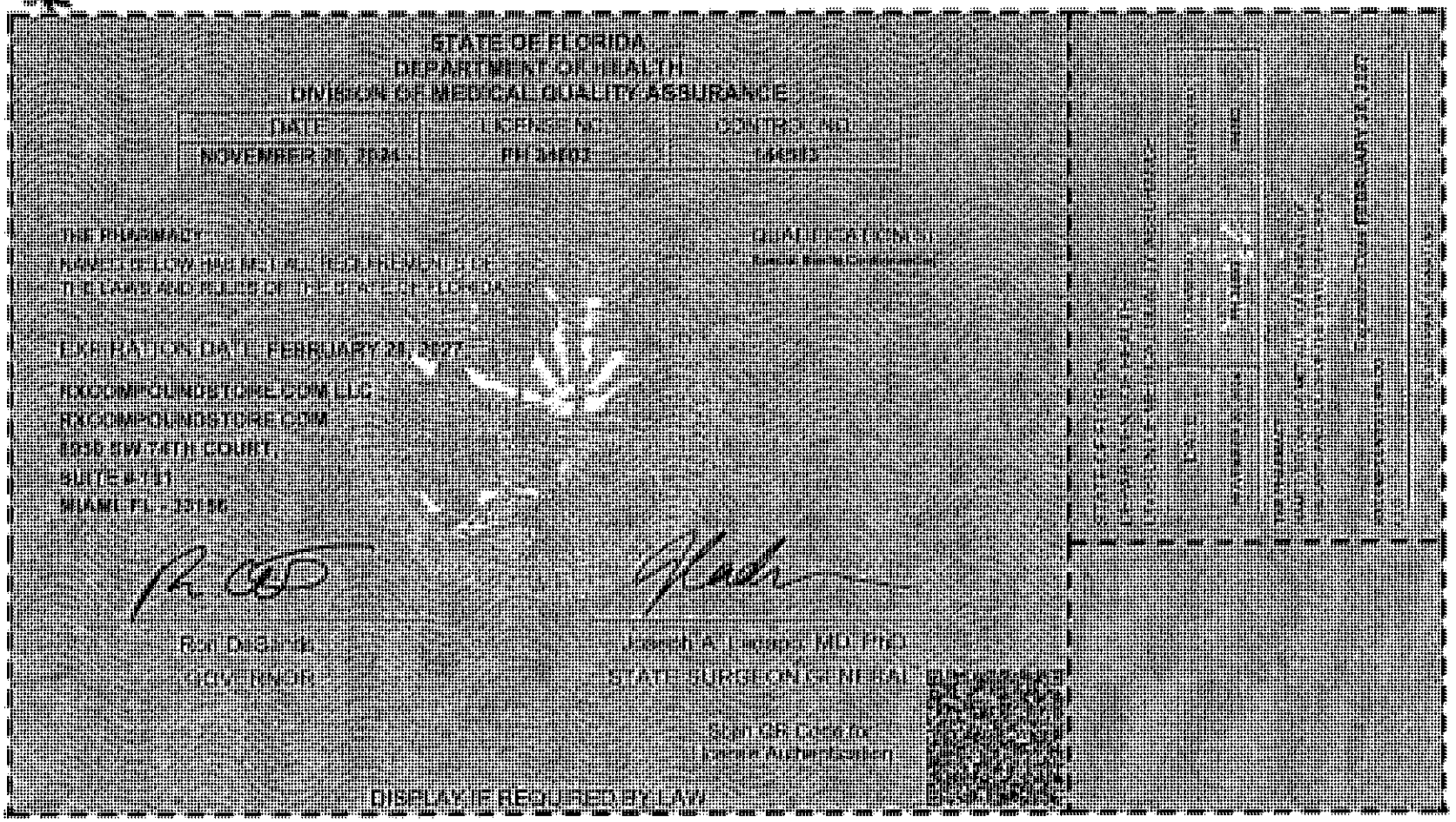
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Data As Of 11/13/2025

License Information | Secondary Locations | Discipline/Admin Action | Supervising Practitioners | Subordinate Practitioners

Profession	Pharmacy
License	PH30412
License Status	Clear/
Qualifications	Community Pharmacy
License Expiration Date	2/28/2027
License Original Issue Date	10/19/2016
Address of Record	8950 SW 74TH CT SUITE 101 MIAMI, FL 33156
Discipline on File	No
Public Complaint	No

Back

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Data As Of 11/13/2025

Profession	Pharmacy
License	PH30412
License Status	Clear/
Qualifications	Community Pharmacy
License Expiration Date	2/28/2027
License Original Issue Date	10/19/2016
Address of Record	8950 SW 74TH CT SUITE 101 MIAMI, FL 33156
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

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Public Records
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Please include the following:
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2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date

Click on the License Number to view License Details for that Practitioner

Subordinate Practitioners

Name	Relationship	Profession	License	Effective Date
RXCOMPOUNDSTORE.COM LLC	STERILE COMPOUNDING	PHARMACY	34603	3/13/2023

Click on the License Number to view License Details for that Practitioner

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

Department of Health

License Verification

Printer Friendly Version

RXCOMPOUNDSTORE.COM LLC

RXCOMPOUNDSTORE.COM

License Number: PH34603

Data As Of 11/13/2025

License Information | Secondary Locations | Discipline/Admin Action | Supervising Practitioners

Profession	Pharmacy
License	PH34603
License Status	Clear/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2027
License Original Issue Date	05/24/2023
Address of Record	8950 SW 74TH COURT, SUITE # 101 MIAMI, FL 33156
Discipline on File	No
Public Complaint	No

Back

For instructions on how to request a license certification of your Florida license to be sent to another state from the Florida Department of Health, please visit the License Certifications web page.

Primary Source Verified

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Department of Health

RXCOMPOUNDSTORE.COM LLC

RXCOMPOUNDSTORE.COM

License Number: PH34603

Data As Of 11/13/2025

Profession	Pharmacy
License	PH34603
License Status	Clear/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2027
License Original Issue Date	05/24/2023
Address of Record	8950 SW 74TH COURT, SUITE # 101 MIAMI, FL 33156
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: RxCompoundStore.com

NV Pharmacy or Outsourcing facility license # (if applicable): PH04469

Physical Address: 8950 SW 74th Ct Ste 101

City: Miami State: FL Zip: 33156

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 786-803-8947 Toll Free # (NAC 639.708, NRS 639.23286): 833-792-6673

Fax: 844-875-0009 Contact Email: shibu.john@rxcs.net

Website: https://rxcompoundstore.com/

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Shibu John

Supervising/Managing Pharmacist NV Pharmacist Registration #: 14862

Name of Designated Person(s) as defined by revised USP-797 guidelines: Shibu John

Email of Designated Person(s): shibu.john@rxcs.net

Telephone of Designated Person(s): 448-230-2986

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ☐ Category 2 ■ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? | Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☐ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? June 2025

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? _____

10. Will you be performing sterile hazardous drug compounding? Yes ■ No

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

1. Semaglutide
2. Tirzepatide
3. Tirzepatide/Pyridoxine
4. Tirzepatide/Methylcobalamin
5. Ascorbic acid
6. Glutathione
7. Methylcobalamin
8. Methionine/Inositol/Choline Chloride/Cyanocobalamin
9. Monomix (Alprostadil)
10. Trimix (Papaverine/Phentolamine/Alprostadil)
11. NAD+
12. Tesomorelin

12. What laboratory performs your sterility or endotoxin testing?

Name: Pharmetric Lab

Address: 7265 Ulmerton Rd.

City: Largo State: FL Zip: 33716

Telephone: 727-209-5778

13. What is your procedure for visual inspection of compounded sterile products?
Upon completion of compounding and prior to releasing and dispensing, the CSPs must undergo a visual inspection by pharmacists to ensure their physical appearance meets expectations. The visual characteristics to be observed include appearance, cleanliness, color, viscosity, particulates, discoloration, uniformity, clarity, turbidity, precipitate, leaks, cracks in the container, improper seals, and other defects. The CSP label must aslo visually inspected to ensure that the CSP and its labeling match the prescription or medication order.

14. How often do you perform glove fingertip and medial fill testing?
Every 3 months for compounding personnel, and annually for designated supervisors.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
All personnel involved in sterile compounding and designated individuals are required to complete an initial and annual training program. This training also includes, but is not limited to, reading the required department SOPs, USP Chapter 797, and understanding CoAs and SDSs.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Please see the attached document: Cleanroom Suite Cleaning and Maintenance Outline.

17. Who performs the sterile compounding process at your facility?

Pharmacy technician: Dayli Caballero, Giselle Canas, Elianny Gonzalez

18. Who is responsible and accountable for the sterile compounding process at your facility?
Pharmacist Hong-Chun Yeh.

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Insulated Foam Shipping Kits or Metallic Insulated Mailers with multiple ice packs were used to ensure the safety and efficacy of products. All packages are shipped overnight, Monday through Thursday, via third-party carriers.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Are you complying with all USP 800 guidelines?	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

1. Semaglutide
2. Tirzepatide
3. Tirzepatide/Pyridoxine
4. Tirzepatide/Methylcobalamin
5. Ascorbic acid
6. Glutathione
7. Methylcobalamin
8. Methionine/Inositol/Choline Chloride/Cyanocobalamin
9. Monomix (Alprostadil)
10. Trimix (Papaverine/Phentolamine/Alprostadil)
11. NAD+
12. Tesomorelin

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

Every 3 months for compounding personnel, and annually for designated supervisors.

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ■ Yes No

4. What is the frequency for completing volumetric active air sampling?

Every 30 days

5. What is the frequency for completing surface sampling? Every week		
6. What is the frequency for using sporicidal agents? Weekly for PECs and equipment inside the PECs, pass-through chamber, work surfaces outside the PEC, floors. Monthly for walls, doors, door frames, ceilings, storage shelving and bins, and equipments outside of the PECs.		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	■ Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	■ Yes	No

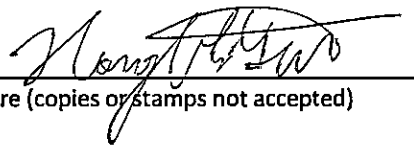
I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hong-Chun Yeh

Name of Person who Completed the Form

Pharmacist

Title



Signature (copies or stamps not accepted)

11/13/2025

11/13/2025

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

Cleanroom Suite Cleaning and Maintenance Outline

1.1. Daily Cleaning

1.1.1. Before Compounding (AM)

1.1.1.1. Remove visible particles or debris if needed - Sterile Water for Irrigation

1.1.1.2. Sterile TB1-3300 followed by sIPA 70% for

1.1.1.2.1. Interior and exterior PEC and CVE

1.1.1.2.2. Equipment inside the PEC

1.1.1.2.3. Pass-through chamber

1.1.1.2.4. Work surfaces outside the PEC: carts, tables

1.1.1.2.5. High touch areas: door handles, touch plates, etc.

1.1.1.3. sIPA 70%

1.1.1.3.1. High touch equipment that may be damaged by disinfectants: computer screen, keyboard, mouse, pen, chairs etc.

1.1.2. After Compounding at the End of the Day (PM)

1.1.2.1. Remove visible particles, debris, or residue if needed - Sterile Water for Irrigation

1.1.2.2. Sterile TB1-3300 followed by sIPA 70% for

1.1.2.2.1. Interior and exterior PEC and CVE

1.1.2.2.2. Equipment inside the PEC

1.1.2.2.3. Pass-through chamber

1.1.2.2.4. Work surfaces outside the PEC: carts, tables

1.1.2.2.5. High touch areas: door handles, touch plates, etc.

1.1.2.2.6. Sink

1.1.2.2.7. Mini Fridge

1.1.2.2.8. Floor

1.1.2.3. sIPA 70%

1.1.2.3.1. High touch equipment that may be damaged by disinfectants: computer screen, keyboard, mouse, pen chairs, etc.

1.1.2.4. Trash discarded.

1.1.2.5. Sticky Mats changed (not located in any classified area)

1.2. Weekly

1.2.1. Remove visible particles, debris, or residue if needed - Sterile Water for Irrigation

1.2.2. Sterile PeridoxRTU followed by sIPA 70% for

1.2.2.1.1. Interior and exterior PEC and CVE

1.2.2.1.2. Equipment inside the PEC

1.2.2.1.3. Pass-through chamber

1.2.2.1.4. Work surfaces outside the PEC: carts, tables

1.2.2.1.5. High touch areas: door handles, touch plates, etc.

1.2.2.1.6. Both bottom vents in Buffer Room and Anteroom

1.2.2.1.7. Sink

1.2.2.1.8. Mini Fridge

1.2.2.1.9. Floor

1.2.2.2. sIPA 70%

1.2.2.2.1. High touch equipment that may be damaged by disinfectants: computer screen, keyboard, mouse, pen, chairs, etc.

1.2.2.3. Trash discarded.

1.2.2.4. Sticky Mats changed (not located in any classified area)

1.3. Monthly

1.3.1. Remove visible particles, debris, or residue if needed - Sterile Water for Irrigation

1.3.2. Sterile PeridoxRTU followed by sIPA 70% for

1.3.2.1.1. Interior and exterior PEC and CVE

1.3.2.1.2. Equipment outside and inside the PEC

1.3.2.1.3. Pass-through chamber

1.3.2.1.4. Work surfaces outside the PEC: carts, tables

1.3.2.1.5. High touch areas: door handles, touch plates, etc.

1.3.2.1.6. Ceilings, walls, doors, door frames

1.3.2.1.7. Storage shelving and bins

1.3.2.1.8. Sink

1.3.2.1.9. Mini Fridge

1.3.2.1.10. Floor

1.3.2.2. sIPA 70%

1.3.2.2.1. High touch equipment that may be damaged by disinfectants: computer screen, keyboard, mouse, pen, chairs, etc.

1.3.2.3. Trash discarded.

1.3.2.4. Sticky Mats changed (not located in any classified area)

2880 Bergey Road, Ste. K
Hatfield, PA 19440
www.envservices.com
800 - 345 - 6094

Presents:

Biological Sampling Report

Control ID #: 228-352940-1-71958V

Prepared for:

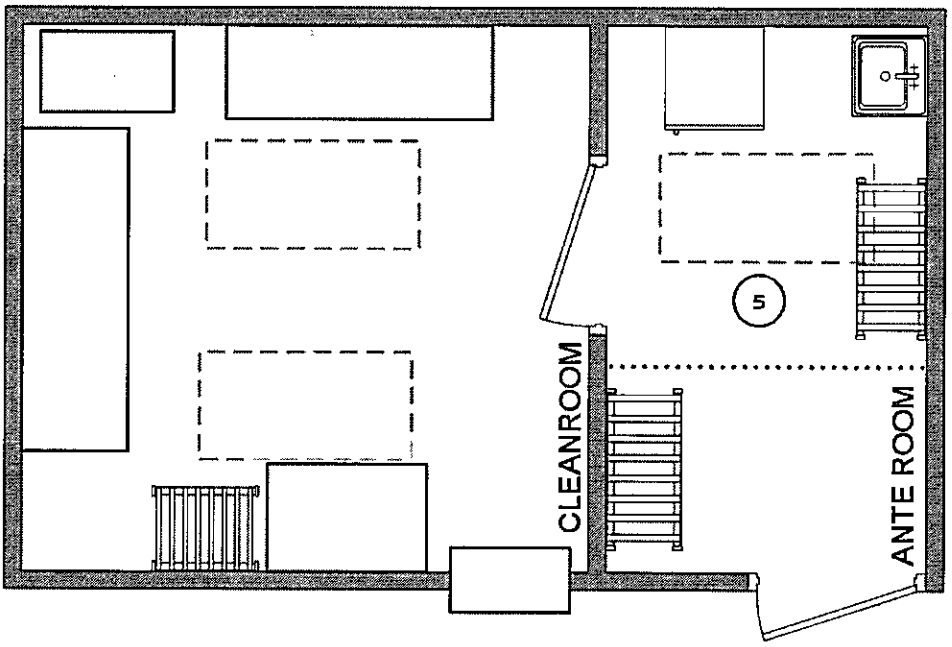
RX COMPOUND STORE
8950 SW 74TH CT, SUITE 101
MIAMI, FL 33156

Location Tested:
CLEANROOM

Date(s) Tested:
11 JUN 2025
Field Service Technician(s):
BOB HOFFMAN

BIOLOGICAL SAMPLING LOCATIONS

CLEANROOM
OPERATIONAL / DYNAMIC
Note: 1 RX COMPOUND STORE employee(s) present during sampling



Sample Location Key

- Air And Surface, Bacteria and Fungal
- Surface Only, Bacteria and Fungal
- Air Only, Bacteria and Fungal

ENV SERVICES, Inc. PROVIDING NATIONWIDE SOLUTIONS, CERTIFICATION, CALIBRATION, VALIDATION, CLEANROOMS	Project: **RX COMPOUND STORE** **8950 SW 74TH CT, SUITE 101** **MIAMI, FL 33156**
Test Date: 11 Jun 2025	Control ID #: 228-352940-1-71958V

TEST EQUIPMENT

CLEANROOM
RX COMPOUND STORE
MIAMI, FL 33156

Equipment Name	Manufacturer	Model	Serial	Calibration Due Date
VIABLE SAMPLER	PBI	SAS DUO 360	08-DC-06375	02 JAN 26

All testing is performed by qualified personnel using instrumentation, procedures and methods which ensure measurements observed are reliable. When specified, testing is performed in accordance with current ISO-17025, ISO-14644, USP-<797> and ENV's Quality Manual. Specifications comply with One or More of the following; applicable IEST recommended practices, CETA CAG-009, Manufacturer Recommendations, and/or customer determined specifications. Measurement instruments used are traceable to The National Institute of Standards and Technology (NIST). Results obtained apply to the specific room or equipment and are reflective of conditions at the time of this test.

Test equipment calibration certificates available upon request.
All viable sampling media plates and swabs supplied by ENV Services, Inc. contain neutralizing additives lecithin and polysorbate 80 per USP<797 > and USP < 825 > requirements.
Company ID: FL2163-001 Unique ID: 638710

RP25061812

M-BioLabs

ISO/IEC 17025:2017 Accredited
PJLA Accreditation # 94315
Testing

12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

USP<797> & USP<825> Viable Sample Report

Client Project ID:

228-352940-1 FL2163-001 RXCOMPOUNDSTORE.COM, LLC

Reported To:
Client Name: ENV Services, Inc
Client Address: 2880 Bergey Road, Suite K
City, State, Zip: Hatfield, PA 19940
Attn: Reports Dept
Sample(s) Condition: Acceptable.

Job ID: 25061211
Date Received: 06/12/2025
Report Generation: 06/18/2025

Overall Comments: No Growth.

Above Action Level Sample Summary

COC No.	Room	Description	Test Method	ISO Class	Result (Total CFUs)	Comments

* Samples with microorganisms above the action levels per USP<825> & USP<797>(2023) or per client request, deemed highly pathogenic. Refer to sample page below for detailed results.

USP<825> & USP<797>(2023) Action Levels for Microbial Contamination

ISO Class	Particulate Size (≥0.5m/m³)	Air (1000L) (CFU/m³/device)	Surface (CFU/device)	After Media-Fill Gloved Fingertip (CFU/device, combined hands)	After Garbing Gloved Fingertip (CFU/device, combined hands)	Media-Fill Test
5	3,520	>1	>3	>3	>0	+ or -
7	352,000	>10	>5	N/A	>0	N/A
8	3,520,000	>100	>50	N/A	>0	N/A
Unclassified SRPA/SCA	N/A	N/A	N/A	N/A	N/A	N/A

Authorized By:

Luis Gutierrez, M.S.
Laboratory Supervisor

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2507

M-BioLabs

12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

Client Name: ENV Services, Inc
Client Project ID: 228-352940-1 FL2163-001 RXCOMPOUNDSTORE.COM, LLC

Job ID: 25061211
Report Generation: 06/18/2025

Pass (<1 CFU): No visible growth present, less than the limit of detection.
Under Action Levels (UAL): Microorganisms under the recommended action levels per USP<797> & USP<825>
Above Action Levels (AAL): Microorganisms above the recommended action levels per USP<797> & USP<825> or per client request, deemed highly pathogenic.
Unclassified (N/A): non-HEPA filtered area.

COC No.	Status	Result (Total CFUs)	ISO Class	Room	Description	Test Method	Sample Volume Date/Time	Lab Sample ID
5		<1 (CFU/m³)	8	ANTE ROOM	CENTER OF ROOM	FUNGAL - AIR	1000(L) 06/11/2025 13:09	25061211.01
N/A	N/A	<1	N/A	N/A	(-) Controls	(-) FUNGAL CONTROL	N/A 06/11/2025 00:00	25061211.02
N/A	N/A	Growth	N/A	N/A	(+) Controls	(+) FUNGAL CONTROL	N/A 06/11/2025 00:00	25061211.03

Media Information

Test Parameter	Media	Manufacturer	Lot#	Exp. Date
FUNGAL - MEDIA	TSA w/neutralizing additives	BioMerieux	1011097690	07/26/2025

Incubation Log

Reporting Matrix	Parameter	Start Date/Time	Temperature (°C)	Stop Date/Time	Temperature (°C)
MEDIA PLATE	Fungal	06/12/2025 11:48	23.3	06/18/2025 09:50	23.8

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2508

M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

Client Name: ENV Services, Inc
Client Project ID: 228-352940-1 FL2163-001 RXCOMPOUNDSTORE.COM, LLC

Job ID: 25061211
Report Generation: 06/18/2025

USP<797> & USP<825> Supplemental Information

1. Growth Media
   - 1.1. Single-Plate Method
     - 1.1.1. The sample undergoes two incubations periods at times and temperatures to promote growth of baeteria and fungi.
       - 1.1.1.1. The sample is incubated inverted at 30°-35° for no less than 48 hours.
       - 1.1.1.2. The sample is examined for growth and results are recorded.
       - 1.1.1.3. Then the sample is incubated inverted at 20°-25° for no less than 5 additional days.
       - 1.1.1.4. The sample is again examined for growth and results are recorded.
   - 1.2. Dual-Plate Method
     - 1.2.1. Bacteria media device is incubated inverted at 30°-35° for no less than 48 hours.
     - 1.2.2. Fungal media device is incubated inverted at 20°-25° for no less than 5 days.

2. Viable Sampling Testing
   - 2.1. Air:
     - 2.1.1. Results are reported as CFU/m^3 of air.
   - 2.2. Surface:
     - 2.2.1. Results are reported as CFU per device.

3. Media-Filled Testing
   - 3.1. Media-filled vial or IV bag is incubated for 7 days at 20°-25° followed by 7 days at 30°-35°.

4. Gloved Fingertip and Thumb Testing
   - 4.1. The sampling device is incubated inverted at a temperature range of 30°-35°C for no less than 48 hours and then at 20°-25°C for no less than 5 additional days.
   - 4.2. Results are reported separately as number of CFU per hand (left hand, right hand).
   - 4.3. Results are also reported as the combined results for both the left hand and right hand.
     - 4.3.1. The combined results determine whether the CFU action level is exceeded.

5. Reporting Information
   - 5.1. The results found in this report are solely tied to the project above and the samples therein.
   - 5.2. Positive controls are unopened samples submitted for growth promotion testing (inoculation) which eliminates false negatives. Negative controls are unopened samples submitted for incubation solely which eliminates false positives.
   - 5.3. A positive-hole correction factor has been applied to all applicable air samples. The positive-hole correction factor accounts for the statistical possibility that multiple viable particles can pass through the same hole of an air sampler head. The positive hole correction factor is applied to the total plate colony count, therefore the sum of individual organism calculated counts may be reported as less than the total plate corrected count.
   - 5.4. MRL (minimum reporting limit) is 1cfu/device unless otherwise stated on comments table.
   - 5.5. "CFU TNTC" CFU exceeds countable limits of media device.
   - 5.6. "*" next to Sample ID, refer to sample comments table for details.
   - 5.7. Reported sampling date/time default to a blank date and time of 00:00 unless sampling date/time provided by client on the chain of custody.
   - 5.8. Growth will be reported to the Genus and species level if a high enough confidence score is reached through MALDI-TOF MS method. If the confidence score threshold results in Genus only, the organism will be reported to Genus level only. If neither option is available, the organism will be subcultured and the new growth will then go through the above process for additional attempts for identification. If the confidence score is still not high enough to report to Genus and species level or Genus only, then additional biochemical analysis is performed. If the test options have been exhausted and the analysis is inconclusive to report at minimum Genus level, then the growth will be reported as "Misc. Gram Positive bacteria" or "Misc. Gram Negative bacteria". Fungi that have not received high confidence score through MALDI-TOF MS method, will be identified to Genus level only using Culture and Morphological identification. This process may result in the general classification of "Non-Sporulating Colony" or "Yeast".

6. References

- USP<797> Pharmaceutical Compounding-Sterile Preparations, 2023.
- USP<825> Radiopharmaceuticals-Preparation, Compounding, Dispensing, And Repackaging, 2020. Jorgensen H., James, et al.
- Manual of Clinical Microbiology: 11th Edition. ASM Press, 2015.
- Holt G., John, et al. Bergey's Manual of Determinative Bacteriology: 9th Edition. Williams & Wilkins, 1994.
- St-Germain, Guy, and Richard Summerbell. Identifying Fungi: A Clinical Laboratory Handbook 2nd Edition. Star Publishing Company, 2011.
- Sciortino, Jr. V., Carmen. Atlas of Clinically Important Fungi. Wiley Blackwell, 2017.
- de Hoog S., G., et al. Atlas of Clinical Fungi: The ultimate benchtool for diagnostics, USB Version 4.1. Centraalbureau voor Schimmelcultures, Utrecht, The Netherlands.

Note: All incubation times and temperatures listed above are not applicable to samples that have been "client incubated" prior to delivery to M-BioLabs.

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BIOMÉRIEUX

REF 420765

LOT 1011097690

Certificate of Analysis
Certificat d' Analyse

REF 420765 Irr Count-Tact 3P Agar Locksure 100PLT

LOT 1011097690 Count Tact Irradiées 3P 100BTES

2025-01-09 YYYY-MM-DD

2025-07-26 YYYY-MM-DD

Revision : 1

Animal or Human origin / Produit d'origine humaine ou animale

Component / Composant	Source / Origine	Risk Category / Catégorie de	Country / Pays
Bovine / Bovin	Bovine / Bovine	IV	Australia / Australie, New Zealand / Nouvelle-Zélande, USA / Etats Unis d Amérique

Animal Origin Notes

BioMérieux, Inc. screens applicable raw materials to ensure that source regions are not implicated in incidents of bovine spongiform encephalitis (BSE) or transmissible spongiform encephalitis (TSE) in compliance with the FDA's Code of Federal Regulations Title 9 Section 94.18.
Countries of origin for bovine materials in this product are restricted to New Zealand, United States and Australia. Bovine components include beef extract from skeletal muscle and/or casein from milk.
BioMérieux, Inc. inspecte les matières premières applicables afin de s'assurer que les régions d'origine ne sont pas impliquées dans des incidents d'encéphalite spongiforme bovine ou d'encéphalite spongiforme transmissible, conformément au Code of Federal Regulations Title 9 Section 94.18 de la FDA.
Les pays d'origine des composants bovins de ce produit sont restraints à le Nouvelle-Zélande, aux USA et à l'Australie. Les composants bovins contiennent des extraits de boeuf de muscle squelettique et/ou de caséine de lait.

Test(s) / Contrôle(s)	Result(s) / Résultat(s)	Specification(s) / Spécification(s)
Maximum Delivered Dose Dose Delivrée Maximale	16.0 kGy	Dose Range 9.1 - 22.0 kGy Dose 9.1 - 22.0 kGy
Minimum Delivered Dose Dose Delivrée Minimale	11.3 kGy	Dose Range 9.1 - 22.0 kGy Dose 9.1 - 22.0 kGy
Date	10-Jan-25	Irradiation Run Date
Appearance Test Test d'Apparence	Conform / Conforme	Lt - Med. Amber, Clear to Trace Hazy, Firm Gel Ambré Clair à Ambré Moyen, De Clair à Légèrement Opalescent, Gel Ferme
pH	7.3	7.3 ± 0.2 @ 25°C
ASPERGILLUS BRASILIENSIS ATCC 16404	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %
BACILLUS SUBTILIS SSP SPIZIZENII ATCC 6633	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %
CANDIDA ALBICANS ATCC 10231	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %
ESCHERICHIA COLI ATCC 8739	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %
PSEUDOMONAS PARAERUGINOSA ATCC 9027	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %
STAPHYLOCOCCUS AUREUS ATCC 6538	Conform / Conforme	Growth - 50 to 200% Recovery Croissance - Taux de Récupération de 50 à 200 %

bioMérieux Inc.
100 Rodolphe Street
Durham, North Carolina 27712 USA
Manufacture site: bioMerieux 1121 N Main St. LOMBARD USA 2510

BIOMÉRIEUX

REF 420765

LOT 1011097690

bioMérieux, Inc. is certified to ISO 9001 and is compliant with FDA Quality System Regulations (QSR) 21CFR820. This product has met all bioMérieux, Inc. quality standards and has been released for distribution.
Irradiated media is validated to a Sterility Assurance Level (SAL) of 10-5 in unopened/undamaged packages. Sterility is evaluated with minimum incubation time of 5 days at 20-25C and 33-37C.
3P is a registered trademark of bioMérieux, Inc. ATCC is a registered trademark of American Type Culture Collection. Growth promotion testing is compliant to requirements by the United States Pharmacopoeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP).
Media pH will vary depending on the age of the product and the type of pH meter and probe used.
bioMérieux, Inc. est certifié ISO 9001 et est conforme au FDA Quality System Regulations (QSR) 21CFR820. Ce produit répond aux standards de qualité de bioMérieux, Inc. et a été libéré pour distribution.
Les milieux de culture irradiés sont validés conformément à un niveau de stérilité de 10-5 dans des emballages non ouverts et non endommagés. La stérilité est évaluée avec un temps d'incubation minimum de 5 jours à 20-25C et 33-37C.
3P est une marque déposée d'bioMérieux, Inc. ATCC est une marque déposée d'American Type Culture Collection. Les tests de croissance sont conformes aux exigences de la Pharmacopée des Etats-Unis (USP), de la Pharmacopée Européenne (EP) et de la Pharmacopée Japonaise.
Le pH varie avec l'âge du produit et le type de pH-mètre et de sonde utilisés.

Lot accepted on / Lot accepté le:	29-JAN-2025	by / par:	Vikas Kewalramani - Manager, Quality Lombard Quality Department / Département Qualité Lombard

Certificate Approved by / Certificate Approuvé par :

Approver Name / Nom de l'Approbateur : PERDUE Eric

Approval Date / Date d'Approbation : 29-JAN-2025

This document has been released electronically / Ce document a été libéré électroniquement

bioMérieux Inc.
100 Rodolphe Street
Durham, North Carolina 27712 USA
Manufacture site: bioMerieux 1121 N Main St. LOMBARD USA

2880 Bergey Road, Ste. K
Hatfield, PA 19440
www.envservices.com
800 - 345 - 6094

Presents:

Certification Report

Control ID #: 228-352940-66702

Prepared for:

RX COMPOUND STORE
8950 SW 74TH CT, SUITE 101
MIAMI, FL 33156

Location Tested:
CLEANROOM

Date(s) Tested:
04 JUN 2025
Field Service Technician(s):
DAVID KURILA

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SUMMARY REPORT

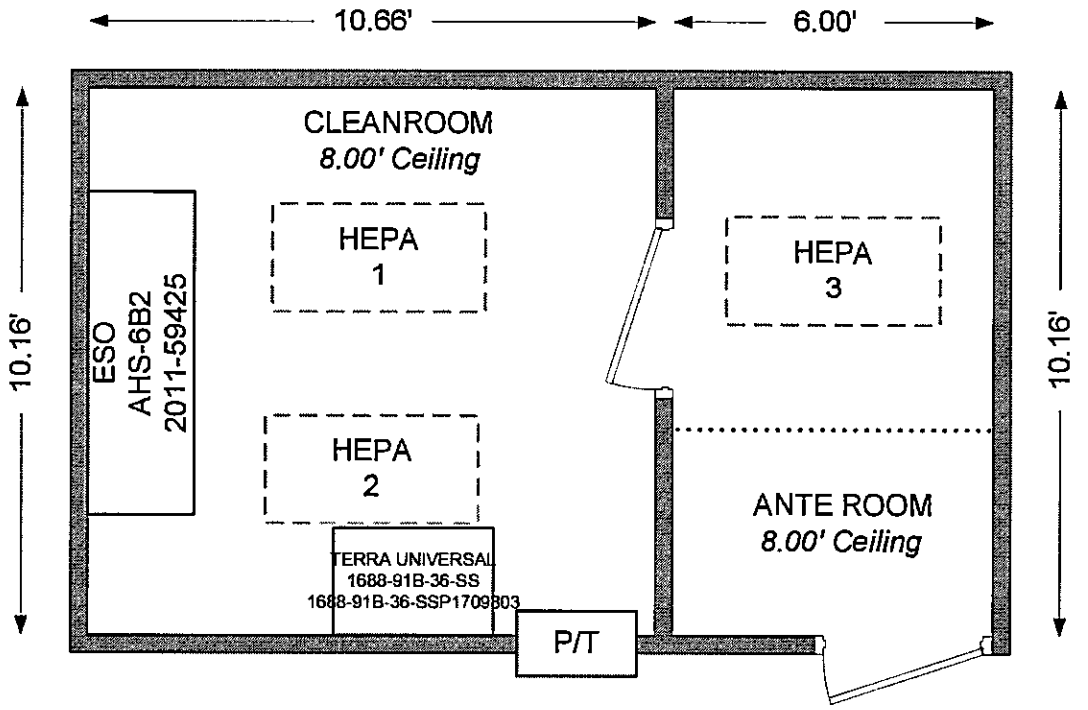
CLEANROOM
RX COMPOUND STORE
MIAMI, FL 33156

All testing is performed by qualified personnel using instrumentation, procedures, and methods which ensure measurements observed are reliable. All Testing is performed in accordance with current versions of ISO-17025, ISO-14644, USP<797>, <USP800>, <USP825>, and ENV's Quality Manual. Specifications comply with applicable IEST recommended practices, Current versions of CETA CAG-003 for Sterile Compounding Facilities, CETA CAG-009 Viable Environmental Monitoring for Sterile Compounding Facilities, and/or customer determined specifications when applicable. Measurement instruments used are traceable to The National Institute of Standards and Technology (NIST). Results obtained apply to the specific room or equipment and are reflective of conditions at the time of this test.

ANTE ROOM				
Test	**Test Result**	**Specification**	**Pass / Fail**	**Comment**
ISO Class	ISO 8 @ 0.5µm	ISO 8 @ 0.5µm	PASS	*2 employees in room.*
Total Air Changes / Hr.	51	≥ 20	PASS	
CLEANROOM				
Test	**Test Result**	**Specification**	**Pass / Fail**	**Comment**
ISO Class	ISO 7 @ 0.5µm	ISO 7 @ 0.5µm	PASS	*2 employees in room.*
Total Air Changes / Hr.	156	≥ 30	PASS	
ESCO AHS-6B2 S/N: 2011-59425				
Test	**Test Result**	**Specification**	**Pass / Fail**	**Comment**
ISO Class	ISO 5 @ 0.5µm	ISO 5 @ 0.5µm	PASS	*2 employees in room.*
HEPA FILTER LEAK TEST				
Test	**Test Result**	**Specification**	**Pass / Fail**	**Comment**
HEPA Leak	≤ 0.01%	≤ 0.01%	PASS	
ROOM PRESSURIZATION				
Test	**Test Result**	**Specification**	**Pass / Fail**	**Comment**
ANTE ROOM TO AMBIENT:	Positive | 0.062	Positive | ≥ 0.020	PASS	
CLEANROOM TO ANTE ROOM:	Positive | 0.110	Positive | ≥ 0.020	PASS	
TERRA UNIVERSAL 1688-91B-36-SS S/N: 1688-91B-36-SSP1709803				
Test	**Test Result**	**Specification**	**Pass / Fail**	**Comment**
ISO Class	ISO 5 @ 0.5µm	ISO 5 @ 0.5µm	PASS	*2 employees in room.*

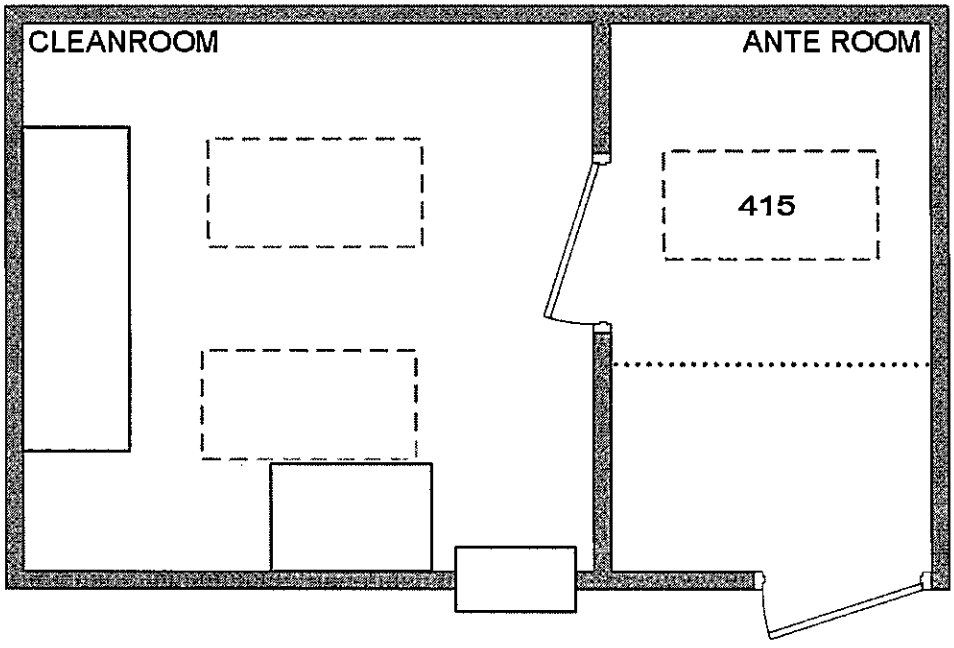
OVERVIEW

CLEANROOM
RX COMPOUND STORE
MIAMI, FL 33156



AIR SUPPLY VOLUMES & AIR CHANGES PER HOUR

CLEANROOM
(UNITS IN CUBIC FEET PER MINUTE) - OPERATIONAL / DYNAMIC
ANTE ROOM

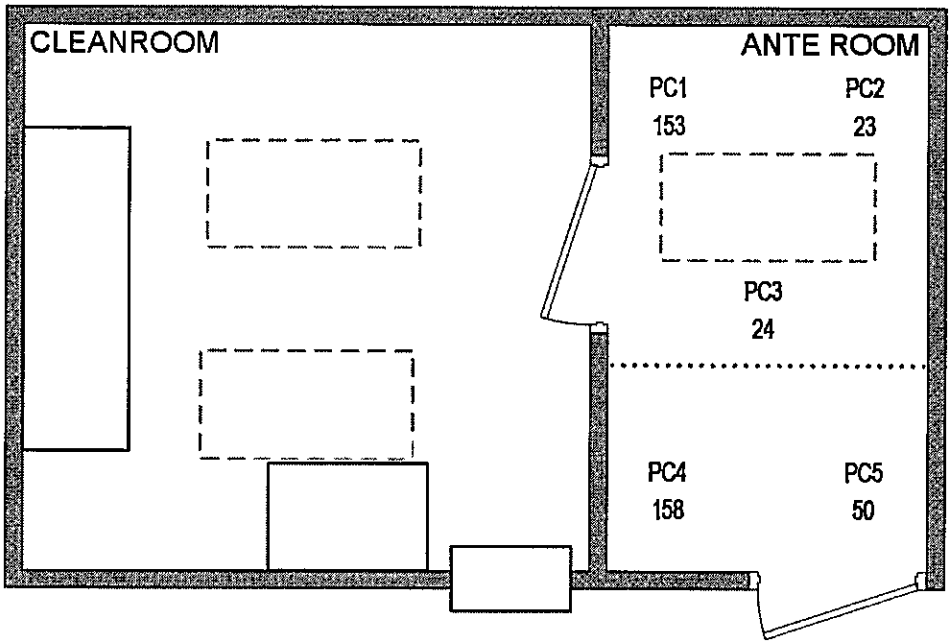


488	Room Volume
1	No. of Readings
415	Total Air Supply Volume
N/A	PEC Air Changes/Hour
51	Room Air Changes/Hour
15	Room ACH Specification
51	Total Air Changes/Hour
20	Total ACH Specification

Test Result
PASS

PARTICLE COUNTS

CLEANROOM
OPERATIONAL / DYNAMIC
ANTE ROOM



The above referenced clean zone has successfully passed the minimum requirements to meet the class listed below per ISO Standard 14644-1:2015 for particle count testing of cleanrooms and associated controlled environments.

Area(ft^2) 60.96

Area(m^2) 5.66

ISO Target Class 8

AT 0.5 MICRONS AND LARGER

Number of Locations	Highest concentration		Average concentration		ISO Class Resulting
	ft^3	m^3	ft^3	m^3	
5	158	5580	82	2882	8

* ISO Class 8 allows a maximum of 3520000 particles 0.5 per cubic meter as an average count at any location as long as the entire clean area meets the required statistical tests.

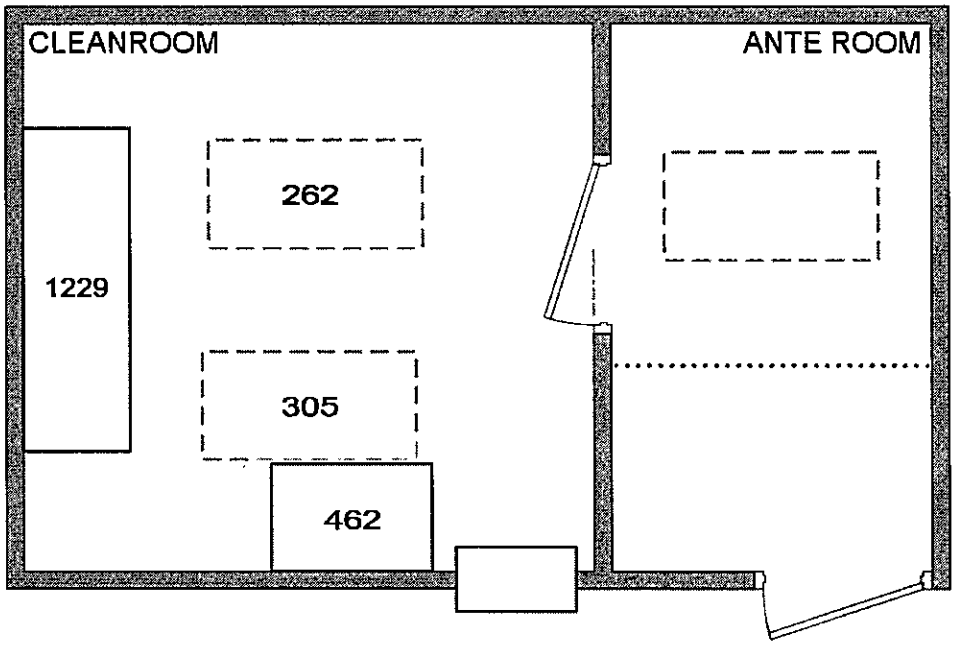
Sample Volume
1.00 ft^3
0.03 m^3
28.32 ℓ

Particulate Sampled
AT 0.5 MICRONS AND LARGER

Test Result
PASS

AIR SUPPLY VOLUMES & AIR CHANGES PER HOUR

CLEANROOM
(UNITS IN CUBIC FEET PER MINUTE) - OPERATIONAL / DYNAMIC
CLEANROOM

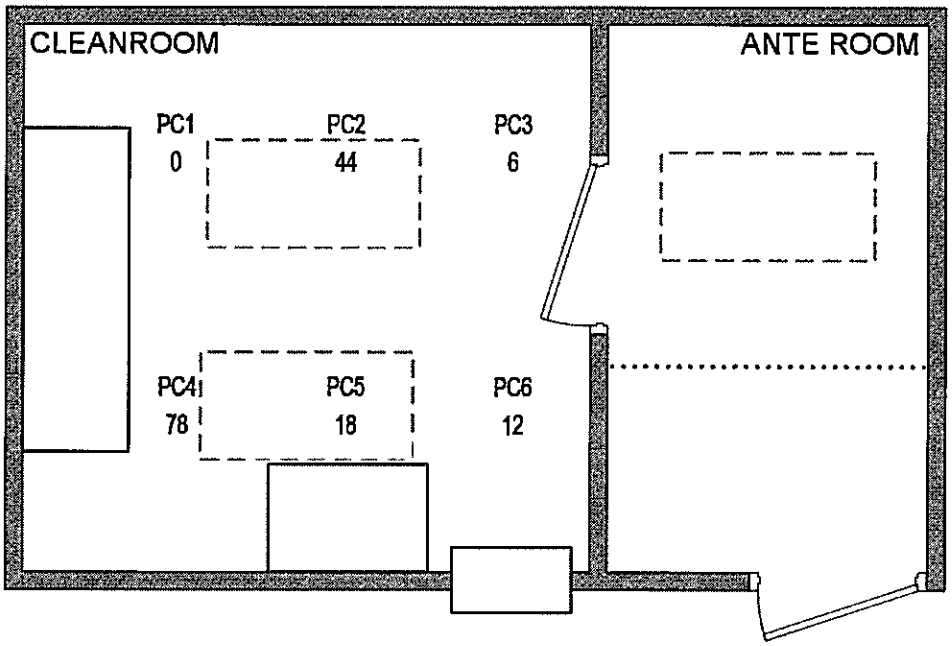


866	Room Volume
4	No. of Readings
2258	Total Air Supply Volume
117	PEC Air Changes/Hour
39	Room Air Changes/Hour
15	Room ACH Specification
156	Total Air Changes/Hour
30	Total ACH Specification

Test Result
PASS

PARTICLE COUNTS

CLEANROOM
OPERATIONAL / DYNAMIC
CLEANROOM



The above referenced clean zone has successfully passed the minimum requirements to meet the class listed below per ISO Standard 14644-1:2015 for particle count testing of cleanrooms and associated controlled environments.

Area(ft^2) 108.31

Area(m^2) 10.06

ISO Target Class 7

AT 0.5 MICRONS AND LARGER

Number of Locations	Highest concentration		Average concentration		ISO Class Resulting
	ft^3	m^3	ft^3	m^3	
6	78	2755	26	930	7

* ISO Class 7 allows a maximum of 352000 particles 0.5 per cubic meter as an average count at any location as long as the entire clean area meets the required statistical tests.

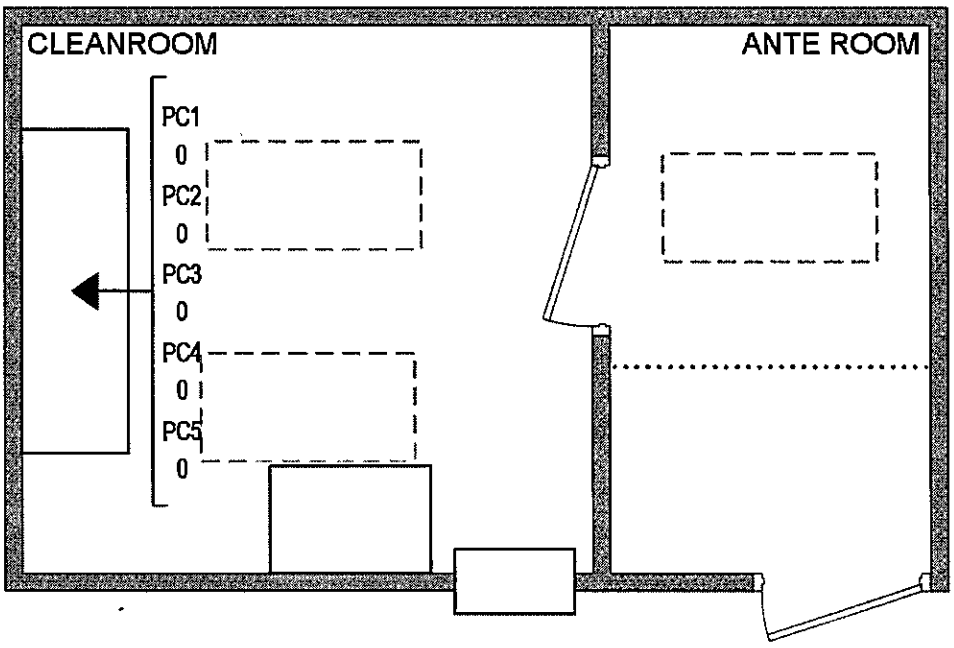
Sample Volume
1.00 ft^3
0.03 m^3
28.32 ℓ

Particulate Sampled
AT 0.5 MICRONS AND LARGER

Test Result
PASS

PARTICLE COUNTS

CLEANROOM
OPERATIONAL / DYNAMIC
CLEANROOM - ESCO AHS-6B2 S/N: 2011-59425



The above referenced clean zone has successfully passed the minimum requirements to meet the class listed below per ISO Standard 14644-1:2015 for particle count testing of cleanrooms and associated controlled environments.

Area(ft²) 12.00

Area(m²) 1.11

ISO Target Class 5

AT 0.5 MICRONS AND LARGER

Number of Locations	Highest concentration ft³	Highest concentration m³	Average concentration ft³	Average concentration m³	ISO Class Resulting
5	0	0	0	0	5

* ISO Class 5 allows a maximum of 3520 particles 0.5 per cubic meter as an average count at any location as long as the entire clean area meets the required statistical tests.

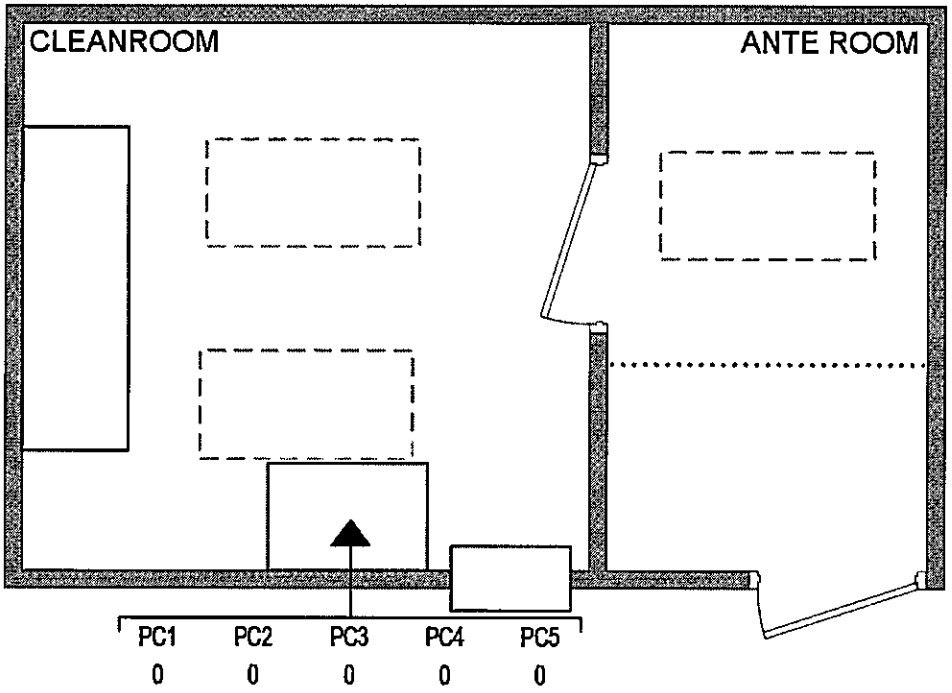
Sample Volume
1.00 ft³
0.03 m³
28.32 ℓ

Particulate Sampled
AT 0.5 MICRONS AND LARGER

Test Result
PASS

PARTICLE COUNTS

CLEANROOM
OPERATIONAL / DYNAMIC
CLEANROOM - TERRA UNIVERSAL 1688-91B-36-SS S/N: 1688-91B-36-SSP1709803



The above referenced clean zone has successfully passed the minimum requirements to meet the class listed below per ISO Standard 14644-1:2015 for particle count testing of cleanrooms and associated controlled environments.

Area(ft²) 6.00

Area(m²) 0.56

ISO Target Class 5

AT 0.5 MICRONS AND LARGER

Number of Locations	Highest concentration ft³	Highest concentration m³	Average concentration ft³	Average concentration m³	ISO Class Resulting
5	0	0	0	0	5

* ISO Class 5 allows a maximum of 3520 particles 0.5 per cubic meter as an average count at any location as long as the entire clean area meets the required statistical tests.

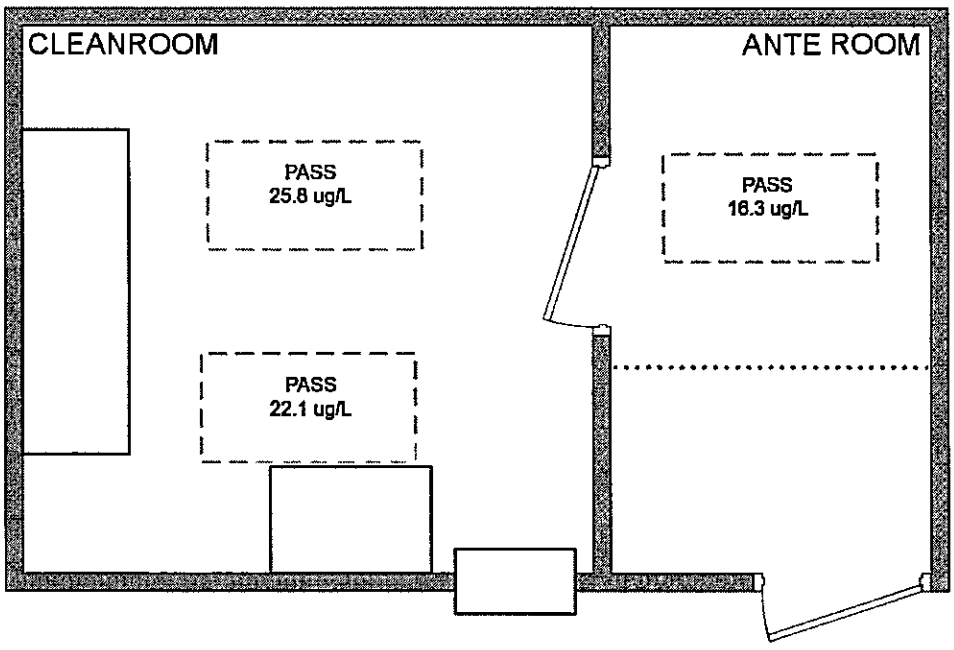
Sample Volume
1.00 ft³
0.03 m³
28.32 ℓ

Particulate Sampled
AT 0.5 MICRONS AND LARGER

Test Result
PASS

HEPA FILTER LEAK TEST

CLEANROOM
OPERATIONAL / DYNAMIC
HEPA FILTER LEAK TEST



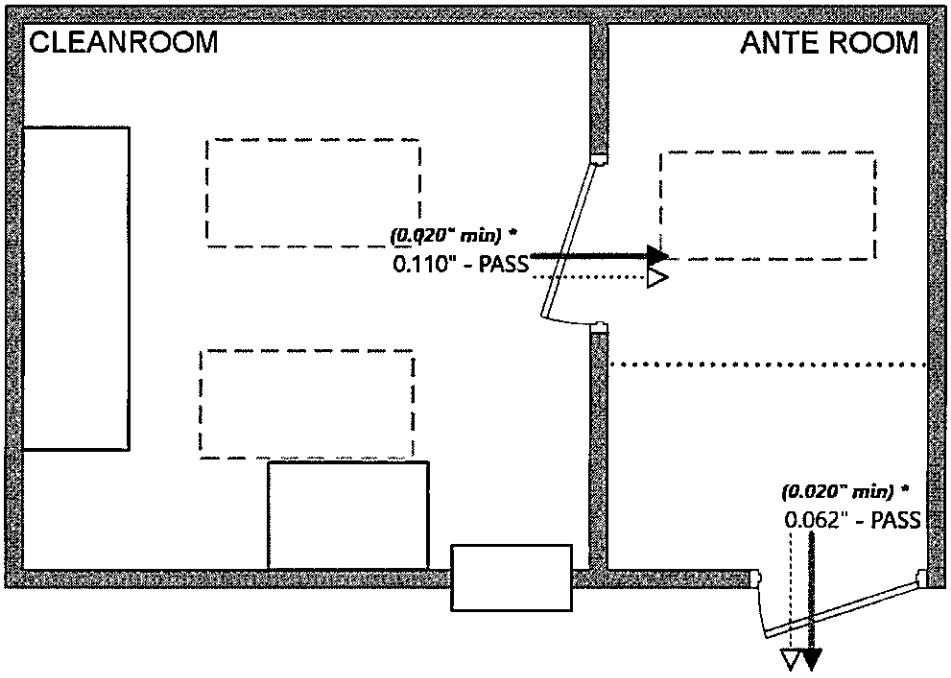
Aerosol challenge concentrations are ≥10ug/L.

PASS = No Leakage Detected

Test Result
PASS

ROOM PRESSURIZATION

CLEANROOM
(UNITS IN INCHES WATER GAUGE) - OPERATIONAL / DYNAMIC
ROOM PRESSURIZATION



Pressurization Actual Direction
Pressurization Design Direction
Pressurization Neutral
* Acceptance Criteria

Test Result
PASS

TEST EQUIPMENT

CLEANROOM
RX COMPOUND STORE
MIAMI, FL 33156

Equipment Name	Manufacturer	Model	Serial	Calibration Due Date
PARTICLE COUNTER	LIGHTHOUSE WORLDWIDE SOLUTIONS	SOLAIR 3100	190904008	08 OCT 25
ELECTRONIC BALANCING TOOL	ALNOR	EBT731	EBT732003024	30 AUG 25
PRESSURE GAUGE	AIR TECHNIQUES	0-30 PSI 6D	37509	18 SEP 25
PHOTOMETER	TEC SERVICES	PH-5	2156	05 DEC 25

Test equipment calibration certificates available upon request.
Company ID: FL2163-001 Unique ID: 638709

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RxCompoundStore.com
6950 Southwest 74th Court
Suite 101, Miami, FL 33156
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FAX: 844.875.0009
Email: orders@rxcompoundstore.com

Next

6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	B. COMPONENT BUDs (Single and Multi-dose Containers) – ALL CATEGORIES

MULTIDOSE CONTAINERS (MDCs): Upon initially entering or puncturing a conventionally manufactured MDC, the MDC is not used for more than 28 days unless otherwise specified by the manufacturer on the labeling. [USP 797 Section 15.2] *BUD 3 months, no Exp date on multi-dose vial. No other BUD assigned*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	The product was dispensed in a multi-dose container with a labeled BUD based on stability study supporting a BUD, leading to the assumption that the default 28-day limit per USP <797> Section 15.2 applies. Although a stability study supporting a 90-day BUD exists, this was not reflected on the container labeling. Additionally, a lack of clarity regarding the distinction between the manufacturer's expiration date and the compounding pharmacy–assigned Beyond-Use Date (BUD) contributed to the assumption that an expiration date was required on the CSP label. In accordance with USP <797> Section 13, only the BUD is required to be labeled on compounded sterile preparations.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

Review and verify that the existing stability report is USP-compliant and product-specific to MFR, container-closure system, and storage conditions. The stability report is condected under stability-indicating analytical methods per USP<51>, <71>, <8S>, and <788> if applicable.

Review the definitions of Beyond-Use Date (BUD) and Expiration Date to ensure the appropriate date, as required by USP <797>, is accurately reflected on the CSP label.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PRDCEDURE CHANGE:

Establish a standardized review process to ensure all assigned BUDs are supported by validated stability data and appropriately documented prior to product release.

Conduct periodic audits of finished product labels to verify that BUDs are clearly indicated, justified, and in compliance with USP <797> requirements.

Maintain a centralized and accessible repository of validated stability studies and supporting documentation to ensure readiness for regulatory inspections and internal quality reviews.

Update relevant standard operating procedures (SOPs) to clearly define and differentiate expiration date and BUD, including specific guidance on labeling requirements for CSPs and multi-dose containers.

SOP REFERENCE

6.006 POTENCY, STABILITY, BUD TESTING FOR CNSP AND CSP
6.020 BEYOND-USE DATING FOR CSP
6.025 BEYOND-USE DATING FOR STERILE COMPOUNDED PREPARATIONS

REVIEW DATE:	7/14/2025	**PHARMACY DESIGNEE:**	Shibu John, Amelia Yeh

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6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	E. EQUIPMENT, SUPPLIES, & COMPONENTS – ALL CATEGORIES

EQUIPMENT SOPs: Written SOPs for the calibration, maintenance, cleaning, and use of equipment are established and are based on the manufacturer's recommendations. Procedures are followed and records are maintained. [USP 797 Section 9.1] *no SOP at time of inspection*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	The SOPs for equipment calibration, maintenance, cleaning, and use were in place; however, they were not readily located or presented during the inspection due to deficiencies in document control and accessibility protocols.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

We immediately retrieved and verified the existence of all required SOPs related to equipment calibration, maintenance, cleaning, and use. In addition, a full internal audit was conducted t to ensure all current SOPs are properly indexed, stored, and accessible in both digital and physical formats.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

Implement a centralized SOP management system with clearly labeled categories and responsible personnel for easy and immediate retrieval.

Train all relevant staff on the updated SOP access procedure, including how to locate and provide SOPs during inspections.

Schedule audits of SOP documentation to verify accessibility, version control, and staff awareness.

Assign a designated compliance officer or SOP coordinator to oversee documentation readiness for future inspections.

SOP REFERENCE

5.002 BALANCES—USE, CLEANING AND MAINTENANCE
5.004 AUTOCLAVE USE, CALIBRATION, CLEANING, MAINT
5.006 INCUBATORS -USE, CALIBRATION, CLEAN, MAINT
5.007 pH METER--USE, CLEANING, CALIBRATION, MAINTENANCE
5.013 DRY HEAT OVEN--USE, CLEAN, CALIBRATION, MAINT

REVIEW DATE:	7/14/2025	**PHARMACY DESIGNEE:**	Shibu John, Amelia Yeh

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6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	H. CERTIFICATION AND RECERTIFICATION – ALL CATEGORIES

MONITORING DEVICE CERTIFICATION: Temperature and humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. [USP 797 Section 4.2] *No SOP or documentation available at the time of inspection*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	Lack of a written standard operating procedure (SOP) and oversight in maintaining documentation of verification activities led to the inability to produce records or guidance during inspection. The process existed informally but was not standardized or documented, resulting in noncompliance.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

SOP Development and Implementation:
A written SOP titled "Monitoring Device Certification" has been developed and approved as of 7/14/2025. This SOP outlines the procedures for initial setup and use of temperature and humidity monitoring devices, frequency of verification or calibration based on manufacturer recommendations (at least every 12 months), acceptable documentation practices for verification activities, including calibration certificates and maintenance logs.

Immediate Documentation:
All current devices in use were reviewed, and calibration/verification certificates have been retrieved or obtained from vendors. These records have been filed under equipment verification logs and are accessible in the designated compliance binder and SharePoint system.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

Annual Review & Tracking System:
- A device verification tracking log has been implemented to monitor due dates for each monitoring device's verification.
- Reminders will be automatically flagged 30 days before each device's due date.

Staff Training:
- All responsible personnel have been trained on the new SOP and documentation requirements.
- Training records have been maintained and stored accordingly.

Internal Audit Inclusion:
- Monitoring device verification and documentation will be added to the quarterly internal audit checklist to ensure continuous compliance.

EFFECTIVENESS CHECK:

A review will be conducted 3 months post-implementation to confirm proper execution and documentation then annual review.

The existence of updated verification records
- Compliance with the new SOP
- Documentation accessibility during inspections

Audit Verification
- Internal Audit Inclusion:
- Monitoring device verification and documentation will be added to the quarterly internal audit checklist to ensure continuous compliance.

SOP REFERENCE

5.017 MONITORING DEVICE CERTIFICATION

REVIEW DATE:	7/14/2025	PHARMACY DESIGNEE:	Shibu John, Amelia Yeh

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6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	H. CERTIFICATION AND RECERTIFICATION – ALL CATEGORIES

CERTIFICATION REPORT REVIEW BY DESIGNATED PERSON: All certification and recertification records are reviewed by the designated person(s). A corrective action plan is implemented and documented in response to any out-of-range results on certification report and data reviewed to confirm that the actions taken have been effective. [UPS 797 Section 5.0] *no document available at the time of inspection*

- ***The certification of dry heat oven and sterilizer were reviewed at the time of inspection .***
- ***The reuesst for the certification of air sampler and repeater pump was missing at the time of inspection.***

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	The absence of documentation was due to a gap in the formal procedure requiring the designated person to review and sign off on certification and recertification reports. While reports were verbally acknowledged and acted upon, the reviews and associated corrective actions were not consistently recorded or maintained in an accessible, centralized location.
☐	Method	
☐	Manpower Training	
☐	Measurements	
☑	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

All certification and recertification reports from the past 12 months were retrospectively reviewed by the designated person.

A signed attestation for each reviewed report has been added to the facility's quality assurance documentation.

Any previously unaddressed out-of-specification findings were reassessed, and appropriate corrective actions were taken and documented.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

The responsibility of the designated person:
- Review all certification and recertification reports within 5 business days of receipt
- Sign and date each report
- Document any required corrective actions and verify their completion and effectiveness

Certification review forms/checklists are now included with each report to ensure completeness and traceability. In addition, all reports and associated documentation are now maintained in a centralized, access-controlled repository (physical or electronic).

SUPPLEMENTARY DOCUMENTS

COA - AIR SAMPLER
COA - REPEATER PUMP

REVIEW DATE:	7/14/2025	**PHARMACY DESIGNEE:**	Shibu John, Amelia Yeh

BIOSCIENCE INTERNATIONAL
Innovative Microbiology Products
11333 Woodglen Drive • Rockville, Maryland 20852
301.231.7400 • www.biosci-intl.com • fax: 301.231.7277

CERTIFICATE OF CALIBRATION

Model:	SAS Duo 360 - Left Head
Air Sampler Serial #:	23-D-20175
Air Sampler Head Serial #:	61717
Customer:	RX Compound Store
Customer Asset ID #:	n/a
Calibration performed at:	Woodglen site (see address above)

Cal. Date:	7 Jul 2025	
Cal. Due:	7 Jul 2026	(12 months)
Procedure:	EOP-030	
Certificate #:	23-D-20175-3845L	
Volume sampled (L):	1000	
Calibrated w/media type:	Hardy Sabdex w/L +T	
Plate Lot #:	660982	
Plate Exp Date:	9/4/2025	

	As Found	In Tolerance	As Left	In Tolerance	Acceptable Range
Battery output (Volts):	14.2	n/a	14.0	n/a	>13.0
Temperature (F°):	77.9	n/a	77.9	n/a	59 - 95
Barometric pressure (in. HG):	29.94	n/a	29.94	n/a	n/a
Time to sample 1000 Liters (min)	5.56	n/a	5.56	n/a	n/a
Temp. & Pressure Standardization Factor:	1.00	n/a	1.00	n/a	n/a
Air velocity reading (ft/min)	100.0	n/a	100.0	n/a	n/a
Air velocity reading (m/sec)	0.508	n/a	0.508	n/a	n/a
Standardized air velocity reading (m/sec)	0.508	n/a	0.508	n/a	n/a
Standardized Air Flow (L/min)	179.7	Yes	179.7	Yes	171 - 189

Additional service-related notes: Please see footnote below regarding +/-2% interchangeability of heads and media types.

Bioscience International certifies that the above described instrument conforms to the original manufacturer's tolerances for the parameters listed (not applicable to As Found data) & has been calibrated in accordance with ISO 17025:2017 guidelines under accredited conditions (pursuant to Bioscience International's A2LA certificate 5699.01) using standards whose accuracies are traceable to the International System of Units (SIs) through the U.S. National Institute of Standards & Technology or International equivalent, have been verified with respect to instrumentation whose accuracy is traceable to NIST, or are derived from accepted values of physical constants. CMC test uncertainty is +/-2.2%. Instruments are calibrated with a test uncertainty ratio of 4:1 or greater whenever possible. In all cases, statistical methods are used to minimize uncertainty using the best commercially available methods. The decision rule used is Simple Acceptance as defined in ILAC G8 with a measurement uncertainty value that will never exceed 50% of the tolerance unless otherwise specified. Voltage readings are for preventative maintenance purposes & not part of the calibration; values other than voltage, temperature, pressure, & air velocity are calculated values. All sampling heads may be used interchangeably with +/-2% equivalence as long as they have the same hole count/size and are kept clean/free of obstructions. Calibration results relate only to the items listed above; the instrument should be recalibrated prior to switching media sizes (e.g., from 90mm Petri dishes to 55mm contact plates or vice versa).

Measurement Standards

ID	Description	Last Cal.	Cal. Due
W-T95451906004	Velocity	9/23/2024	9/23/2025
W-6530-240523257	Temperature & Pressure	7/3/2024	7/3/2026

Work performed by / date: Brenda Fernandez / 07 Jul 2025 Reviewed by / date: AMKA / 08 Jul 2025

BIOSCIENCE INTERNATIONAL

Innovative Microbiology Products
11333 Woodglen Drive • Rockville, Maryland 20852
301.231.7400 • www.biosci-intl.com • fax: 301.231.7277

CERTIFICATE OF CALIBRATION

Model:	SAS Duo 360 - Right Head
Air Sampler Serial #:	23-D-20175
Air Sampler Head Serial #:	61718
Customer:	RX Compound Store
Customer Asset ID #:	n/a
Calibration performed at:	Woodglen site (see address above)

Cal. Date:	7 Jul 2025	
Cal. Due:	7 Jul 2026	(12 months)
Procedure:	EOP-030	
Certificate #:	23-D-20175-3845R	
Volume sampled (L):	1000	
Calibrated w/media type:	Hardy Sabdex w/L+T	
Plate Lot #:	657224	
Plate Exp Date:	7/23/2025	

	As Found	In Tolerance	As Left	In Tolerance	Acceptable Range
Battery output (Volts):	13.8	n/a	13.6	n/a	>13.0
Temperature (F°):	77.9	n/a	77.9	n/a	59 - 95
Barometric pressure (in. HG):	29.94	n/a	29.93	n/a	n/a
Time to sample 1000 Liters (min)	5.45	n/a	5.51	n/a	n/a
Temp. & Pressure Standardization Factor:	1.00	n/a	1.00	n/a	n/a
Air velocity reading (ft/min)	102.0	n/a	101.0	n/a	n/a
Air velocity reading (m/sec)	0.518	n/a	0.513	n/a	n/a
Standardized air velocity reading (m/sec)	0.518	n/a	0.513	n/a	n/a
Standardized Air Flow (L/min)	183.3	Yes	181.5	Yes	171 - 189

Additional service-related notes: Please see footnote below regarding +/-2% interchangeability of heads and media types.

Bioscience International certifies that the above described instrument conforms to the original manufacturer's tolerances for the parameters listed (not applicable to As Found data) & has been calibrated in accordance with ISO 17025:2017 guidelines under accredited conditions (pursuant to Bioscience International's A2LA certificate 5699.01) using standards whose accuracies are traceable to the International System of Units (SIs) through the U.S. National Institute of Standards & Technology or International equivalent, have been verified with respect to instrumentation whose accuracy is traceable to NIST, or are derived from accepted values of physical constants. CMC test uncertainty is +/-2.2%. Instruments are calibrated with a test uncertainty ratio of 4:1 or greater whenever possible. In all cases, statistical methods are used to minimize uncertainty using the best commercially available methods. The decision rule used is Simple Acceptance as defined in ILAC G8 with a measurement uncertainty value that will never exceed 50% of the tolerance unless otherwise specified. Voltage readings are for preventative maintenance purposes & not part of the calibration; values other than voltage, temperature, pressure, & air velocity are calculated values. All sampling heads may be used interchangeably with +/-2% equivalence as long as they have the same hole count/size and are kept clean/free of obstructions. Calibration results relate only to the items listed above; the instrument should be recalibrated prior to switching media sizes (e.g., from 90mm Petri dishes to 55mm contact plates or vice versa).

Measurement Standards

ID	Description	Last Cal.	Cal. Due
W-T95451906004	Velocity	9/23/2024	9/23/2025
W-6530-240523257	Temperature & Pressure	7/3/2024	7/3/2026

Work performed by / date: Brandon Fernandez / 07 Jul 2025 Reviewed by / date: [signature] / 08 Jul 2025

CERTIFICATE OF CALIBRATION

TSI Incorporated, 500 Cardigan Road, Shoreview, MN 55126 USA
Tel: 1-800-874-2811 1-651-490-2811 Fax: 1-651-490-3824 http://www.tsi.com

ANAB

CUSTOMER NAME:	CERTIFICATE NUMBER	300628660
BIOSCIENCE INTRNTL 11333 WOODGLEN DR STE 201 ROCKVILLE MD 20852-3071 USA	DATE OF CALIBRATION	23 SEPTEMBER, 2024
	PAGE	1 OF 1

ENVIRONMENT CONDITIONS		
TEMPERATURE	72.17 (22.3)	°F (°C)
RELATIVE HUMIDITY	42	%RH
BAROMETRIC PRESSURE	29.10 (985.4)	inHg (hPa)

MODEL	9545
SERIAL NUMBER	T95451906004

☒ AS LEFT ☒ IN TOLERANCE
☐ AS FOUND ☐ OUT OF TOLERANCE

CALIBRATION VERIFICATION RESULTS

Unit: °F (°C)

TEMPERATURE VERIFICATION — SYSTEM T-101
METHOD USED: 10000086234
UNCERTAINTY: +/-0.22 DEGREES F (0.12 C)

#	STANDARD	MEASURED	ALLOWABLE RANGE	#	STANDARD	MEASURED	ALLOWABLE RANGE
1	32.0 (0.0)	32.0 (0.0)	31.5–32.6 (-0.3–0.3)	2	139.9 (59.9)	140.0 (60.0)	139.3–140.4 (59.5–60.2)

Unit: %RH

HUMIDITY VERIFICATION — SYSTEM H-102
METHOD USED: 10000086233
UNCERTAINTY: 0.5% + LST %RH

#	STANDARD	MEASURED	ALLOWABLE RANGE	#	STANDARD	MEASURED	ALLOWABLE RANGE
1	10.0	10.3	7.0–13.0	4	70.0	70.8	67.0–73.0
2	30.1	30.9	27.1–33.1	5	90.0	90.0	87.0–93.0
3	50.0	51.1	47.0–53.0				

Units ft/min (m/s)

VELOCITY VERIFICATION — SYSTEM V-111
METHOD USED: 10000086237
UNCERTAINTY: +/-2.6 %

#	STANDARD	MEASURED	ALLOWABLE RANGE	#	STANDARD	MEASURED	ALLOWABLE RANGE
1	† 1 (0.01)	0 (0.00)	-2–4 (-0.01–0.02)	7	653 (3.32)	653 (3.31)	634–673 (3.22–3.42)
2	35 (0.18)	36 (0.18)	32–38 (0.16–0.20)	8	997 (5.07)	997 (5.07)	967–1027 (4.91–5.22)
3	65 (0.33)	65 (0.33)	62–68 (0.31–0.34)	9	1472 (7.48)	1471 (7.47)	1428–1516 (7.25–7.70)
4	99 (0.50)	98 (0.50)	96–102 (0.49–0.52)	10	2494 (12.67)	2485 (12.62)	2419–2569 (12.29–13.05)
5	161 (0.82)	160 (0.81)	156–166 (0.79–0.84)	11	4503 (22.88)	4504 (22.88)	4368–4639 (22.19–23.56)
6	329 (1.67)	328 (1.66)	319–339 (1.62–1.72)	12	5809 (29.51)	5799 (29.46)	5635–5983 (28.62–30.40)

† Has excluded from ISO 17025 calibrations.

TSI Incorporated does hereby certify that the above described instrument conforms to the manufacturer's specifications (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the International System of Units (SI) through the National Institute of Standards and Technology (NIST) within the limitations of NIST's calibration services or have been derived from accepted values of natural physical constants or have been derived by the ratio type of self-calibration techniques. TSI is registered to ISO 9001:2015. TSI is accredited to ISO 17025:2017 by ANAB Certificate Number AC-2850.

The aforementioned uncertainty values represent expanded uncertainty and are based on a standard uncertainty multiplied by a coverage factor k=2 providing a confidence level of approximately 95%. This report may not be reproduced unless permission is obtained in writing from the TSI calibration service department issuing this report. The unit is found to have passed when the readings are within the specification limits of the device as presented as the allowable range stated with each measurement above. The customer shall assess the results and uncertainty in order to determine if the results meet their needs.

Measurement Variable	System ID	Last Cal.	Cal. Due
Temperature	E010657	03-31-24	03-31-25
Temperature	E010656	03-31-24	03-31-25
DC Voltage	E004018	06-12-24	06-30-25
Pressure	E003541	07-12-24	01-31-25
Velocity	E010408	12-14-21	12-31-24

Measurement Variable	System ID	Last Cal.	Cal. Due
Temperature	E010658	03-11-24	03-31-25
Humidity	E011511	05-26-24	11-30-24
Temperature	E004398	04-10-24	10-31-24
Pressure	E011250	07-12-24	01-31-25

Performed By	Signature	Approved By	Signature	Date Issued
Kathleen Kathleen	Kathleen	Ly Sound	Ly Sound	09-23-2024

DOC ID: CERT_DEFAULT
END OF REPORT

TSI PM 2300157

Calibration complies with ISO/IEC 17025, ANSI/NCSL Z540-1, and 9001

Cert. No.: 6530-15243718

Traceable® Certificate of Calibration for Digital Barometer

Manufactured for and distributed by : Traceable® Products 12554 Galveston Rd B230, Webster, TX 77598

Instrument Identification:

Model: 6530,68000-49 S/N: 240523257 Manufacturer: Control Company

Standards/Equipment:

Description	Serial Number	Due Date	NIST Traceable Reference
Digital Barometer	D4540001	14 Nov 2024	1000498202
Chilled Mirror Hygrometer	44654/2H3737	09 Feb 2025	22198
Climate Chamber	W613.0046		
Digital Thermometer	200821229	23 Jan 2025	4000-14784177

Certificate Information:

Technician: 57 Procedure: CAL-31 Cal Date: 03 Jul 2024 Cal Due Date: 03 Jul 2026

Test Conditions: 62.62%RH 23.86°C 1017mBar

Calibration Data: (New Instrument)

Unit(s)	Nominal	As Found	In Tol	Nominal	As Left	In Tol	Min	Max	±U	TUR
%RH	N.A.	N.A.		50.50	53	Y	48	54	0.74	>4:1
°C	N.A.	N.A.		25.08	25.1	Y	24.68	25.48	0.05	>4:1
mb/hPa	N.A.	N.A.		805.20	805	Y	801	809	0.62	>4:1
mb/hPa	N.A.	N.A.		910.05	911	Y	906	914	0.62	>4:1
mb/hPa	N.A.	N.A.		1018.45	1020	Y	1014	1022	0.62	>4:1

This certificate indicates Traceability to standards provided by (NIST) National Institute of Standards and Technology and/or a National Standards Laboratory.

A Test Uncertainty Ratio of at least 4:1 is maintained unless otherwise stated and is calculated using the expanded measurement uncertainty. Uncertainty evaluation includes the instrument under test and is calculated in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement : (GUM). The uncertainty represents an expanded uncertainty using a coverage factor k=2 to approximate a 95% confidence level. Conformance based on Simple Acceptance as a Decision Rule, as defined in ILAC G8, with a measurement uncertainty value that will not exceed 50% of the tolerance unless otherwise stated by the customer. The results contained herein relate only to the item calibrated. This certificate shall not be reproduced except in full, without written approval of Control Company.

Nominal=Standard's Reading; As Left=Instrument's Reading; In Tol=In Tolerance; Min/Max=Acceptance Range; ± U=Expanded Measurement Uncertainty; TUR=Test Uncertainty Ratio; Accuracy=±(Max-Min)/2; Min=As Left Nominal(Rounded) – Tolerance; Max= As Left Nominal(Rounded) + Tolerance;

Nicol Rodriguez

Nicol Rodriguez, Quality Manager

Note :

Maintaining Accuracy:

In our opinion once calibrated your Digital Barometer should maintain its accuracy. There is no exact way to determine how long calibration will be maintained. Digital Barometer change little, if any at all, but can be affected by aging, temperature, shock, and contamination.

Recalibration:

For factory calibration and re-certification traceable to National Institute of Standards and Technology contact Control Company.

Issue Date : 03 Jul 2024

CONTROL COMPANY 12554 Galveston RD Suite BZ30 Webster TX USA 77598
Phone 281 482-1714 Fax 281 482-9448 sales@control3.com www.traceable.com

Control Company is an ISO/IEC 17025:2017 Calibration Laboratory Accredited by (A2LA) American Association for Laboratory Accreditation, Certificate No. 1750.01.
Control Company is ISO 9001:2015 Quality Certified by DNV GL, Certificate No. CERT-01805-2006-AQ-HOU-ANAB.
International Laboratory Accreditation Cooperation - Multilateral Recognition Arrangement (ILAC-MRA).

Traceable® is a registered trademark of Control Company © 2017 Control Company

BIOSCIENCE INTERNATIONAL

Innovative Microbiology Products

July 7, 2025

BIOSCIENCE INTERNATIONAL, INC.
SHIPMENT PACKING LIST

SHIP TO: RX Compound Store

DESCRIPTION	QUANTITY
ISO 17025 Accredited Calibration & Full PM Service SAS Duo 360, Serial #: 23-D-20175; Head #: 61717 & 61718	1

Service Notes:

- The unit was received, inspected and found to be within manufacturer specifications (179.7 l/m on the left side & 183.3 l/m on the right side); please see attached calibration certificate for details.
- Performed ISO 17025 accredited calibration in wind tunnel.
- Performed full PM checklist, tightened hardware, stress tested battery, battery charger and all components.

Please contact Customer Support at support@biosci-intl.com or 301-231-7400 with any questions.

IT IS A PLEASURE TO SERVE YOU!

11333 Woodglen Drive • Rockville, Maryland 20852 • www.biosci-intl.com

301.231.7400 • fax: 301.231.7277

IMS
INTEGRATED MEDICAL SYSTEMS
594 Territorial Drive
Bolingbrook, IL 60440
800-755-3800

Equipment Inspection Report

Transforming Healthcare Together, Beyond Distribution
Solutions. Technology. Service

Model: Baxter Repeater Pump
S/N: pl0024602

Test Id: 587755

Inspection Date 07/10/2025
Inspection Status **Passed**
Next PM Due 07/10/2026

Inspected by MMaddox

Test	Passed	Test Result	Test Notes
Chassis Housing - Visual Check	Yes		
AC Power Cord - Visual Check	Yes		
AC Power Cord Plug - Visual Check	Yes		
AC Power Cord Strain Relief - Visual Check	Yes		
Control Switches / Keypad - Functional Check	Yes		
Compressor / Motor / Fan - Functional Check	Yes		
Displays / Indicators - Visual Check	Yes		
Unit POST - Functional Check	Yes		
Ground Resistance - Functional Check	Yes	0.01 Ohms	
Electrical Leakage - Functional Check	Yes	289.00 Micro amps	
Volumetric Accuracy - 20/120 - 1%	Yes	20.01 ML	

FDA REGULATION 21 CFR 821
Requires that these devices be tracked

List Back

RxCompoundStore.com
8950 Southwest 74th Court
Suite 101, Miami, FL 33156
PH: 786.803.6947
FAX: 844.875.0009
Email: orders@rxcompoundstore.com

Next

6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	K. CATEGORY 2 EXTENDED BUD REQUIREMENTS USP <797> Section 18 – Category 3 Requirements

CATEGORY 2 BUDs FOR ASEPTICALLY PROCESSED CSPs WITH STERILITY TESTING: Category 2 CSPs compounded aseptically, and which have passed sterility testing do not exceed the following BUDs: 30 days room temperature, 45 days refrigerated, or 60 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *visual inspection of CSP vial: BUD 90 days*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	At the time of inspection, a compounded sterile preparation (CSP) was observed with a Beyond-Use Date (BUD) of 90 days, which exceeds the Category 2 BUD limits despite the CSP being aseptically prepared and only supported by sterility testing. This occurred due to the overlap in implementing Category 3 procedures and a lack of documentation confirming that all Category 3 requirements were fully established at the time the 90-day BUD was assigned.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

The CSP with the 90-day BUD was quarantined and evaluated for compliance with current USP <797> Category 3 standards.

A full review of the sterility testing and stability-indicating study supporting the BUD was conducted.

Any product with a BUD exceeding Category 2 limits without documented conformance to Category 3 standards was reassigned an appropriate BUD or discarded.

Staff were re-trained on distinguishing BUD limitations between Category 2 and Category 3.

Stability-Indicating Testing: particulate matter testing required by Category 3 was conducted by the third-party lab.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

As of July 1st, we have formally implemented Category 3 compounding protocols in compliance with USP <797>. This includes full adherence to the following Category 3 requirements:

- Use of sterile, single-use, low-lint garb that covers the entire body (hood, gown, boot covers, face cover, sterile gloves).
- No reuse of garb unless resterilized and disinfected per SOPs.

Personnel qualification

- Initial training and every 3 months: visual inspection of hand hygiene and garbing, media fill testing, gloved fingertip sampling and surface sampling, aseptic technique training and competency evaluations

Environmental Monitoring:

- Surface sampling performed weekly
- Viable air sampling performed monthly
- Nonviable air monitoring for particle counts during dynamic conditions certification every 3 months

Stability-Indicating Testing:

- BUDs > Category 2 limits are assigned only if supported by validated stability-indicating studies, including sterility, endotoxin, and potency.particulate matter testing.

EFFECTIVENESS CHECK:

Monthly audit of compounded sterile product batches for compliance with assigned BUDs and alignment with 3 requirements.

Quarterly internal review of environmental monitoring data, staff qualifications, and documentation to confirm ongoing adherence to Category 3.

Documentation verification during pharmacist release review to ensure assigned BUDs match supporting data and category classification.

SUPPLEMENTARY DOCUMENTS

PARTICULAT-MATTER TESTING			
REVIEW DATE:	7/14/2025	PHARMACY DESIGNEE:	Shibu John, Amelia Yeh

List Back

RxCompoundStore.com
8950 Southwest 74th Court
Suite 101, Miami, FL 33156
PH: 786.803.8947
FAX: 844.875.0009
Email: orders@rxcompoundstore.com

Next

6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	K. CATEGORY 2 EXTENDED BUD REQUIREMENTS USP <797> Section 18 – Category 3 Requirements

CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITH STERILITY TESTING: Category 2 CSPs terminally sterilized, and which have passed sterility testing do not exceed the following BUDs: 45 days room temperature, 60 days refrigerated, or 90 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *90 days BUD with refrigeration*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	At the time of inspection, a compounded sterile preparation (CSP) was observed with a Beyond-Use Date (BUD) of 90 days, which exceeds the Category 2 BUD limits despite the CSP being aseptically prepared and only supported by sterility testing. This occurred due to the overlap in implementing Category 3 procedures and a lack of documentation confirming that all Category 3 requirements were fully established at the time the 90-day BUD was assigned.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

The CSP with the 90-day BUD was quarantined and evaluated for compliance with current USP <797> Category 3 standards.

A full review of the sterility testing and stability-indicating study supporting the BUD was conducted.

Any product with a BUD exceeding Category 2 limits without documented conformance to Category 3 standards was reassigned an appropriate BUD or discarded.

Staff were re-trained on distinguishing BUD limitations between Category 2 and Category 3.

Stability-Indicating Testing: particulate matter testing required by Category 3 was conducted by the third-party lab.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

As of July 1st, we have formally implemented Category 3 compounding protocols in compliance with USP <797>. This includes full adherence to the following Category 3 requirements:

- Use of sterile, single-use, low-lint garb that covers the entire body (hood, gown, boot covers, face cover, sterile gloves).
- No reuse of garb unless resterilized and disinfected per SOPs.

Personnel qualification

- initial training and every 3 months: visual inspection of hand hygiene and garbing, media fill testing, gloved fingertip sampling and surface sampling, aseptic technique training and competency evaluations

Environmental Monitoring:

- Surface sampling performed weekly
- Viable air sampling performed monthly
- Nonviable air monitoring for particle counts during dynamic conditions certification every 3 months

Stability-Indicating Testing:

- BUDs > Category 2 limits are assigned only if supported by validated stability-indicating studies, including sterility, endotoxin, and potency.particulate matter testing.

EFFECTIVENESS CHECK:

Monthly audit of compounded sterile product batches for compliance with assigned BUDs and alignment with 3 requirements.

Quarterly internal review of environmental monitoring data, staff qualifications, and documentation to confirm ongoing adherence to Category 3.

Documentation verification during pharmacist release review to ensure assigned BUDs match supporting data and category classification.

SUPPLEMENTARY DOCUMENTS			
PARTICULAT-MATTER TESTING			
REVIEW DATE:	7/14/2025	PHARMACY DESIGNEE:	Shibu John, Amelia Yeh

PHARMETRIC LABORATORY

CERTIFICATE OF ANALYSIS (CoA)

Issue #:	0	**SAMPLE #:**	S338453
CoA RELEASE DATE:		Jun 09, 2025	

Pharmetric Laboratory
7265 Ulmerton Road
Largo, FL, 33771

CLIENT:	RXCompoundStore.com, LLC		**CONTACT:**		
CLIENT ADDRESS:	8950 SW 74 CT, #101, Miami, FL 33156				
DESCRIPTION:	*SEMAGLUTIDE 5MG/ML INJECTION*		***LOT #:***	*05162025SEMA5A*	
STRENGTH:	-		***CONTAINER:***	*5.0 ml Vial*	
STORAGE CONDITIONS:	*Refrigerated (2°C ta 8°C)*		***BATCH SIZE:***	*n/a*	***EXP.:*** *Not Provided*
DATE(S) RECEIVED:	6/4/2025		**QUANTITY RECEIVED:**	10	

TEST DATE	TEST	QTY	ACCEPTANCE CRITERIA	RESULTS	COMPLIANCE STATEMENT
Jun 9, 2025	USP <788> Particulate Matter in Injections Light Obscuration	10	part/Container: ≥ 10 µm: ≤ 6000, ≥ 25 µm: ≤ 600	part/Container: ≥ 10 µm: 74.00, ≥ 25 µm: 0.33	PASS

TEST DATE refers to start date. Please note some tests are carried out over multiple days.
The results on this CoA relate only to the item(s) tested and apply to the sample as received. This Report shall not be reproduced except in full without approval of the laboratory.

ACCREDITED TESTING LABORATORY. ACCREDITATION NUMBER 5386.01

COMMENTS	QUALITY SIGNATURE
	Yovany Gomez Quality Associate 6/9/2025 5:54:08 PM

PHARMETRIC LABORATORY

CERTIFICATE OF ANALYSIS (CoA)

Issue #:	0	**SAMPLE #:**	S338447
CoA RELEASE DATE:		Jun 09, 2025	

Pharmetric Laboratory
7265 Ulmerton Road
Largo, FL, 33771

CLIENT:	RXCompoundStore.com, LLC	**CONTACT:**			
CLIENT ADDRESS:	8950 SW 74 CT, #101, Miami, FL, 33156				
DESCRIPTION:	*TIRZEPATIDE 15MG/ML SOLUTION*	***LOT #:***	*05232025TIRZ15A*		
STRENGTH:	-	***CONTAINER:***	*5.0 ml Vial*		
STORAGE CONDITIONS:	*Refrigerated (2°C to 8°C)*	***BATCH SIZE:***	*n/a*	***EXP.:***	*Not Provided*
DATE(S) RECEIVED:	6/4/2025	**QUANTITY RECEIVED:**	10		

TEST DATE	TEST	QTY	ACCEPTANCE CRITERIA	RESULTS	COMPLIANCE STATEMENT
Jun 9, 2025	USP <788> Particulate Matter in Injections Light Obscuration	10	part/Container: ≥ 10 µm: ≤ 6000, ≥ 25 µm: ≤ 600	part/Container: ≥ 10 µm: 418.67, ≥ 25 µm: 0.00	PASS

TEST DATE refers to start date. Please note some tests are carried out over multiple days.
The results on this CoA relate only to the item(s) tested and apply to the sample as received. This Report shall not be reproduced except in full without approval of the laboratory.

ACCREDITED TESTING LABORATORY. ACCREDITATION NUMBER 5386.01

COMMENTS	QUALITY SIGNATURE
	Yovany Gomez Quality Associate 6/9/2025 5:53:39 PM

PHARMETRIC LABORATORY

CERTIFICATE OF ANALYSIS (CoA)

Issue #:	0	**SAMPLE #:**	S338440
CoA RELEASE DATE:		Jun 09, 2025	

Pharmetric Laboratory
7265 Ulmerton Road
Largo, FL, 33771

CLIENT:	RXCompoundStore.com, LLC		**CONTACT:**		
CLIENT ADDRESS:	8950 SW 74 CT, #101, Miami, FL, 33156				
DESCRIPTION:	*TIRZEPATIDE 15 MG/PYRIDOXINE HCL 20 MG/ML SOLUTION*		***LOT #:***	*06032025TIRZ15PYR20A*	
STRENGTH:	-		***CONTAINER:***	*5.0 ml Vial*	
STORAGE CONDITIONS:	*Refrigerated (2°C to 8°C)*		***BATCH SIZE:***	*n/a*	***EXP.:*** *Not Provided*
DATE(S) RECEIVED:	6/4/2025		**QUANTITY RECEIVED:**	10	

TEST DATE	TEST	QTY	ACCEPTANCE CRITERIA	RESULTS	COMPLIANCE STATEMENT
Jun 9, 2025	USP <788> Particulate Matter in Injections Light Obscuration	10	part/Container: ≥ 10 µm: ≤ 6000, ≥ 25 µm: ≤ 600	part/Container: ≥ 10 µm: 278.67, ≥ 25 µm: 1.67	PASS

TEST DATE refers to start date. Please note some tests are carried out over multiple days.
The results on this CoA relate only to the item(s) tested and apply to the sample as received. This Report shall not be reproduced except in full without approval of the laboratory.

ACCREDITED TESTING LABORATORY. ACCREDITATION NUMBER 5386.01

COMMENTS	QUALITY SIGNATURE
	Yovany Gomez Quality Associate 6/9/2025 5:52:55 PM

List Back

CompoundStore.com
8950 Southwest 74th Court
Suite 101, Miami, FL 33156
PH: 786.803.8947
FAX: 844.875.0009
Email: orders@rxcompoundstore.com

Next

6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	K. CATEGORY 2 EXTENDED BUD REQUIREMENTS

INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]

not available at the time of inspection

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	At the time of inspection, documentation related to the investigation of sterility test failures—including microbial identification, procedural evaluation, facility assessment, personnel involvement, and resulting corrective actions—was not readily retrievable.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

Located and reviewed the sterility failure investigation documentation that was previously completed and confirmed to be compliant with USP <797> Section 12.2.

Provided the documentation to internal quality personnel and prepared it for immediate availability in case of future inspections.

Re-trained responsible personnel on document control procedures for inspection readiness.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

Established a centralized quality folder (physical or electronic) to store all related reports, microbial identifications, evaluations, and corrective actions.

Updated the Document Control SOP to include a requirement for tagging and indexing all sterility test failure investigations by batch number and date.

Implemented a quarterly QA review to ensure all sterility failure investigations are complete, traceable, and accessible.

Conducted a refresher training session for compounding and QA staff on USP <797> Section 12.2, investigation expectations, and documentation practices.

SUPPLEMENTARY DOCUMENT

6.015 RECALL, QUARANTINE, AUDIT TRAIL OF COMP PREP

MICROBIAL IDENTIFICAION

CAPA FOR FAILED STERILITY

REVIEW DATE:	7/14/2025	**PHARMACY DESIGNEE:**	Shibu John, Amelia Yeh

CompoundStore.com
8950 Southwest 74th Court
Suite 101, Miami, FL 33156
PH: 786.803.8947
FAX: 844.875.0009
Email: orders@rxcompoundstore.com

6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	2/18/2025	**INSPECTIING BODY/PERSONNEL:**	Designated Persons
DESCRIBE THE PROBLEM:		**REFERENCE:**	Sterility Inestigation Report (02172025SEMA5A); USP <797>

A compounded sterile preparation (CSP) from Lot # 02172025SEMA5A failed routine sterility testing, indicating potential microbial contamination. This deviation is in direct violation of USP <797> sterility assurance requirements for finished CSPs.

DESCRIBE THE IMMEDIATE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

The affected lot was immediately quarantined in the pharmacy and removed from distribution.
A recall was promptly issued for all dispensed units associated with the lot.
All potentially impacted patients and providers were notified of the recall, and instructions were provided for discontinuation and proper return or disposal.
Dispensing of other lots compounded under similar conditions was temporarily halted pending review.

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	A comprehensive investigation was conducted to determine the root cause of the contamination. The investigation included:
☑	Method	- Review of compounding records, aseptic technique logs, and environmental monitoring data
☐	Manpower Training	- Assessment of equipment calibration and maintenance records
☐	Measurements	- Review of personnel training and garbing procedures
☐	Materials	- Evaluation of sterilization and filtration methods used for the CSP
☐	Milieu/Environment	

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

Personnel re-training on aseptic technique, garbing, and compounding protocols
Enhanced environmental monitoring during compounding and post-compounding cleaning verification
Re-validation of the sterilization and filtration process, including filter integrity testing procedures
Review and revision of SOPs related to sterility testing, lot release, and quarantine handling
Implementation of stricter lot release criteria, requiring dual review and documentation of sterility assurance checks

REVIEW DATE:	2/18/2025	**PHARMACY DESIGNEE:**	Amelia Yeh

R 02-002.05	**Sterility Test Investigation Report (SOP 02-002.05)**	PHARMETRIC LABORATORY PAGE 1 of 5

STIR ID: S317363

SECTION I: PRODUCT INFORMATION — Attached Receiving Report ✓

Product Name: SEMAGLUTIDE 5MG/ML INJECTION	Sample ID: S317363
Company: RXCompoundStore.com, LLC	Lot: 02172025SEMA5A

Quantity Received: 2	Fill Volume: 0.5 mL	Received Date: Feb 24, 2025	
Container Type: Vial	Product Type: Aqueous	Batch Size: 4	USP <71> Complaint: Yes
Received Container - Closure Condition: CCI ☐ Bad ☑ Good	Punctured ☑ No ☐ Yes	Method Suitability On File: ○ No ◉ Yes	ID: S234865

Additional comments, If any:
No damage was evident. Attached sample received confirmation with photo of vials.

SECTION II: STERILITY TEST PROCESS INFORMATION — Attached R 07-001 ✓

Processing Date: Feb 24, 2025	Total of Test Performed: 22	Test Method: USP <71>
Processing Technician: Tristan Tubbs, Rene Lugo Cabrera	Volume tested per container: 0.5	Rinse Fluid Used: FA

Any deviation, discrepancy, or unusual circumstances that occurred during the execution of the test (e.g. integrity of tubes):
Testing technician: Amanda Howard

Interview with the analyst / check video camera:
Nothing was noted in processing records for session 46224

SECTION III: STERILITY TEST RESULTS — Attached R 07-014 ✓ Attached R 07-002 ☐

Reading Date	Reading Time	Reading Technician	Sample Result (RLU)	Control Limit (RLU)

Were any sample media turbid? TSB ☐ No ☑ Yes FTM ☐ No ☑ Yes	Were any control media turbid? TSB ☑ No ☐ Yes FTM ☑ No ☐ Yes
Number of additional failing test: 0	Diluent - Rinse Fluid result: PASS

System Suitability	Spec	Result

Sterility Test Investigation Report (SOP 02-002.05)

PHARMETRIC LABORATORY

STIR ID: S317363

	N/A		
	Mon 17 Mar 2025		

Any deviation, discrepancy, or unusual circumstances that occurred during reading or additional comment:

The media was turbid since March 3rd, 2025 (after 6 incubation days)

SECTION IV: CONTAMINATION INFORMATION

Attached R 02-001 ☐ ID Report ☑

☐ FTM In Fresh FTM ☐ TSA With FTM ☐ SDA With FTM ☑ TSB In Fresh TSB ☐ TSA With TSB ☐ SDA With TSB

Identification of contaminant (species level): Microbacterium paraoxydans

Classification: ☑ Bacteria ☐ Fungus / Yeast ☑ Gram (+) ☐ Facultative Anaerobe ☑ Aerobe ☐ Anaerobe ☐ Gram (-) ☐ Spore Forming

Contaminant brief info:

Microbacterium paraoxydans is a Gram-positive, non-spore-forming, rod-shaped bacterium belonging to the genus Microbacterium.M. paraoxydans has been isolated from human clinical specimens, including blood cultures from immunocompromised patients. It has been associated with bacteremia in individuals with conditions like leukemia and chronic kidney disease.

SECTION V: QUALITY CONTROL OF TEST CONTROLS

Attached CoAs ☑

Controls Name	Lot	Expiration Date	Quality Controls Test
Fluid A	FAXXX400-035	1/31/2026	☑ Visual ☑ GP ☑ Sterility ☑ pH
TSB	649322	1/23/2026	☑ Visual ☑ GP ☑ Sterility ☑ pH
FTM	648963	7/22/2025	☑ Visual ☑ GP ☑ Sterility ☑ pH

LuminAMP Reagent Lot:	LuminEX Reagent Lot:	LuminATE Reagent Lot:
Forceps Sterilization ID: N/A	BioIndicator Results: ☐ Fail ☑ N/A ☐ Pass	Control Results (After 14D): ☐ Fail ☑ N/A ☐ Pass

Additional comments, if any:

N/A

SECTION VI: ENVIRONMENTAL AND PERSONNEL MONITORING RESULTS

Attached R 08-010

Temperature: 19.00°C	Humidity: 48.5%RH	Pressure: N/A	Personnel Viable Count (CFU): N/A

STIR ID: S317363

Particle Count In BSC (∑N /m³ (>5µM)): Conf	Viable Air Count (CFU): N/A	Viable Surface Count (CFU): N/A

Identification of any isolates found:
N/A
① Conforms (0 Particle Count)

Additional comments, if any:
The Bioquell Qube EM processing data showed that the particle count was within the state of control.

SECTION VII: EQUIPMENT PERFORMANCE

Equipment Id	Date of most recent calibration (successfully)	Equipment Id	Date of most recent calibration (successfully)
INC-007	11/7/2024	N/A	N/A
INC-009	11/15/2024		

Additional comments, if any:
HEPA certification of Pharmetric Laboratory space is carried out every 6 months. The most recent acceptable certification was completed on Jan, 2025 including the Bioquell Qubes.

SECTION VIII: DISINFECTION PROCEDURES

Additional comments, if any:
No deviation during the cleaning process.

SECTION IX: TRAINING RECORDS

Technicians	Date of most recent training (successfully)
Amanda Howard	Sep 3, 2024

Review of operator(s) training records:
The technician was trained in hand washing, sterile gloving, sterile gowning, aseptic technique, sterility processing and passed the required qualification.

STIR ID: S317363

Additional comments:
N/A

SECTION X: TESTING HISTORY RESULTS (FROM PREVIOUS LOTS)

Sample Id	Expected	Result
S325650	No Evidence of growth	No Evidence of growth
S325687	No Evidence of growth	No Evidence of growth
S324364	No Evidence of growth	No Evidence of growth
S297201	No Evidence of growth	No Evidence of growth
S293602	No Evidence of growth	No Evidence of growth

Additional comments, if any:
N/A

SECTION XI: ADDITIONAL TESTING, IF ANY

Test Date: N/A	Technician: N/A
Sample Id: N/A	Result: ☐ Fail ☐ Pass

Additional comments, if any:
N/A

SECTION XII: CONCLUSION

SITUATIONS FOR INVALIDATING A STERILITY TEST POSITIVE RESULT

1. Identification (to the genetic level) of the same organism(s) in the test environment as that found in the positive sterility test coupled with absence of the organism(s) in the environment or on personnel samples on the day(s) of manufacturing, as provided by the client	◉ No ○ Yes
2. Growth in the control samples (e.g., rinse controls, media controls, forceps control).	◉ No ○ Yes
3. Growth in the unopened media bottles or diluents (i.e., failed sterility test of media carried out on each lot).	◉ No ○ Yes

STIR ID: S317363

4. Complete loss of the integrity of the cleanroom and hoods	◉ No ○ Yes
5. Complete loss of the integrity of the incubated test assembly	◉ No ○ Yes
6. Demonstrated failure to follow the sterility test SOP	◉ No ○ Yes
7. Demonstration of failure to maintain clean environment in the cleanroom and hoods by environmental monitoring data	◉ No ○ Yes

Additional comments, if any:

Based on the information gathered, no situations were identified that would invalidate the Sterility Test Failure, and Pharmetric Laboratory considers the sterility test failure a valid result.

SECTION XIII: CAPA ◉ No ○ Yes

Action Plan	Responsible	Target Date

SECTION XIV: DOCUMENTAL APPROVAL

	Name	Signature	Date
Prepared By	Karelia Maynegra	K Maynegra	4/17/2025 5:46:53 PM
Reviewed By			
Approved By	Yorany Gomes	MW	19 Apr 2025

PHARMETRIC LABORATORY

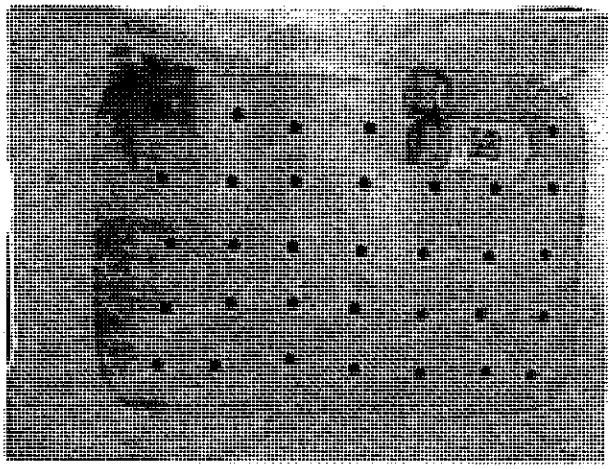
7265 Ulmerton Road
Largo, FL 33771
Telephone: (727) 209-5778

SAMPLE RECEIVED CONFIRMATION

CLIENT:	RXCompoundStore.com, LLC
SAMPLE #:	S317363
DESCRIPTION:	SEMAGLUTIDE 5MG/ML
STRENGTH:	5MG/ML
PRESENTATION:	0.5 ml Vial
LOT #:	02172025sema5a
ESTIMATED RELEASE DATE:	3/11/2025

TOTAL OF UNITS RECEIVED:	2	**EXTRAS:**	0	**BATCH SIZE:**	4

TEST TYPE	Qty. Expected	USP Compliant	Receiving Today	Total Rcvd
USP <71> 14D Sterility Test	2	Yes	2	2



RECEIVED BY:
Amanda Howard
Technician
2/24/2025 10:22:37 AM

Samples accepted by Pharmetric Laboratory, LLC, are assumed to be prepared by the customer within the guidelines of USP <71> regarding sample size and number of units sampled. Pharmetric Laboratory, LLC conducts sterility testing using bioluminescence technology. Per USP <797> "A method not described in the USP may be used if verification results demonstrate that the alternative method is at least effective and reliable as the USP membrane filtration method as described in USP<71>." Sterility Testing performed by Pharmetric Laboratory using bioluminescence technology was validated as equal to compendial test by direct comparison. Validation documents are on file at Pharmetric Laboratory.

This document related ONLY to the item listed under the description.

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R 07-001-08

STERILITY PROCESSING REPORT
(SOP 07-001.09)

46224

PHARMETRIC LABORATORY

DATE	START TIME	END TIME	ROOM
Feb 24, 2025	Feb 24, 2025 10:47:11	Feb 25, 2025 10:22:57	238

TECHNICIANS
Amanda Howard (Filtering), Richard Orta-Santiago (Filtering), Christopher Piric (Filtering), Juan Carlos Martinez Rodriguez (Filtering),

EQUIPMENT INFORMATION

CODE	TYPE
INC-007	Incubator
INC-009	Incubator

MATERIALS INFORMATION

SPECIFICATION	LOTS USED
Sterisart® NF	[Lot#:2446036035 Exp:11/30/2027],
FA	[Lot#:FAXXX400-035 Exp:1/31/2026],
FTM	[Lot#:648953 Exp:7/22/2025],
TSB	[Lot#:649322 Exp:1/23/2026],
Sterile Forceps	

PROCESSING - CRITICAL STEPS — **TECH INITIALS AND DATE**

- [x] The LFH or BSC was properly disinfected before sterility processing.
- [x] The samples were properly disinfected prior to being placed inside LFH or BSC.
- [x] The funnels match the samples to process, if applicable.
- [x] The samples were tested according to method suitability requirements (rinse fluid and media).
- [x] Correct aseptic technique during filtering process.
- [x] EM performed during filtering process.

Filtering technician: 26 Feb 25

- [x] Racks and tubes were disinfected prior to being placed in the cabinet.
- [x] Correct aseptic technique during filtering process.
- [x] EM performed during cutting membrane process.

Cutting technician: 26 Feb 25

NO RUSH SAMPLES TESTED

USP <71> 14D SAMPLES TESTED | QUANTITY OF SAMPLES: 22 | INCUBATION TIME: Feb 25, 2025 10:13:22 Richard | RESULT DATE: Mar 11, 2025

SAMPLE NUMBER	DIRECT INOC.	FILTER VOL CONT	FILTER	RINSE VOL	RINSE FLUID	MEDIA VOL	MEDIA ADDITIVE	ADDITIONAL COMMENTS (IF ANY) (EXAMPLE: PARTICULATES, DIFFICULTY FILTERING, ETC)
S317683						100		TSB-FTM 100 mL Media Control (CLOSED)
S317348		3	Sterisart® NF	300	FA	100		
S317349		1	Sterisart® NF	300	FA	100		
S317350		2	Sterisart® NF	300	FA	100		
S317351		5	Sterisart® NF	300	FA	100		
S317352		1	Sterisart® NF	300	FA	100		

R 07-001-08

STERILITY PROCESSING REPORT
(SOP 07-001-09)

46224

PHARMETRIC LABORATORY

S317353		6	Sterisart® NF	300	FA	100		
S317355		2	Sterisart® NF	300	FA	100		
S317356		2	Sterisart® NF	300	FA	100		
S317357		1	Sterisart® NF	300	FA	100		
S317359		1	Sterisart® NF	300	FA	100		
S317361		5	Sterisart® NF	300	FA	100		
S317362		1	Sterisart® NF	300	FA	100		
S317363		5	Sterisart® NF	300	FA	100		
S317364		1	Sterisart® NF	300	FA	100		
S317365		2	Sterisart® NF	300	FA	100		
S317366		5	Sterisart® NF	300	FA	100		
S317662		60	Sterisart® NF	300	FA	100		FA Control
S317701-H	X					100		
S317702-H	X					100		
S317703-H	X					100		
S317705-H	X					100		

OVERALL COMMENTS (IF ANY)

TECHNICIAN(S) SIGNATURE AND DATE				QC SIGNATURE AND DATE	QA SIGNATURE AND DATE
Amanda Howard 25-FEB-2025 9:59:11	Richard Orta-Sandiego 24-FEB-2025 17:10:28	Christopher Pino 24-FEB-2025 17:14:15	Rodriguez 24-FEB-2025 11:28:17		

R 07-001-08	STERILITY PROCESSING REPORT (SOP 07-001.09) **46224**	PHARMETRIC LABORATORY PAGE 1 of 1

CRITICAL STEPS

- [x] INCUBATION VESSEL/TUBES INTEGRITY ARE INTACT (NO CRACKS OR BROKEN GLASS)
- [x] NUMBER OF TUBES IN RACKS MATCHING THE OF SAMPLES TESTED IN SESSION.
- [x] ALL TUBES HAVE MEMBRANE INSIDE THE MEDIA.
- [x] ALL TUBES CAPS WERE CORRECTLY CLOSED.
- [x] THE MEDIA WAS PROPERLY INCUBATED UNDER THE CORRECT TEMPERATURE.
- [x] CORRECT MEDIA USED.

INCUBATION VERIFICATION

GROUP OF SAMPLES	QTY IN LIMS SESSION	QTY IN RACKS
No Rush USP <71> 14D 100 ML	22	22

SIGNATURES

INCUBATION TECHNICIAN SIGNATURE AND DATE	QC REVIEWER SIGNATURE AND DATE
Tristan Tubbs Feb 26, 2025 10:22:18 AM	27 Feb 2025

Kay 27 Feb 2025

R 07-014.02	COMPENDIAL STERILITY TEST OBSERVATION RECORD (SOP 07-010.02) 46285	PHARMETRIC LABORATORY
		PAGE 1 of 2

PROCESSED DATE: Feb 25, 2025	INCUBATION TIME IN: Feb 25, 2025 10:13:23	TECHNICIAN: Richard Orta-Santiago
RELEASED DATE: Mar 11, 2025 10:20:56	INCUBATION TIME OUT: Mar 11, 2025 10:20:23	TECHNICIAN: Christopher Piric

SAMPLE NUMBER	VISUAL INSPECTION																														FINAL RESULTS SPEC: (-) NO GROWTH
	DAY 0 Feb 25, 2025		DAY 1 Feb 26, 2025		DAY 6 Mar 3, 2025		DAY 8 Mar 5, 2025		DAY 10 Mar 7, 2025		DAY 13 Mar 10, 2025		DAY 14 Mar 11, 2025		DAY		DAY		DAY		DAY		DAY		DAY		DAY		DAY		
	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	
S317348	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317349	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317350	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317351	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317352	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317353	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317355	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317356	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317357	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317359	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317361	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317362	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317363	(+)	(+)	(+)	(+)	(+)	(+)	(+)	(+)	(+)	(+)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(+)
S317364	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317365	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317366	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317662	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)

R 07-014.02

COMPENDIAL STERILITY TEST OBSERVATION RECORD
(SOP 07-010.02)
46285

PHARMETRIC LABORATORY

SAMPLE NUMBER	VISUAL INSPECTION																												FINAL RESULTS SPEC: (-) NO GROWTH
	DAY 0 Feb 25, 2025		DAY 1 Feb 26, 2025		DAY 6 Mar 3, 2025		DAY 8 Mar 5, 2025		DAY 10 Mar 7, 2025		DAY 13 Mar 10, 2025		DAY 14 Mar 11, 2025		DAY		DAY		DAY		DAY		DAY		DAY		DAY		DAY		
	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	FTM	TSB	
S317863	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	(-)
S317701-H	(-)	(-)	(-)	(-)	(-)	(-)	S	S	S	S	S	S	S	S	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	+4
S317702-H	(-)	(-)	(-)	(-)	(-)	(-)	S	S	S	S	S	S	S	S	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	+4
S317703-H	(-)	(-)	(-)	(-)	(-)	(-)	S	S	S	S	S	S	S	S	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	+4
S317705-H	(-)	(-)	(-)	(-)	(-)	(-)	S	S	S	S	S	S	S	S	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	+4
TECHNICIAN	Christopher Piric		Christopher Piric		Christopher Piric		Christopher Piric		Christopher Piric		Christopher Piric		Christopher Piric		N/A		N/A		N/A		N/A		N/A		N/A		N/A		N/A		

OVERALL COMMENTS (IF ANY)

TECHNICIAN(S) SIGNATURE AND DATE

Richard Otta-Santiago
11-MAR-2025 10:20:18

Christopher Piric
25-FEB-2025 10:17:49

QC SIGNATURE AND DATE

11-MAR-2025

QA SIGNATURE AND DATE

11 MAR 2025

#: (-) = NO Growth; (+) = Growth; S = Sample induce turbidity (Ex: oily or suspension samples); +4 = Require 4 more incubation days.
Incubation Temperatures: TSB (22.5 ± 2.5)°C and FTM (32.5 ± 2.5)°C, according to USP <71>

CERTIFICATE OF ANALYSIS (CoA)

PHARMETRIC LABORATORY

Issue #:	0	SAMPLE #:	S317363
CoA RELEASE DATE:	Mar 11, 2025		

Pharmetric Laboratory
7265 Ulmerton Road
Largo, FL, 33771
Ph: 727-209-5778, Fax: 727-573-0535

CLIENT:	RXCompoundStore.com, LLC	CONTACT:	
CLIENT ADDRESS:	8950 SW 74 CT, #101, Miami, FL, 33156		
DESCRIPTION:	SEMAGLUTIDE 5MG/ML	LOT #:	02172025SEMA5A
STRENGTH:	5MG/ML	CONTAINER:	0.5 ml Vial
STORAGE CONDITIONS:	Refrigerated (2°C to 8°C)	BATCH SIZE: 4	EXP.: 5/17/2025
DATE(S) RECEIVED:	2/24/2025	QUANTITY RECEIVED:	2

TEST DATE	TEST	QTY	ACCEPTANCE CRITERIA	RESULTS	COMPLIANCE STATEMENT
Feb 24, 2025	USP <71> 14D Sterility Test	2	No Evidence of growth	Evidence of growth	FAIL

STERILITY TEST (BATCH & SIZE COMPLIANCE)	USP 71 COMPLIANT	METHOD SUITABILITY ON FILE	Yes

TEST DATE refers to start date. Please note some tests are carried out over multiple days.
The results on this CoA relate only to the item(s) tested and apply to the sample as received. This Report shall not be reproduced except in full without approval of the laboratory.

ACCREDITED TESTING LABORATORY, ACCREDITATION NUMBER 5386.01

COMMENTS	QUALITY CONTROL	QUALITY ASSURANCE
	Carlos Diaz QC Manager 3/11/2025 10:43:10 AM	Yovany Gomez Quality Associate 3/11/2025 10:46:20 AM

charles river

Processing Lab:
614 Interchange Blvd
Newark, DE 19711
www.criver.com/accugenix
Dsl-CustomerSupport@crl.com
Phone +1.302.292.8888

ACCREDITED
CERT #4423.01

Accugenix®
AccuGENX-ID® Report
NEW-SOP-00130

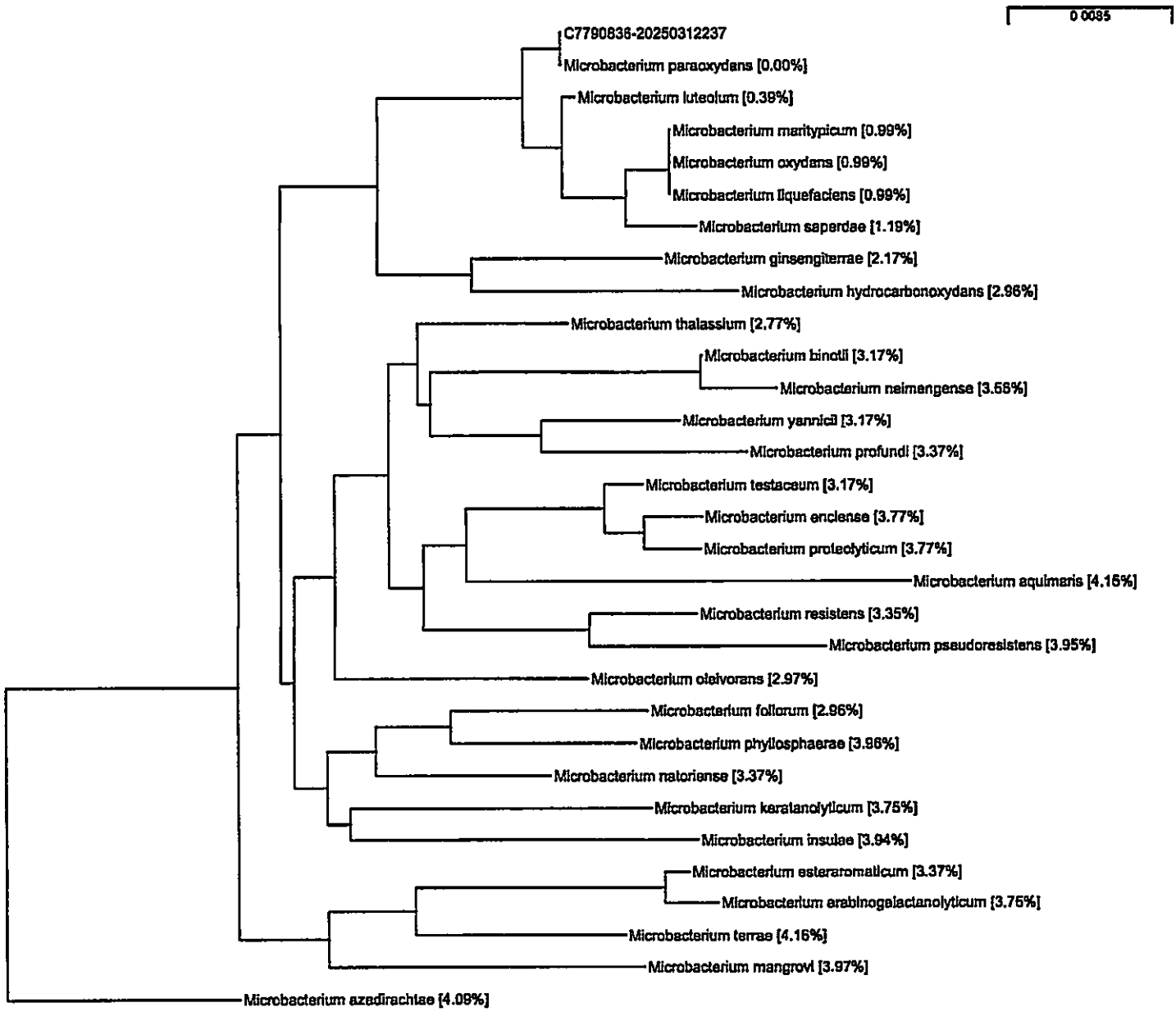
Customer:	Pharmetric Laboratory	Account:	602418 (BET2)
Address:	11880 28th Street North Suite 210, St. Petersburg, FL, 33716, United States		
Accugenix®C# / Run Date:	C7790836-20250312237 / 2025-03-12 12:24:25	ID Request Form#:	789337
Customer Sample ID:	STIR S317363-TSB	Due Date:	2025-03-12

AccuGENX-ID® Database Search Result - Bacterial Library

Identification: ***Microbacterium paraoxydans***

Confidence Level: **Species**
•Based on published literature, the above identified species has been described as a Gram-positive, rod-shaped bacteria. Click HERE for more information on this organism.

Neighbor Joining Tree



The value shown in the bracket represents the percent difference in the sequence alignment between the unknown and each individual library entry.

Not intended for *in vitro* diagnostic use. The results apply to the sample as received.

Prepared By Lauren Bailey at Newark, DE, United States on 2025-03-12 13:51:43 EDT
Reviewed By Robert Stevens at Newark, DE, United States on 2025-03-12 14:02:07 EDT
QA Approved By James Joseph Pagano at Newark, DE, United States on 2025-03-12 15:11:37 EDT
This document has been signed electronically by the individual(s) shown above, in compliance with FDA regulation CFR 21 Part 11.

PHARMETRIC LABORATORY

CERTIFICATE OF ANALYSIS (CoA)

Issue #:	0	SAMPLE #:	S313048
CoA RELEASE DATE:	Feb 10, 2025		

Pharmetric Laboratory
11880 28th Street North, Suite 100
St. Petersburg, FL, 33716
Ph: 727-209-5778, Fax: 727-573-0535

CLIENT:	Pharmetric Laboratory	CONTACT:	Carlos Diaz
CLIENT ADDRESS:	11880 28th St North, Suite 210, St. Petersburg, FL, 33716		
DESCRIPTION:	Fluid A, 500 mL Glass Bottle, 400 ml	LOT #:	FAXXX400-035
STRENGTH:	N/A	CONTAINER:	400 mL Bottle
STORAGE CONDITIONS:	Refrigerated (2°C to 8°C)	BATCH SIZE: 100	EXP.: 1/31/2026
DATE(S) RECEIVED:	2/3/2025	QUANTITY RECEIVED:	5

TEST DATE	TEST	QTY	ACCEPTANCE CRITERIA	RESULTS	COMPLIANCE STATEMENT
Feb 5, 2025	Appearance	0	Clear, light to medium amber; with no precipitate and free of visible particle	Clear, light to medium amber; with no precipitate and free of visible particle	Conforms
Feb 5, 2025	USP <791> pH	0	6.9 - 7.3	7.2	PASS
Feb 4, 2025	Growth Promotion	0	A.brasiliensis (+), C.Albicans (+), P.aeruginosa (+), S.Aureus (+)	A.brasiliensis (+), C.Albicans (+), P.aeruginosa (+), S.Aureus (+)	PASS
Feb 8, 2025	Sterility-ATP Bioluminescence Test	5	No Evidence of growth	No Evidence of growth	PASS

STERILITY TEST (BATCH & SIZE COMPLIANCE)	N/A	METHOD SUITABILITY ON FILE	Yes

Samples accepted by Pharmetric Lab are assumed to be prepared by the customer within the guidelines of USP <71> regarding sample size and number of units sampled. Pharmetric conducts sterility testing using bioluminescence technology. Per USP <797> "A method not described in the USP may be used if verification results demonstrate that the alternative method is at least effective and reliable as the USP membrane filtration method as described in USP<71>." Sterility Testing performed by Pharmetric Lab using bioluminescence technology was validated as equal to compendial test by direct comparison. Validation documents are on file at Pharmetric Lab, LLC.

TEST DATE refers to start date. Please note some tests are carried out over multiple days.
The results on this CoA relate only to the item(s) tested and apply to the sample as received. This Report shall not be reproduced except in full without approval of the laboratory.

COMMENTS	QUALITY CONTROL	QUALITY ASSURANCE
Appearance, pH and Growth Promotion tests were carried out on product drawn from the Sterility assay sample.	Carlos Diaz QC Manager 2/10/2025 12:36:43 PM	Yovany Gomez Quality Associate 2/10/2025 1:18:04 PM

SAMPLE NUMBER
S313048

GROWTH PROMOTION ANNEX

PHARMETRIC LABORATORY

Bacteria	Visual Read Media 1	Visual Read Media 2	Visual Read	Visual Read Result	Control CFU	Limits (per Control)	Percentage vs Control	Result	Final Result	ADDITIONAL COMMENTS (IF ANY)
Pseudomonas aeruginosa	(+)	(+)	(+)	Pass	19.0	(+)	N/A	Pass	Pass	
Staphylococcus aureus	(+)	(+)	(+)	Pass	50.0	(+)	N/A	Pass	Pass	
Yeast	**Visual Read Media 1**	**Visual Read Media 2**	**Visual Read**	**Visual Read Result**	**Control CFU**	**Limits (per Control)**	**Percentage vs Control**	**Result**	**Final Result**	**ADDITIONAL COMMENTS (IF ANY)**
Candida albicans	(+)	(+)	(+)	Pass	26.0	(+)	N/A	Pass	Pass	
Fungus	**Visual Read Media 1**	**Visual Read Media 2**	**Visual Read**	**Visual Read Result**	**Control CFU**	**Limits (per Control)**	**Percentage vs Control**	**Result**	**Final Result**	**ADDITIONAL COMMENTS (IF ANY)**
Aspergillus brasiliensis	(+)	(+)	(+)	Pass	14.5	(+)	N/A	Pass	Pass	

PHARMETRIC LABORATORY

CERTIFICATE OF ANALYSIS (CoA)

Issue #:	0	SAMPLE #:	S316511
CoA RELEASE DATE:	Feb 24, 2025		

Pharmetric Laboratory
7265 Ulmerton Road
Largo, FL, 33771
Ph: 727-209-5778, Fax: 727-573-0535

CLIENT:	Pharmetric Laboratory	CONTACT:	Carlos Diaz
CLIENT ADDRESS:	11880 28th St North, Suite 210, St. Petersburg, FL, 33716		
DESCRIPTION:	Fluid Thioglycollate Medium (FTM), USP Vial, 100 mL	LOT #:	648963
STRENGTH:	NA	CONTAINER:	100 mL Vial
STORAGE CONDITIONS:	Room Temperature (20°C to 25°C)	BATCH SIZE: 600	EXP.: 7/22/2025
DATE(S) RECEIVED:	2/18/2025	QUANTITY RECEIVED:	11

TEST DATE	TEST	QTY	ACCEPTANCE CRITERIA	RESULTS	COMPLIANCE STATEMENT
Feb 19, 2025	Appearance	0	Translucent, light amber with a pink layer at the medium-air interface	Translucent, light amber with a pink layer at the medium-air interface	Conforms
Feb 19, 2025	Growth Promotion	1	C. Sporogenes (+), P.aeruginosa (+), S.Aureus (+)	C. Sporogenes (+), P.aeruginosa (+), S.Aureus (+)	PASS
Feb 24, 2025	Sterility-ATP Bioluminescence Test	10	No Evidence of growth	No Evidence of growth	PASS

STERILITY TEST (BATCH & SIZE COMPLIANCE)	NOT USP 71 COMPLIANT	METHOD SUITABILITY ON FILE	No

Samples accepted by Pharmetric Lab are assumed to be prepared by the customer within the guidelines of USP <71> regarding sample size and number of units sampled. Pharmetric conducts sterility testing using bioluminescence technology. Per USP <797> "A method not described in the USP may be used if verification results demonstrate that the alternative method is at least effective and reliable as the USP membrane filtration method as described in USP<71>." Sterility Testing performed by Pharmetric Lab using bioluminescence technology was validated as equal to compendial test by direct comparison. Validation documents are on file at Pharmetric Lab, LLC.

TEST DATE refers to start date. Please note some tests are carried out over multiple days.
The results on this CoA relate only to the item(s) tested and apply to the sample as received. This Report shall not be reproduced except in full without approval of the laboratory.

COMMENTS	QUALITY CONTROL	QUALITY ASSURANCE
	Carlos Diaz QC Manager 2/24/2025 11:21:04 AM	Yovany Gomez Quality Associate 2/24/2025 3:39:48 PM

CERTIFICATE OF ANALYSIS (CoA)

PHARMETRIC LABORATORY

Issue #:	0	SAMPLE #:	S316508
CoA RELEASE DATE:		Feb 24, 2025	

Pharmetric Laboratory
7265 Ulmerton Road
Largo, FL, 33771
Ph: 727-209-5778, Fax: 727-573-0535

CLIENT:	Pharmetric Laboratory	CONTACT:	Carlos Diaz
CLIENT ADDRESS:	11880 28th St North, Suite 210, St. Petersburg, FL, 33716		
DESCRIPTION:	Tryptic Soy Broth, USP Vial, 100 mL	LOT #:	649322
STRENGTH:	NA	CONTAINER:	100 mL Vial
STORAGE CONDITIONS:	Room Temperature (20°C to 25°C)	BATCH SIZE: 660	EXP.: 1/23/2026
DATE(S) RECEIVED:	2/18/2025	QUANTITY RECEIVED:	12

TEST DATE	TEST	QTY	ACCEPTANCE CRITERIA	RESULTS	COMPLIANCE STATEMENT
Feb 19, 2025	Appearance	0	Clear, light amber	Clear, light amber	Conforms
Feb 19, 2025	Growth Promotion	1	A.brasiliensis (+), B. subtilis (+), C.Albicans (+), P.aeruginosa (+), S.Aureus (+)	A.brasiliensis (+), B. subtilis (+), C.Albicans (+), P.aeruginosa (+), S.Aureus (+)	PASS
Feb 24, 2025	Sterility-ATP Bioluminescence Test	11	No Evidence of growth	No Evidence of growth	PASS
STERILITY TEST (BATCH & SIZE COMPLIANCE)		NOT USP 71 COMPLIANT	METHOD SUITABILITY ON FILE	No	

Samples accepted by Pharmetric Lab are assumed to be prepared by the customer within the guidelines of USP <71> regarding sample size and number of units sampled. Pharmetric conducts sterility testing using bioluminescence technology. Per USP <797> "A method not described in the USP may be used if verification results demonstrate that the alternative method is at least effective and reliable as the USP membrane filtration method as described in USP<71>." Sterility Testing performed by Pharmetric Lab using bioluminescence technology was validated as equal to compendial test by direct comparison. Validation documents are on file at Pharmetric Lab, LLC.

TEST DATE refers to start date. Please note some tests are carried out over multiple days.
The results on this CoA relate only to the item(s) tested and apply to the sample as received. This Report shall not be reproduced except in full without approval of the laboratory.

COMMENTS	QUALITY CONTROL	QUALITY ASSURANCE
	Carlos Diaz QC Manager 2/24/2025 12:35:20 PM	Yovany Gomez Quality Associate 2/24/2025 2:53:51 PM

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6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	M. PERSONNEL TRAINING & COMPETENCIES - ALL CATEGORIES

ONGOING CATEGORY 1 AND 2- GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency evaluation and GFT every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2] *GFT done annually for 1 Tech 4/30/25 and 8/7/24. 3 new personnel less than 6 months*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	The primary issue stemmed from the absence of a centralized and automated tracking system to manage and alert for required GFT and garbing and media fill reassessments. The technician in question had been incorrectly classified as non-compounding staff, resulting in an annual rather than semiannual reassessment schedule. Additionally, while documentation for new employees was maintained, it was not organized in a manner that allowed for immediate retrieval during the inspection.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

The technician was promptly reclassified as compounding personnel and completed a corrective GFT to meet the semiannual requirement (category 2)

A full audit of all GFT records was performed to identify any additional discrepancies or misclassifications.

Documentation verifying completion of initial garbing and GFT assessments for the three new employees was retrieved and reviewed.

Documents were reorganized within SharePoint for centralized storage and rapid accessibility.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

A GFT and garbing competency tracker was implemented in SharePoint, with role-based intervals and automated alerts for upcoming reassessments.

Personnel classifications were reviewed and updated to ensure appropriate assignment of reassessment frequencies.

The DP will conduct monthly audits of the tracker to validate compliance and accuracy of staff roles.

The relevant SOP is being revised to clearly define responsibilities for tracking competencies and required escalation steps when evaluations are missed or delayed.

REVIEW DATE:	7/14/2025	**PHARMACY DESIGNEE:**	Shibu John, Amelia Yeh

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6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	M. PERSONNEL TRAINING & COMPETENCIES - ALL CATEGORIES

ONGOING CATEGORY 1 AND 2- MEDIA FILL & ASSESSMENT: After initial aseptic manipulations competency evaluations, compounding personnel complete aseptic technique competency, media fill, GFTs, and surface sampling of DCA every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete media fill every 12 months. GFTs and surface samples are appropriately incubated. [USP 797 Section 2.3] *GFT done annually for 1 Tech 4/30/25 and 8/7/24. 3 new personnel less than 6 months*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	The primary issue stemmed from the absence of a centralized and automated tracking system to manage and alert for required GFT and garbing and media fill reassessments. The technician in question had been incorrectly classified as non-compounding staff, resulting in an annual rather than semiannual reassessment schedule. Additionally, white documentation for new employees was maintained, it was not organized in a manner that allowed for immediate retrieval during the inspection.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

The technician was promptly reclassified as compounding personnel and completed a corrective MF to meet the semiannual requirement (category 2).

A full audit of all MF records was performed to identify any additional discrepancies or misclassifications.

Documentation verifying completion of MF assessments for the three new employees was retrieved and reviewed.

Documents were reorganized within SharePoint for centralized storage and rapid accessibility.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

A centralized competency tracking system was implemented via SharePoint, with automated alerts based on personnel roles and assessment frequency.

Personnel classifications were reviewed and updated to ensure appropriate assignment of reassessment frequencies.

The DP will conduct monthly audits of the tracker to validate compliance and accuracy of staff roles.

The relevant SOP is being revised to clearly define responsibilities for tracking competencies and required escalation steps when evaluations are missed or delayed.

REVIEW DATE:	7/14/2025	**PHARMACY DESIGNEE:**	Shibu John, Amelia Yeh

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6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	M. PERSONNEL TRAINING & COMPETENCIES - ALL CATEGORIES

CLEANING PERSONNEL: Cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures. Cleaning personnel demonstrate knowledge and competency of core skills related to cleaning, disinfection, and maintenance of environmental conditions initially and at least once every 12 months. [USP 797 Sections 7 & 2.1] *No documentation available at the time of inspection*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	Documentation of cleaning personnel's training and competency assessments was not maintained in an easily accessible format for inspection readiness. The existing records were stored in a location that was not promptly retrievable by staff during the inspection.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

All current training and competency records for cleaning personnel were reviewed and compiled into a centralized and accessible file system.

A checklist was created to verify that each cleaning staff member has completed initial and annual competency evaluations in alignment with USP <797> requirements.

The records have been electronically archived and backed up for future accessibility.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

A policy has been implemented to require that all cleaning personnel competency assessments be completed upon hire and every 3 months (category 3)

All documentation will be maintained in both physical and electronic formats in a designated compliance folder accessible by authorized personnel.

Staff responsible for training oversight have been retrained on document retention protocols and inspection readiness.

A quarterly internal audit process will be implemented to ensure training documentation remains current and accessible.

REVIEW DATE:	7/14/2025	**PHARMACY DESIGNEE:**	Shibu John, Amelia Yeh

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6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	O. CLEANING AND DISINFECTING: ALL CATEGORIES

PEC SANITIZATION WITH STERILE 70% IPA: Sterile 70% IPA is applied to the horizontal work surface, including removable trays, immediately before initiating compounding and at least every 30 minutes. If a compounding process takes more than 30 minutes, the work surface is disinfected immediately after the end of the compounding process. Sterile 70% IPA is allowed to dry. [USP 797 Section 7] *compounding syringes and equipment introduced to PEC prior to cleaning of surface*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	Lack of procedural clarity and personnel awareness resulted in the premature introduction of equipment and syringes into the PEC before proper disinfection of the work surface was completed.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

Immediate: reinforced with all compounding personnel the requirement that no equipment may be introduced into the PEC until after full surface disinfection with sterile 70% IPA is completed and allowed to dry.

Conducted immediate retraining for all staff on the USP <797> requirements related to PEC sanitization timing and sequence.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

Review standard operating procedure (SOP) to explicitly outline the proper sequence for PEC disinfection and equipment placement.

Monthly observational audits will be implemented to verify adherence to PEC sanitization protocols

Incorporate PEC sanitization and equipment introduction steps into annual media fill and aseptic technique requalification training.

Perform direct observation audits weekly for the next 3 months to confirm compliance with sanitization sequence.

Eequire sign-off by techinicians and DP on PEC cleaning logs, verifying completion of IPA application prior to equipment introduction.

REVIEW DATE:	7/14/2025	**PHARMACY DESIGNEE:**	Shibu John, Amelia Yeh

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6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	P. COMPOUNDING CSPs FROM NONSTERILE COMPONENTS OR SUPPLIES – CATEGORY 2 & 3

API MANUFACTURERS: APIs are manufactured by an FDA-registered facility in the U.S. or comply with the laws and regulations of the applicable regulatory jurisdictions outside of the U.S. [USP 797 Section 9.3.1] *manufactured in china*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	Lack of accessible documentation demonstrating that the Chinese API manufacturer is registered with the FDA or complies with the applicable regulatory requirements outside of the U.S., as required under USP <797> Section 9.3.1.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

Immediately obtained and reviewed the FDA registration list. It is also confirmed that the manufacturer is listed with the FDA as a registered API facility

Updated the vendor qualification file with the documentation demonstrating compliance with regulatory requirements.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

Implement a standardized vendor qualification checklist to include FDA registration or GMP compliance verification for all U.S. and non-U.S. API manufacturers.

Conduct annual audits or reviews of all active API supplier documentation.

Train procurement and quality assurance personnel on USP <797> Section 9.3.1 requirements to ensure continuous compliance.

Perform a quarterly audit of API vendor files to ensure complete documentation is on record.

Verify that all new API sources are vetted using the revised checklist.

SUPPLEMENTARY DOCUMENT

Firm Name	FDA Establishment Identifier	DUNS	Business Operation	Address	Registration Expiration Date
Harbin Jixianglong Biotech Co., Ltd.	3024038751	539959367	API MANUFACTURE	North of Baoan Road, East of Changqing Street, Limin Development Zone, Harbin City, Heilongjiang Province 150025, China (CHN)	12/31/2025
Qingdao Biopeptek Co., Ltd.	3009110908	417988990	API MANUFACTURE	218 Shuangyuan Road, Chengyang, Qingdao, Shandong 266000, China (CHN)	12/31/2025
Fujian Genohope Biotech Ltd.	3025263427	706128759	API MANUFACTURE; MANUFACTURE	No. 288,Renyang, Binglun Village, Hushi Town, Xiuyu District, Putian, Fujian 351148, China (CHN)	12/31/2025
Zhejiang Peptites Biotech Co., Ltd	3015685285	560465455	ANALYSIS; API MANUFACTURE	No.8,Hengyizhi Road, Sanjie Town, Shengzhou City, Shaoxing City, Zhejiang 312452, China (CHN)	12/31/2025
Hangzhou XinHan Biopharma Co., Ltd.	3032587041	452304774	API MANUFACTURE	No 600 Yinhai Road, Xiasha Street, Qiantang District, Hangzhou, Zhejiang 310000, China (CHN)	12/31/2025
SMS Lifesciences India Limited	3005343706	650460947	API MANUFACTURE; LABEL; PACK; ANALYSIS;	Unit-I, Sy No. 180/2,Kazipally Village, Jinnaram Mandal, Sangareddy, Telangana 502319, India (IND)	12/31/2025
Hybio Pharmaceutical (Wuhan) Co., Ltd.	3016069760	544358390	API MANUFACTURE; LABEL; PACK; ANALYSIS	No.9, Linkong West Street, Hengdian Street, Huangpi District, Wuhan, Hubei 430301, China (CHN)	12/31/2025
Spectrum Pharmaceuticals, Inc.	3005383580	790888002	MANUFACTURE	2 Atlantic Ave Fl 6, Boston, Massachusetts (MA) 02110-3978, United States (USA)	12/31/2025
Fagron Inc	1000174332	121183016	API MANUFACTURE; MANUFACTURE; RELABEL; REPACK	2400 Pilot Knob Road, St Paul, Minnesota (MN) 55120, United States (USA)	12/31/2025

REVIEW DATE:	7/14/2025	PHARMACY DESIGNEE:	Shibu John, Amelia Yeh

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6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	P. COMPOUNDING CSPs FROM NONSTERILE COMPONENTS OR SUPPLIES – CATEGORY 2 & 3

STERILE, DEPYROGENATED SUPPLIES: Supplies in direct contact with CSPs are sterile and depyrogenated. A COA or similar conformance documentation is reviewed. [USP 797 Section 9.3.1] *no document available or reviewed by designated person at the time of inspection*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	The Certificate of Analysis (COA) was available and shown during the inspection; however, it was not reviewed or acknowledged by the designated person at the time, and was not formally included in the accessible documentation file.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

The COA for the sterile, depyrogenated supplies is attached to this CAPA for reference and inspection record.

The COA has been filed in the designated quality documentation folder or link to download COA for future accessibility.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

Establish a documentation review checklist for all sterile, depyrogenated supplies to ensure COAs are reviewed and signed by the designated person prior to inspection.

Maintain all COAs in a centralized and indexed electronic filing system for rapid retrieval.

Retrain designated personnel on documentation responsibilities and inspection readiness.

Review documentation retrieval logs quarterly to ensure accessibility and staff compliance.

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6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	P. COMPOUNDING CSPs FROM NONSTERILE COMPONENTS OR SUPPLIES – CATEGORY 2 & 3

STERILIZATION OF INJECTABLES WITHIN 6 HOURS OF COMPLETION: Injectable CSPs containing nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during compounding are sterilized within 6 hours of completion. [USP 797 Section 10] *CSP discarded if it comes into contact with non-sterile components.*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	The discrepancy may have resulted from a miscommunication or lack of clarity in how the question was presented during the inspection. The compounding team followed the procedure of sterilizing applicable CSPs within 6 hours of completion, in accordance with USP <797> standards. However, the information may not have been clearly conveyed or documented in a way that fully addressed the specific intent of the inspector's inquiry.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLEM:

Verified that all injectable CSPs compounded with non-sterile components or devices are consistently sterilized within 6 hours of completion.

Verified that all injectable CSPs compounded with non-sterile components or devices are consistently sterilized within 6 hours of completion.

Ensured that documentation is clear, specific, and retrievable during inspections to accurately reflect compliance.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

Re-trained designated personnel on how to clearly and thoroughly communicate practices and documentation during regulatory inspections

Enhanced internal inspection readiness checklist to specifically include verification of sterilization timing and proper record presentation.

Included clear SOP references and batch record identifiers in inspection binders to ensure easy traceability of compliance activities.

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6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	Q. STERILIZATION OF CSPs - CATEGORY 2 & 3

CSP PREFILTRATION: When CSPs are known to contain excessive particulate matter, prefiltration is performed using a filter of larger nominal pore size (e.g., 1.2 µm) or a separate filter of larger nominal pore size placed upstream of (i.e., prior to) the sterilizing filter. [USP 797 Section 10.2] *refiltered CSP is done using 0.22micron filter. does not match SOP*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	There was a misunderstanding regarding the distinction between prefiltration and refiltration. CSP prefiltration, as outlined in the SOP, applies when a compounded sterile preparation contains excessive particulate matter prior to passing through the sterilizing-grade filter. In such cases, a filter with a larger nominal pore size (e.g., 1.2 µm) will be used upstream of the 0.22 µm sterilizing filter, if applicable. The reference to "refiltering" with a 0.22 µm filter was misinterpreted as a deviation; however, no CSPs compounded to date have required prefiltration, as no excessive particulate burden has been observed. The filter label reviewed during the inspection pertained to the standard sterilizing-grade 0.22 µm filter, which was appropriately used.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

The SOP has been reviewed and clarified to emphasize that prefiltration is only required when excessive particulate matter is present, and that the use of a 0.22 µm filter alone is appropriate for standard sterilizing filtration.

Documentation has been updated to remove misleading language about "refiltering" with 0.22 µm unless specifically required due to a processing deviation.

Staff were retrained on the difference between prefiltration (used upstream for particulate removal) and sterilizing filtration (standard 0.22 µm final filter) to ensure consistent understanding.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

Future CSPs will be visually assessed and documented for particulate burden prior to filtration. If excessive particulates are noted, prefiltration will be performed using an appropriate filter in accordance with USP <797> and SOP.

A clarification memo has been distributed summarizing the proper application of prefiltration vs. refiltration to reduce ambiguity in documentation and practice.

SOP REFERENCE

4.006 Sterilization Process

REVIEW DATE:	7/14/2025	**PHARMACY DESIGNEE:**	Shibu John, Amelia Yeh

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6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	Q. STERILIZATION OF CSPs - CATEGORY 2 & 3

CSP TERMINAL STERILIZATION SOP includes: 1) A description of CSP terminal sterilization process(es), including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization methods and equipment. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. [USP 797 Section 10] *No personnel log available at the time of inspection*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	Terminal sterilization is not practiced at our facility because all compounded sterile preparations (CSPs) are heat-sensitive and would be degraded by terminal sterilization processes. Therefore, personnel have not undergone training specific to terminal sterilization, and no log was maintained.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

The SOP will be updated to clearly state that terminal sterilization is not utilized due to the thermal sensitivity of all CSPs compounded at the facility.

A formal notation will be added to the training matrix indicating that terminal sterilization is not an applicable method for current compounding processes.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

Ensure that future SOP reviews clearly document the rationale for exclusion of certain sterilization methods and their relevance to current practices.

Include a section in the personnel training log that designates which sterilization methods are applicable, with justification for non-applicable methods.

SOP REFERENCE

4.006 Sterilization Method

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DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	Q. STERILIZATION OF CSPs - CATEGORY 2 & 3

CALIBRATED DATA RECORDER: A calibrated data recorder or chart is used to monitor each steam or dry heat sterilization cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure). The calibrated oven is equipped with temperature controls and a timer. [USP 797 Section 10.3 & 10.4] *not available at the time of inspection*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	The data recording log for sterilization cycles was not maintained in an accessible and standardized format, leading to its unavailability during inspection.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

Reinforce the procedure requiring documentation of each sterilization cycle using a calibrated data recorder or chart.

Implement a standardized log format for recording temperature, pressure, calibration dates, and any observed deviations.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

Designate a responsible person to complete and review the sterilization log after each use.

Conduct periodic audits (monthly) to ensure logs are properly completed, reviewed, and readily retrievable for inspection.

Include the use of this log in staff training and competency assessments.

SUPPLEMENTARY DOCUMENT

DEPYROGENATION OVEN

Date	Cycle Start Time	Cycle End Time	Temperature (°C)	Heat Duration (Min)	Deviations Observed If Any	Verified By
6/19/2025	16:30	17:50	250	30		AY
6/20/2025	17:30	18:50	250	30		AY
6/21/2025	17:30	18:50	250	30		JF
6/23/2025	16:30	17:50	250	30		AY
6/24/2025	17:30	18:50	250	30		AY
6/25/2025	16:30	17:50	250	30		JF
6/26/2025	17:30	18:50	250	30		AY
6/27/2025	16:30	17:50	250	30		JF
6/28/2025	16:30	17:50	250	30		AY
6/30/2025	16:30	17:50	250	30		JF
7/1/2025	17:30	18:50	250	30		AY
7/2/2025	17:30	18:50	250	30		AY
7/3/2025	17:30	18:50	250	30		JF
7/4/2025	17:30	18:50	250	30		AY
7/5/2025	16:30	17:50	250	30		JF
7/6/2025	17:30	18:50	250	30		JF
7/7/2025	17:30	18:50	250	30		JF
7/8/2025	16:30	17:50	250	30		JF
7/9/2025	16:30	17:50	250	30		AY
7/10/2025	16:30	17:50	250	30		AY
7/11/2025	16:30	17:50	250	30		JF
7/12/2025	17:30	18:50	250	30		JF
7/14/2025	17:30	18:50	250	30		AY

STERILIZER (AUTOCALVE)

Date	Cycle Start Time	Cycle End Time	Temperature (°C)	Heat Duration (Min)	Pressure (Psi)	Deviations Observed If Any	Verified By
6/19/2025	9:00	11:00	275	30	15		AY
6/20/2025	9:00	11:00	275	30	15		AY
6/21/2025	8:30	10:30	275	30	15		JF
6/23/2025	9:00	11:00	275	30	15		AY
6/24/2025	9:00	11:00	275	30	15		AY
6/25/2025	8:30	10:30	275	30	15		JF
6/26/2025	9:00	11:00	275	30	15		AY
6/27/2025	8:30	10:30	275	30	15		JF
6/28/2025	8:30	10:30	275	30	15		AY
6/30/2025	8:30	10:30	275	30	15		JF
7/1/2025	9:00	11:00	275	30	15		AY
7/2/2025	8:30	10:30	275	30	15		AY
7/3/2025	8:30	10:30	275	30	15		JF
7/4/2025	9:00	11:00	275	30	15		AY
7/5/2025	9:00	11:00	275	30	15		JF
7/6/2025	9:00	11:00	275	30	15		JF
7/7/2025	8:30	10:30	275	30	15		JF
7/8/2025	8:30	10:30	275	30	15		JF
7/9/2025	8:30	10:30	275	30	15		AY
7/10/2025	9:00	11:00	275	30	15		AY
7/11/2025	8:30	10:30	275	30	15		JF
7/12/2025	9:00	11:00	275	30	15		JF
7/14/2025	9:00	11:00	275	30	15		AY

REVIEW DATE:	7/14/2025	PHARMACY DESIGNEE:	Shibu John, Amelia Yeh

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6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTIING BDDY/PERSDNNEL:**	Florida Department of Health
DESCRIBE THE PRDBLEM:		**REFERENCE:**	R. STERILIZATION & DEPYROGENATION OF SUPPLIES & CONTAINER CLOSURE SYSTEMS - CATEGORY 2 & 3

STERILIZATION & DEPYROGENATION SOP's include: 1) A description of sterilization and depyrogenation process(es) used to sterilize and/or depyrogenated compounding supplies and container closure systems, including the temperature, duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. [USP 797 Section 10] *SOP does not include personnel training or competency at the time of inspection*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	The original SOP focused primarily on the technical parameters of sterilization and depyrogenation (e.g., temperature, duration, load conditions, use of biological indicators), but inadvertently omitted structured documentation and procedures regarding personnel training and competency evaluation.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE/IMMEDIATE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

The Sterilization and Depyrogenation SOP has been updated to include:
- Initial training procedures for all personnel performing or overseeing sterilization and depyrogenation.
- Required competency assessments, including observation checklists and practical demonstrations.
- Ongoing competency reassessment every 12 months or when procedural changes occur.

A training log template has been developed and implemented to document training completion and competency evaluation.

Staff currently responsible for sterilization and depyrogenation will undergo re-training and complete competency assessments.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIDNS AND PDLICY AND/OR PROCEDURE CHANGE:

All SOPs will be reviewed and revised quarterly by the Quality Assurance Team to ensure training and competency requirements are clearly outlined.

A master training matrix will be maintained to track all personnel training and reassessment timelines.

SOP REFERENCE

3.002 DOC OF SOP TRAINING
5.004 AUTOCLAVE USE, CALIBRATION, CLEANING, MAINT
5.013 DRY HEAT OVEN--USE, CLEAN, CALIBRATION, MAINT
Sterilization & Depyrogenation Training & Personnel Competency Checklist

REVIEW DATE:	7/14/2025	**PHARMACY DESIGNEE:**	Shibu John, Amelia Yeh

Attachment C: Personnel Training Checklist

Title: Sterilization & Depyrogenation Training Checklist

Authorized by: Amelia Yeh **Date: 7/14/2025**

Trainee Name: _____

Trainer Name: _____

Date of Training: _____

Training Item	Trainer Initials	Trainee Initials	Date Completed
Overview of SOP 10.001 (Sterilization & Depyrogenation)			
Purpose and scope of sterilization and depyrogenation			
Understanding moist heat sterilization principles and parameters			
Understanding dry heat depyrogenation principles and parameters			
Proper load configuration and permissible load size			
Use of Biological Indicators (BI)			
Use of Endotoxin Challenge Vials (ECV)			

Reviewing sterilizer/autoclave data (charts, logs, temperature, pressure)

Recognizing and responding to sterilization cycle irregularities

Safe operation of sterilizer and depyrogenation oven

Documentation and log completion

PPE and safety protocols

Trainer Signature: _____

Trainee Signature: _____

Date of Completion: _____

Attachment D: Competency Assessment Form

Title: Sterilization & Depyrogenation Personnel Competency Evaluation

Employee Name: _____

Evaluator Name: _____

Date of Evaluation: _____

Assessment Criteria	Pass/Fail	Comments
Demonstrates knowledge of sterilization and depyrogenation cycle parameters (temp, time, pressure, load)		
Correctly identifies equipment used for steam sterilization and dry heat depyrogenation		
Prepares items correctly for sterilization or depyrogenation		
Configures load in compliance with SOP		
Operates sterilization equipment per manufacturer and SOP		
Places and documents use of BI and/or ECV properly		
Reviews and interprets cycle charts or electronic data correctly		
Identifies deviations and takes appropriate corrective actions		
Completes sterilization log correctly and consistently		

Demonstrates proper use of
PPE and aseptic technique
during handling

Overall Assessment Result: ☐ Competent ☐ Needs Retraining

Evaluator Signature: _____

Employee Signature: _____

Date: _____

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DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	R. STERILIZATION & DEPYROGENATION OF SUPPLIES & CONTAINER CLOSURE SYSTEMS - CATEGORY 2 & 3

STERILIZATION CYCLE VALIDATION: When performed onsite, the efficacy of sterilization cycles used for supplies or container closure systems are established and documented. Each sterilization run or load is verified and documented by using appropriate biological indicators (e.g., spores of Geobacillus stearothermophilus) and other confirmation methods. [USP 797 Section 9.3.1 & USP 1229] *no report available at the time of inspection*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	While sterilization procedures were performed in accordance with internal protocols, the validation documentation, including the interpretation of process indicators, was not formally compiled into a report nor filed in the inspection-ready documentation system.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

A validated procedures is implemented to verify and document the effectiveness of each steam sterilization run. This includes the use of appropriate biological indicators, such as physicochemical process indicators. As shown in the attached image, we utilize physicochemical indicators during each cycle to provide visual confirmation that critical sterilization parameters, such as time, temperature, and steam exposure, have been consistently achieved.

The sterilization SOP has been updated to:
- Require the completion and retention of a Sterilization Cycle Validation Report for each sterilization run.
- Include documentation procedures for the interpretation of chemical indicators (e.g., steam process indicator color change from pink to brown/black).
- Specify that validation reports must include the load contents, date, indicator lot, result interpretation, and personnel signatures.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

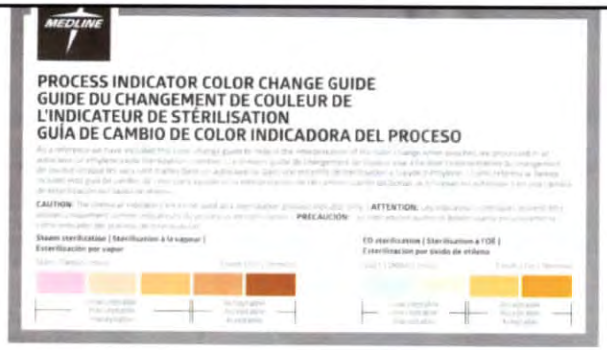
A Sterilization Cycle Documentation Log has been implemented to ensure tracking of all sterilization runs with corresponding indicator verification and validation notes.

Staff performing sterilization have been retrained on documentation requirements and the proper use and interpretation of chemical/physical indicators.

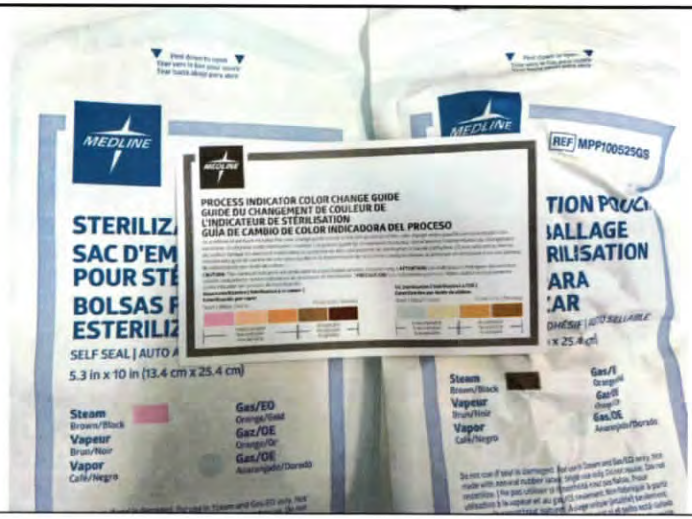
Reports will be stored both physically and electronically for rapid retrieval during inspections.

SUPPLEMENTARY DOCUMENT

STERILIZATION CYCLE VALIDATION LOG TEMPLATE



PROCESS INDICATOR COLOR CHANGE GUIDE
GUIDE DU CHANGEMENT DE COULEUR DE L'INDICATEUR DE STÉRILISATION
GUÍA DE CAMBIO DE COLOR INDICADORA DEL PROCESO



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DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	T. RELEASE INSPECTION AND TESTING – ALL CATEGORIES

CSP REJECTION & QUARANTINE: CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock. [USP 797 Section 12.1] products not meeting standards are sent back into cleanroom and filtered again. If CSP does not pass inspection the second time it is discarded. No separation of stock or labeling "rejected".

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	Not adhere to the existing SOP for rejection and quarantine of nonconforming CSPs may be due to a lapse in attention to procedural compliance and a lack of ongoing reinforcement of expectations.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE/IMMEDIATE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

Personnel Re-Training:
- All relevant compounding staff will be retrained on the existing CSP Rejection and Quarantine SOP with emphasis on:
- Immediate labeling of CSPs as "REJECTED" upon identification of defects or failure to meet standards.
- Prompt segregation of rejected CSPs from active stock into the designated quarantine area.
- Documentation of rejection and any authorized reprocessing per protocol.

Accountability Measures:
Supervising pharmacists will conduct random checks during and after batch review to confirm rejected CSPs are properly labeled and quarantined per SOP.

Documentation Review:
A review of recent batch records and QA inspection logs will be conducted to identify any other instances of deviation and ensure retrospective documentation is corrected where necessary.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

A spot-audit form will be created and used by QA or designated staff to check CSP rejection handling compliance at least twice per month.

Monthly staff huddles will include review of common procedural lapses, including proper rejection and quarantine practices.

SOP REFERENCE

6.015 RECALL, QUARANTINE, AUDIT TRAIL OF COMP PREP

REVIEW DATE:	7/14/2025	**PHARMACY DESIGNEE:**	Shibu John, Amelia Yeh

List Back

RxCompoundStore.com
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PH: 786.803.8947
FAX: 844.875.0009
Email: orders@rxcompoundstore.com

Next

6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	U. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, & TRANSPORT – ALL

STORAGE AREA TEMPERATURE MONITORING: Temperature in CSP & component storage areas is monitored at least once daily and recorded on a log on days when the facility is open or by a continuous temperature recording device; temperature data is readily retrievable. Monitoring equipment is calibrated or verified for accuracy as recommended by the manufacturer or every 12 months. When CSPs have been exposed to temperature excursions above or below storage temperature limits for the CSP, a Designated Person determines whether the CSP has retained its integrity or quality. [USP 797 Sections 9.3 & 19.1]

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	The absence of a continuous monitoring system was due to reliance on manual temperature logs and daily readings, which were previously considered sufficient for ensuring temperature control. However, this method lacked real-time alerts and historical data logging features necessary for optimal compliance and oversight.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

A continuous temperature monitoring system, MECRO, was installed and activated immediately following the inspection. This system provides:
- 24/7 real-time monitoring of temperature and humidity conditions
- Automated alerts in case of deviations from defined thresholds
- Cloud-based data storage for historical temperature reports
- Compliance with USP <797> data integrity requirements
- Training was provided to designated staff on how to access, interpret, and respond to alerts and data generated by MECRO.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

The system is programmed to send alerts to designated personnel via email/SMS for any out-of-range conditions.

Monthly audits will be conducted to verify continuous functionality and documentation.

Ongoing staff training will occur annually or when system updates are made.

SOP REFERENCE

5.003 REFRIGERATOR FREEZER—USE, CLEANING, AND MAINTENANCE

REVIEW DATE:	7/14/2025	**PHARMACY DESIGNEE:**	Shibu John, Amelia Yeh

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6.017 CORRECTIVE AND PREVENTITIVE ACTION (CAPA) AND/OR POLICY AND PROCEDURE CHANGE

DATE OF INSPECTION:	6/18/2025	**INSPECTIING BODY/PERSONNEL:**	Florida Department of Health
DESCRIBE THE PROBLEM:		**REFERENCE:**	V. STERILE QUALITY PROGRAM, SOP's & DOCUMENTATION- ALL CATEGORIES

ADR & COMPLAINT DOCUMENTATION: A complete record of each reported complaint and adverse reaction is created and retained per USP 797. [USP 797 Section 18.1] *no record available at the time of inspection*

ROOT CAUSE:		**DESCRIPTION:**
☐	Machines	A gap was identified in the current workflow regarding documentation and retention of complaints and ADRs. Although verbal and informal documentation may heve occurred, no formal, centralized, and retrievable record was maintained. This failure resulted from a lack of designated procedures and personnel accountability for properly documenting and archiving these reports.
☑	Method	
☐	Manpower Training	
☐	Measurements	
☐	Materials	
☐	Milieu/Environment	

DESCRIBE THE CORRECTIVE ACTION(S) TAKEN TO CONTAIN THE PROBLRM:

All past ADRs and complaints reported to the pharmacy will be retrospectively reviewed and documented using the approved Complaint & ADR Documentation Form.

Records will be compiled into a centralized log that includes the date of the event, nature of the complaint or reaction, product involved, actions taken, outcome, and follow-up communication.

Documentation will be maintained in both physical and digital formats, readily retrievable during inspections or audits.

PERMANENT CORRECTIVE AND PREVENTATIVE ACTIONS AND POLICY AND/OR PROCEDURE CHANGE:

Implement and train all staff on a standardized Complaint and Adverse Reaction Reporting SOP that includes:
- Procedures for intake, evaluation, documentation, and follow-up.
- Defined timelines and responsible personnel for reporting and documentation.

Designate a Compliance Officer to review and sign off on all complaints and ADRs within 48 hours of receipt.

Integrate ADR and complaint documentation into quality assurance audits on a quarterly basis to ensure ongoing compliance.

Include this documentation requirement in onboarding and annual competency training for all pharmacists and support staff.

SOP REFERENCE

6.003 ADVERSE EVENT REPORTING
6.019 INCIDENT REPORTING

REVIEW DATE:	7/14/2025	**PHARMACY DESIGNEE:**	Shibu John, Amelia Yeh

3.002 DOCUMENTATION OF SOP TRAINING

Authorized by: Shibu John, Amelia Yeh **Date: 7/15/2025**

1.0 PURPOSE

1.1 The purpose of this standard operating procedure (SOP) is to establish the format and documentation of the training, education, and documentation of the SOPs associated with department-specific and facility-wide policies and procedures that must be followed by all personnel employed at RX COMPOUNDSTORE .

2.0 SCOPE

2.1 This procedure applies to all personnel employed at RX COMPOUNDSTORE.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge (PIC) must supervise this procedure and is responsible for employee training.

3.2 Supervisors/ Trainers are responsible for training, education, and documentation of new employees, students, and/or interns.

3.3 The PIC is responsible for ensuring all RX COMPOUNDSTORE personnel receive proper training for their assigned department and that documentation is complete.

4.0 REFRENCES

4.1 RX COMPOUNDSTORE SOPs

5.0 DEFINITIONS

5.1 SOP—Standard Operating Procedure(s)

6.0 FREQUENCY

6.1 Ongoing.

7.0 EQUPMENT & SUPPLIES

7.1 RX COMPOUNDSTORE SOP Manual

8.0 GENERAL INFORMATION

8.1 All personnel who compound or have direct oversight of compounding personnel must be initially trained and qualified by demonstrating knowledge and competency in compounding preparations according to requirements in USP chapters related to compounding.

8.2 Compounding personnel are responsible for ensuring that compounded preparations are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed and or distributed.

8.2.1 These performance responsibilities include maintaining appropriate cleanliness conditions and providing labeling and supplementary instructions for the proper clinical administration of compound preparations.

8.3 Compounding personnel are responsible for compounding preparations of acceptable strength, quality, and purity in accordance with the prescription or medication order.

8.4 Compounding personnel are also responsible for dispensing the finished preparation, with appropriate packaging and labeling, and in compliance with the requirements established by the applicable state agencies, state boards of pharmacy, federal law, and other regulatory agencies where appropriate.

9.0 PROCEDURE

9.1 As part of orientation and onboarding of new personnel, candidates mustbe assigned to read and follow the SOPs associated with their designated department.

9.1.1 This is a self-paced reading assignment with a completion deadline of 90 days after starting employment with RX COMPOUNDSTORE.

9.1.2 The compliance officer will ensure deadlines are met and appropriate training documentation is signed off on.

9.2 Individuals who are engaged in drug or dietary supplement compounding mustbe proficient in compounding and should continually expand their compounding knowledge by participating in seminars and slash or studying appropriate literature.

9.3 All personnel who compound or have direct oversight of compounding personnel must be proficient in the SOPs of RX COMPOUNDSTORE.

9.4 All training received by employees will be documented and maintained in the employee training file.

9.5 This will be facilitated using the Documentation of Completion of Standard Operating Procedures log.

10.0 ATTACHMENTS

10.1 F.3.002.1 Documentation of Completion of Standard Operating Procedures log

11.0 HISTORY

11.1 Original. Brenda Poland. 04-01-2023

11.2 Reviewed. Shibu John. 03-25-2025

11.3 Edited. Amelia Yeh. 03-15-2025

4.006 STERILIZATION METHODS

Authorized by: Shibu John, Amelia Yeh **Date Effective: 7/15/2025**

1.0 PURPOSE

1.1 This SOP will outline sterilization methods employed by aseptic processing personnel at RX COMPOUNDSTORE.

2.0 SCOPE

2.1 This procedure applies to all aseptic processing compounding personnel at RX COMPOUNDSTORE.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge (PIC) must supervise this procedure and ensure proper training of all personnel.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 USP Current Version <800> "Safe Handling of Hazardous Drugs in the Healthcare Setting"

5.0 DEFINITIONS

5.1 Aseptic Processing—A mode of processing pharmaceutical and medical products that involves the separate sterilization of the product and the package and the transfer of the product into the container and its closure under at least ISO class 5 conditions

5.2 CSP – Compounded Sterile Preparation

5.3 Sterilization – Process to render articles or preparations free from viable microorganisms

5.4 Terminal Sterilization – Applying a lethal process to sealed containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10^{-6}, or a probability of less than one in one million of a non-sterile unit.

5.5 Sterilizing Grade Membrane—Membranes what are documented to retain 100% of a culture of 10^{7} microorganisms of a strain of Brevundimonas (pseudomonas) diminuta per square centimeter of membrane surface under pressure of not less than 30PSI (2.0 bar). Such filter membranes are nominally at 0.22 µm or 0.2 µm nominal pore size, depending on the manufacturer's practice.

5.6 Sterilization by Filtration—Passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

6.0 FREQUENCY

6.1 With each sterilization process.

7.0 EQUIPMENT & SUPPLIES

7.1 Autoclave

7.2 Dry Heat Oven

7.3 Sterilizing Grade Membrane Syringe Filters

8.0 GENERAL INFORMATION

8.1 The staff pharmacists who supervise sterile compounding at RX COMPOUNDSTORE must be responsible for determining that the selected sterilization method both sterilizes and maintains the strength, purity, quality, and packaging integrity of CSPSs.

8.1.1 The selected sterilization process is obtained from experience and appropriate information sources.

8.2 General guidelines for matching CSPs and components to appropriate sterilization methods include the following:

8.2.1 CSPs have been ascertained to remain physically and chemically stable when subjected to the selected sterilization method

8.2.2 Glass and metal devices may be covered tightly with aluminum foil, then exposed to dry heat in an oven at a mean temperature of 250° C for 30 minutes to achieve sterility and depyrogenation. Such items are either used immediately or stored until use in an environment suitable for compounding.

8.2.3 Personnel ascertain from appropriate information sources that the sterile microporous membrane filter used to sterilize CSP solutions, during either compounding or administration, is chemically and physically compatible with the CSP.

8.3 Achieving and maintaining sterility and overall freedom from contamination of a CSP is dependent on the quality status of the components incorporated, the process utilized, personnel performance, and the environmental conditions under which the process is performed.

8.4 The standards required for the environmental conditions depend on the amount of exposure of the CSP to the immediate environment anticipated during processing.

8.5 The quality and control of environmental conditions for Category 1,2 and 3 CSPs is explained in USP Chapter <797>.

8.6 Processes using non-sterile components require the use of a method of preparation designed to produce a sterile preparation.

9.0 PROCEDURE

9.1 Sterilization methods must be determined based on the unique properties of the chemicals or materials being sterilized to prevent degradation, destruction, or unwanted modification. An appropriate method both sterilizes and maintains the strength, purity, quality, and packaging integrity of the CSP. The selected sterilization method must preserve chemical and physical integrity, and must be documented with device details, temperature requirements, and length of exposure in the formulation record as applicable.

9.2 Sterilization by Filtration

9.2.1 Applies to CSPs that are heat sensitive.

9.2.2 Sterilizing filters must be sterile, depyrogenated, have a nominal pore size of 0.22 µm or smaller, and be appropriate for pharmaceutical use.

9.2.2.1 Filters labeled "for laboratory use only" or similar statement must not be used for compounding CSPs

9.2.2.2 Refer to Certificate of Analysis (CoA)

9.2.3 Commercially available sterile filters must be approved for human-use applications and sterilizing pharmaceutical fluids.

9.2.4 The compounding supervisor must ensure, directly or from appropriate documentation, that the filters are chemically and physically stable at the pressure and temperature conditions to be used, that they have enough capacity to filter the required volumes, and that they will achieve sterility and maintained pre filtration pharmaceutical quality, including strength of ingredients of the specific CSP.

9.2.5 Sterilizing filters must be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta per square centimeter of

upstream filter surface area under conditions similar to those in which the CSPs will be filtered. (i.e., pressure, flow rate, and volume filtered)

9.2.6 The filter dimensions in liquid material to be sterile filtered must permit the sterilization process to be completed rapidly, without the replacement of the filter during the process.

9.2.7 When CSPs are known to contain excessive particulate matter, a prefiltration step must be performed by placing a larger nominal pore size membrane is placed upstream from the sterilizing filter to remove gross particulate contaminants in order to maximize the efficiency of the sterilizing filter.

9.2.8 Filtration is a process that removes, but does not destroy, microorganisms. Filtration is the method of choice for solutions when terminal sterilization is not suitable.

9.2.8.1 Commercially available, pharmaceutical-grade, sterile filters, approved for use in sterilizing compounded sterile preparations must be used.

9.2.8.2 Sterilizing filters must be disposable, sterile, pyrogen-free, and have a nominal porosity of 0.2µm, or 0.22µm.

9.2.8.3 Category 2 CSPs should be filtered within six hours to minimize the generation of bacterial endotoxins.

9.2.9 Filter selection must consider the following:

9.2.9.1 Compatibility – Great caution must be used to ensure that the microporous membrane filter is chemically and physically compatible with the CSP. Biological products, alcohols, glycols, and Dimethyl sulfoxide (DMSO) are examples of products that can result in filter membrane incompatibilities with the CSP.

9.2.9.2 Pore size – Sterilizing filters of 0.2µm or 0.22µm or smaller porosity must be used for sterilization. Colloidal or viscous preparations may require a 0.45µm filter; however, extreme caution must be exercised in these circumstances and more stringent end product testing will be required.

9.2.9.3 Filters with a pore size of 0.45 to 1 µm are used for removing particulate prior to sterilization by 0.22µm filter or prior to terminal sterilization.

9.2.9.4 Fluid Volume – To provide a practical flow rate of a solution, a filter with the appropriate surface area must be used. Multiple filters may be required for large volumes.

9.2.9.5 Particulate Load – Some CSPs will have a large load of particulate matter. When compounds are known to have excessive particulate matter, a prefilter with a larger porosity membrane may be placed upstream of the sterilizing filter to remove gross particulate contaminants, and thus maximize the efficiency and endurance of the sterilizing filter.

9.2.10 Integrity tests (bubble point test) must be performed on all sterilizing filters as soon as possible after filtration. Results must be documented on filter package backing using a permanent marker which is then taped to original formula log sheet.

9.2.10.1 Extremely low test results indicate that the filter was defective, compromised, or ruptured during the sterilization process. The pharmacist in charge must be notified of any failures. Further testing, re-sterilization, or destruction of the CSP may be necessary.

9.2.10.1.1 A solution may only be refiltered for sterilization one additional time.

9.2.10.2 Test results lower than manufacturer's indicated specifications may not be an indication of a true failure. If the filter's membranes are not fully wetted at the time of the bubble point test, air can pass through the filter, resulting in a false bubble point. Pass additional 10 mL or more of a solution with the same physical properties of the CSP (i.e. aqueous, oil, alcohol) through the filter, making sure to hold the syringe and filter straight up so the solution passes over all the membranes. Retest the bubble point.

9.3 Terminal Sterilization by Dry Heat

9.3.1 Dry heat sterilization is employed for items that cannot be sterilized by steam or other means when the moisture would damage the material of the wrapping is impermeable.

9.3.2 Sterilization by dry heat requires higher temperatures and longer exposure times than does sterilization by steam.

9.3.3 Sterilization by dry heat is performed at temperatures lower and duration longer than those used to achieve depyrogenation.

9.3.4 Dry heat sterilization is usually done as a batch process in an oven designed for sterilization.

9.3.5 Heated filtered air must be evenly distributed throughout the chamber by a blower device.

9.3.6 The oven should be equipped with a system for controlling temperature and exposure.

9.3.7 During sterilization, sufficient space must be left between materials to allow for good circulation of the hot air.

9.3.8 Refer to reference material for time limits and temperature requirements for each component of the CSP. The active ingredient must remain potent and stable.

9.3.8.1 Dry heat sterilization is less efficient than moist heat and requires longer exposure and higher temperatures.

9.3.8.2 Materials that may be dry heated: bulk powders, petrolatum, oils, greases, and waxes.

9.3.8.3 Timing of the cycle does not begin until the specified temperature is reached. Temperature of the center of the CSP is measured rather than the chamber. Place probe of the thermometer in a beaker containing a liquid with the same physical properties as the CSP.

9.3.8.4 Each load sterilized by Dry Heat must be monitored every 30 minutes with the physical thermometer and documented on the *Sterilization and Depyrogenation* Log.

9.3.9 Description of dry heat sterilization conditions and duration for specific CSP must be included in written documentation.

9.3.10 The effectiveness of dry heat sterilization must be verified using appropriate Biological Indicator strips with organisms such as geobacillus stearothermophilus or bacillus subtilis.

9.3.11 Other confirmation methods such as temperature sensing devices must be used.

9.4 Depyrogenation by Dry Heat—See SOP 4.008 Depyrogenation

9.4.1 Dry heat depyrogenation must be used to render glassware or containers such as vials free from pyrogens as well as viable microbes.

9.4.2 The depyrogenation cycle should be 30 minutes at 250° C

9.4.3 The description of the dry heat depyrogenation cycle and duration for specific load items must be included in written documentation.

9.4.4 The effectiveness of the dry heat depyrogenation cycle must be verified using endotoxin challenge vials (ECVs).

9.4.5 The bacterial endotoxin test should be performed on the ECVs to verify that the cycle is capable of achieving a 3-log reduction in endotoxin.

9.5 Terminal Sterilization by Steam (Autoclave)

9.5.1 The process of thermal sterilization by employing saturated steam under pressure, or autoclaving, is the preferred method to terminally sterilize aqueous preparations that have been verified to maintain their full chemical and physical stability under the conditions employed.

9.5.2 Not directly exposing items to pressurized steam may result in survival of microbial organisms and spores.

9.5.3 Sealed containers must be able to generate steam internally; Thus, a stoppered and crimped empty vial must contain a small amount of moisture to generate steam in order to sterilize the inside of the vial.

9.5.4 Refer to reference material for time limits and temperature requirements for each component of the CSP.

9.5.4.1 The active ingredient must remain potent and stable.

9.5.4.2 Autoclaving should be reserved for items that can be penetrated by water vapor (steam).

9.5.4.3 Dry, sealed containers, oils, and waxes are not suitable for steam sterilization.

9.5.5 To achieve sterility, materials must be exposed to steam at 121°C for a minimum of 15 minutes under pressure of about one atmosphere or 15 pounds per square inch (psi).

9.5.6 The Autoclave sterilization cycle must be verified by placing a Biological Indicator strip laden with organisms such as geobacilus stearothermophilus or bacillus subtilis in with each load.

9.5.6.1 Monitoring data from each cycle (i.e. a printout of the preset and actual parameters of the cycle) must be recorded to ensure that all critical parameters are within specified limits.

9.5.6.1.1 Remove printout from the autoclave printer and attach to formula worksheet as documentation of processed CSP.

9.5.6.2 The CSP or equipment load must be inspected for damage that may have occurred during the sterilization cycle.

9.5.7 Plastic, glass, and metal devices must be placed in low-particle shedding envelopes to prevent post-sterilization contamination.

9.5.8 The description of steam sterilization conditions and duration for specific CSPs must be included in written documentation.

9.5.9 The effectiveness of steam sterilization must be verified using appropriate Biological Indicator strips laden with organisms such geobacilus stearothermophilus or bacillus subtilis.

9.5.10 Other confirmation methods such as temperature sensing devices must be used.

9.5.11 The steam sterilization time/temperature/pressure documentation tape should be affixed to all formula records for CSPs terminally sterilized using steam.

9.6 Sterilization Indicators such as Biological Indicator strips to validate terminal sterilization processes, bacterial and fungal growth media plates and test tubes must be used for environmental monitoring, personnel monitoring and to validate sterile processes during aseptic manipulation.

9.6.1 Sterilization Indicator via Direct Inoculation – Fluid Thioglycolate (Thio), USP

9.6.1.1 Ingredients: Pancreatic Digest of Casein, Dextrose, Yeast Extract, Sodium Chloride, Sodium Thioglycolate, L-Cystine, Agar, Resazurin Indicator, Deionized Water.

9.6.1.2 Storage: 2-25°C, away from direct light. Media should not be used if there are any signs of deterioration (discoloration), contamination, or if the expiration date has passed. Media should appear translucent and light amber in color. Containers with oxygen present will have a pink layer at the medium-air interface – see procedure.

9.6.1.3 Intended Use: Recommended for cultivation of aerobic, microaerophilic, and anaerobic microorganisms in normally sterile materials. Recommended by FDA, NIH, NF, and USP for sterility testing of clear fluid biologics and other sterile products. Resazurin is an oxidation-reduction indicator that turns pink when increased oxidation has occurred.

9.6.1.4 Procedure: Media may become oxidized in the vial during shipping. Either heat media up to 100°C in a water bath (do not boil more than once) or allow vials to stand still for a few hours to restore to proper condition. It is common for a whitish precipitation to from, due to the agar content, but this does not affect the performance of the medium. Also due to the agar, a slight turbidity of haziness may be present. For CSP testing, inoculate the medium as soon as possible after the CSP is completed.

9.6.1.5 Incubation: Sterile adhesive seals should be aseptically affixed to the rubber closure, then incubate at 30-35°C for a minimum of 14 days. Keep shaking to a minimum to maintain anaerobic conditions.

9.6.2 Sterilization Indicator via Direct Inoculation for fungal growth – Sabouraud Dextrose Broth (SabDex), USP

9.6.2.1 Sabouraud Dextrose Broth (SDB) is designed for the cultivation of yeasts and molds as well as for the determination of the fungistatic activity of pharmaceutical products.

9.6.2.2 Storage: 2-25°C, away from direct light. Media should not be used if there are any signs of deterioration (discoloration), contamination, or if the expiration date has passed. The broth is clear and yellowish in color.

9.6.2.3 Intended Use: Recommended for cultivation of aerobic, microaerophilic, and anaerobic microorganisms in normally sterile materials. Recommended by FDA, NIH, NF, and USP for sterility testing of clear fluid biologics and other sterile products.

9.6.2.4 Procedure: For CSP testing, inoculate the medium as soon as possible after the CSP is completed. For strain subculture, the strain to be examined is directly inoculated into the broth and incubated at 20--25°C for 48 hours. The broth is then incubated at 30-35°C for 5 days. NOTE— The incubation time varies according to the type of microorganism (consult professional references). After incubation, microbial growth can be observed by turbidity of the broth.

9.6.2.5 For sample preparation, the product to be tested should be prepared as described in EP (2.6.12). 10 ml or the quantity corresponding to not less

than 1 g or 1 ml is inoculated into 100 ml of Sabouraud Dextrose Broth and mixed.

9.6.2.6 Incubation: Incubate at 20—25 C x 48 hours then 30—35 C x 5 days. Avoid shaking to maintain anaerobic conditions.

9.6.3 Sterilization Indicator via Direct Inoculation – Tryptic Soy Broth (TSB), USP (also known as Soybean-Casein Digest)

9.6.3.1 Ingredients: Pancreatic Digest of Casein, Sodium Chloride, Papaic Digest of Soybean Meal, Dextrose, Dipotassium Phosphate, Deionized Water.

9.6.3.2 Storage: 2-25°C, away from direct light. Do not use if there are any sign of deterioration (discoloration), contamination, or expiration date has passed. Media should appear clear, and light amber in color.

9.6.3.3 Intended Use: General purpose medium for isolation and cultivation of a wide variety of bacteria and fungi. USP NF describes its use for sterility testing. Supports growth of the majority of bacteria and fungi. Recommended for sterility testing to detect contamination with low incidence fungi and aerobic bacteria. Promotes exponential colonization of bacteria that are most likely to be transmitted to CSPs from compounding personnel and the environment.

9.6.3.4 Procedure: Inoculate the medium as soon as possible after the CSP is completed.

9.6.3.5 Incubation: Incubate at 30—35°C x 5 days.

9.6.4 Biological Indicator of Sterilization—Steam or Dry Heat Sterilization: SporView Culture Set

9.6.4.1 Bromocresol purple.

9.6.4.2 Storage: Controlled room temperature. Do not use if there are any sign of deterioration (discoloration), contamination, or expiration date has passed. Media should appear clear, and light purple in color.

9.6.4.3 Intended Use: Biological Indicator (BI) system certified for use with steam, EO gas, chemical vapor, and dry heat. Biological indicators can be used to verify sterilization equipment and the sterilization of CSPs and equipment/materials used in sterile compounding. Monitors all sterilization processes requiring Geobacillus stearothermophilus, bacillus subtilis or B. atrophaeus spores.

9.6.4.4 Procedure: Place one or more BI strips inside the sterilizing chamber. Test the most challenging areas as indicated per equipment manual. After processing the load according to manufacturer's instructions, transfer the strip the cleanroom. Aseptically (the media must not be contaminated by personnel) transfer the BI strip into the Bromocresol Purple culture media tube. Tube is then placed in the appropriate incubator. Record date and time placed in incubator on log.

9.6.4.5 Steam sterilizers should be biologically tested at least weekly as recommended by AAMI, ADA, and CDC.

9.6.4.6 Incubation:

9.6.4.6.1 For Steam: Incubate in dry incubation cube at 56 ± 2°C for 7 days. Check samples in incubator daily and record results on log.

9.6.4.6.2 For Dry Heat: Incubate at 30—35 C for 7 days. Check samples in incubator daily and record results on log

9.6.4.7 Record final result on log. Purple colored media indicates cycle was properly sterilized. Media that turns to yellow is indicative of a fail and the sterilization cycle on the items that had been processed in the failing cycle must be quarantined, recorded, and destroyed.

9.6.4.8 Sterile department manager, staff pharmacist, and QMT must be notified of any failures.

9.6.5 Sterilization Indicator – Tryptic Soy Agar (TSA) Plates

9.6.5.1 Ingredients: Pancreatic Digest of Casein, Peptic Digest of Soybean Meal, Sodium Chloride, Tween 80, Lecithin, Agar, Deionized Water.

9.6.5.2 Storage: 2-8°C, away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Media should appear clear to slightly hazy and light amber in color.

9.6.5.3 Intended Use: General growth medium for establishing microbiological trends, alerts and action levels in biologically controlled environments. Prepared according to USP standard formula for Soybean-Casein Digest Agar to promote growth. Use for surface and fingertip sampling post CSP processing. Used during Environmental Monitoring (EM) to validate state of control of classified areas.

9.6.5.4 Never perform EM while active compounding is occurring.

9.6.5.5 Procedure: If condensation of the packaging or plate occurs, remove from innermost bag in a sterile environment and allow to dry to 10-15 minutes prior to use. Allow media to warm to room temperature and dry before use. Do not invert the lid while removed to avoid exposure to falling sediment. Plate edges should be wrapped with lab film after use to create a barrier against uncontrolled air quality.

9.6.5.6 Incubation: Incubate at 30-35°C inverted for 48 hours, then at 20—25 °C for 5 days. Samples must be monitored daily for growth and results recorded on log in Simplifi.

9.6.6 Sterilization Indicator – Sabouraud Dextrose Agar (SabDex) Plates

9.6.6.1 Ingredients: Dextrose (Glucose), Peptone, Agar, Distilled Water.

9.6.6.2 Storage: 2-8°C, away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Media should appear clear to slightly hazy and light amber in color.

9.6.6.3 Intended Use: General growth medium for establishing microbiological trends, alerts and action levels in biologically controlled environments. Use for surface and fingertip sampling post CSP processing. Used during Environmental Monitoring (EM) to validate state of control of classified areas.

9.6.6.4 Never perform EM while active compounding is occurring.

9.6.6.5 Procedure: If condensation of the packaging or plate occurs, remove from innermost bag in a sterile environment and allow to dry to 10-15 minutes prior to use. Allow media to warm to room temperature and dry before use. Do not invert the lid while removed to avoid exposure to falling sediment. Plate edges should be wrapped with lab film after use to create a barrier against uncontrolled air quality.

9.6.6.6 Incubation: Incubate at 20—25 °C for no less than 5 days. Samples must be monitored daily for growth and results recorded on log in Simplifi.

9.6.7 Users of commercially prepared media may be required to perform quality testing with at least one known organism to demonstrate growth or a positive reaction.

9.6.8 Sterilization Indicators should be handled by Aseptic Personnel only.

9.6.9 Observe biohazard precautions and aseptic technique. Biohazard waste samples should be sterilized before disposal.

10.0 ATTACHMENT

10.1 N/A

11.0 HISTORY

11.1 Original. Brenda Poland. 04-01-2023

11.2 Reviewed. 03-25-2024

11.3 Updated. 03-15-2025

5.002 BALANCES—USE, CLEANING, AND MAINTENANCE

Authorized by: Shibu John, Amelia Yeh **Date Effective: 7/15/2025**

1.0 PURPOSE

1.1 The purpose of this procedure is to outline the use, calibration and maintenance of the precision weighing Balances at RX COMPOUNDSTORE.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at RX COMPOUNDSTORE.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and is responsible for personnel training and compliance.

4.0 REFERENCES

4.1 Instruction manual(s)

4.2 USP Current Version <41> "Weights and Balances"

4.3 USP Current Version <1251> "Weighing on an Analytical Balance"

5.0 FREQUENCY

5.1 Calibration check (verification) must be performed daily when the balance is in use

6.0 DEFINITIONS

6.1 Tare – the deduction of the weight of a container used to calculate the weight of its contents.

6.2 Measurement Uncertainty – random plus systematic error.

6.3 Analytical Balance – a balance with a minimum sensitivity of 0.0001g.

6.4 Top-Loading Balance – a pan-loading balance with a typical sensitivity of 0.01g or 0.1g.

7.0 EQUIPMENT & SUPPLIES

7.1 Weight set

7.2 Receivers (weigh boats, weighing paper, beakers, flasks, weighing bottles, etc.)

7.3 Lint-free cloth or equivalent

7.4 Spatula or appropriate tool to transfer the sample to be weighed from the container to the receiver

7.5 Mild detergent

7.6 Isopropyl alcohol 70%--IPA 70%

7.7 Forceps or hemostats

8.0 GENERAL INFORMATION

8.1 Allow at least twenty minutes of warm up time before using the balance to give internal components sufficient time to stabilize. Analytical Class I balances require at least 2 hours of warm-up time.

8.2 Keep the operating environment as clean as possible to avoid an adverse effect on the reliability and accuracy of the unit.

8.3 Always set up the unit on a level surface in a clean, draft-free area. When using the balance in a hood or glove box, make sure the doors remain closed during weighing.

8.4 Do not install the balance near air conditioning or heating vents.

8.5 Do not install the balance near vibrating, rotating or reciprocating equipment.

8.6 Do not install the balance near magnetic fields or equipment that generates magnetic fields.

8.7 Do not disturb the balance while calibration is being performed.

8.8 The weight of the receiver plus the weight to be measured cannot exceed the limit of the balance.

8.9 It is necessary to differentiate between calibration and verification.

8.9.1 All balances must be calibrated on a yearly basis by an outside contractor. A balance that is new can be verified for the first year and then must be calibrated by the outside contractor every year thereafter.

8.9.2 Calibration may substitute for verification, but verification may not substitute for calibration.

9.0 PROCEDURE

9.1 Use

9.1.1 Verify that the balance is level prior to weighing. If the balance is not level or has been moved, then follow the steps below.

9.1.1.1 Viewing the balance from above, turn the leveling foot opposite of the location of the bubble clockwise or counterclockwise until the bubble is positioned in the center of the black ring.

NOTE: The bubble moves toward a foot when that foot is turned clockwise, and the bubble moves away from a foot when that foot is turned counterclockwise.

9.1.1.2 Repeat step 9.1.1.1 with the other leveling foot until the bubble is positioned in the center of the black ring.

9.1.1.3 Avoid extending the leveling feet too far.

9.1.1 Balances and analytical balances in the non-sterile and sterile labs

9.1.1.1 To tare the balance, press the zero button or the tare button

9.1.1.2 Place items to be weighed on the balance pan, and wait for the value to stabilize

9.1.1.3 When using a container to weigh items, place the empty container on the balance pan, wait for the value to stabilize, and then tare the balance. When the display reads zero, add the item to the container, wait for the value to stabilize and read the weight on the display.

9.1.1.4 Double-check the accuracy of weighing against the compounding formula before proceeding with the compounding procedure and print

9.1.1.5 Remove any chemical or material that has spilled on the pan or under the pan with a damp low-lint wipe or a scale brush.

9.1.1.6 Remove any chemical or material that has spilled on the pan or under the pan with a damp low-lint wipe or a scale brush.

9.2 Cleaning/Maintenance

9.2.1 Balances must be thoroughly cleaned before and after use and between processes to prevent cross-contamination.

9.2.1.1 Remove weigh pan and wipe down all horizontal and vertical surfaces of the balance with a disposable wiper wetted with IPA 70%.

9.2.2 Cleaning should be performed after spills occur or if the balance is visibly dirty.

9.2.3 Clean the balance with a mild detergent using a soft cloth or a low-lint wipe.

9.2.4 Keep calibration masses in a safe, dry place.

9.2.5 If any error messages display, notify Pharmacist-in-Charge (PIC) or other management.

10.0 ATTACHMENTS

10.1 NA

11.0 HISTORY

11.1 Original. Brenda Poland. 04-01-2023
11.2 Reviewed. Shibu John. 03-25-2025
11.3 Edited. Amelia Yeh. 03-15-2025

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5.003 REFRIGERATOR FREEZER—USE, CLEANING, AND MAINTENANCE

Authorized by: Shibu John **Date Effective: 4/1/2023**

1.0 PURPOSE

1.1. The purpose of this procedure is to outline the use, calibration and maintenance of the drug product refrigerator and freezer at RX COMPOUNDSTORE

2.0 SCOPE

2.1. This procedure applies to all compounding personnel utilizing the drug product refrigerator and/or freezer at RX COMPOUNDSTORE.

3.0 RESPONSIBILITY

3.1. The Pharmacist in Charge (PIC) must supervise this procedure and is responsible for personnel training.

4.0 REFERENCES

4.1. USP Current Version <797> ""Pharmaceutical Compounding – Sterile Preparations"

4.2. USP Current Version <795> ""Pharmaceutical Compounding – Non-Sterile Preparations"

4.3. Refrigerator manual

4.4. Freezer manual

5.0 DEFINITIONS

5.1. N/A

6.0 FREQUENCY

6.1. Temperature monitoring must be completed once daily during normal business hours.

6.2. Cleaning of the drug product refrigerator and freezer must be completed and documented monthly.

6.3. Temperature calibration must be completed annually or whenever there are multiple temperature shifts noted during daily monitoring.

6.4. Maintenance must be performed annually or according to the manufacturer's specifications.

7.0 EQUIPMENT/MATERIALS

7.1. Calibrated refrigerator/freezer thermometer - MECRO

7.2. Cleaning and disinfecting solution

8.0 GENERAL INFORMATION

8.1. N/A

9.0 PROCEDURE

9.1 Use and Daily Monitoring

9.1.1 When items are placed in or removed from the drug product refrigerator or freezer, they should be added or removed quickly, and the door should be closed immediately.

9.1.2 A calibrated refrigerator or freezer thermometer, that can be read from the outside without opening the door, must be positioned in the middle of one of the drug product refrigerator or freezer shelves, or as near to the center as possible.

9.1.3 The designated temperature range for the drug product refrigerator and freezer (according to USP <797> and <795>) is 2°C to 8°C and -20°C to -10°C, respectively. The appropriate temperature range should be clearly labeled on the drug product refrigerator or freezer.

9.1.4 Daily temperature readings of the drug product refrigerator and freezer must be recorded electronically on the appropriate log sheet.

9.1.5 If the observed temperature of the drug product refrigerator or freezer does not fall within the designated range, adjustment should be made, and the temperature rechecked in 30 minutes.

9.1.5.1 If the observed temperature of the drug product refrigerator or freezer does not fall within the designated range, adjustment should be made, and the temperature rechecked in 30 minutes.

9.5.1.2 If the observed temperature of the drug product refrigerator or freezer does not fall within the designated range, drug products must be removed immediately and placed in an alternate, properly calibrated drug product refrigerator or freezer.

9.1.6 Discard any products that are damaged or potentially damaged by the variation in temperature.

9.1.7 At the end of each month, the daily monitoring logs must be reviewed by the Pharmacist-in-charge and must be retained in the quality assurance file

9.2 Cleaning

9.2.1 Remove any materials that may be harmed by 70% isopropyl alcohol or by the temperature change that will occur when the refrigerator or freezer door is open for cleaning. Place materials in a cooler box with ice packs or alternate fridge during cleaning.

9.2.2 Working from top to bottom, the interior top surface, side walls, shelves and bottom surface of the unit should be cleaned with a low-lint wiper saturated with 70% isopropyl alcohol.

9.2.3 Allow the interior to dry thoroughly before closing the unit. If there is visible cleaning solution on any surface, dry with a disposable wiper.

9.2.4 The exterior should be cleaned using a suitable cleaning and disinfecting solution.

9.2.5 Document monthly cleaning of the drug product refrigerator and freezer appropriately.

9.3 Calibration

9.3.1 A calibrated refrigerator or freezer thermometer, that can be read externally, must be positioned inside near the center of the refrigerator or freezer.

9.3.2 Allow one hour for the thermometer to equilibrate with the environment.

9.3.3 Once one hour has elapsed, read the thermometer. If the reading does not fall within the desired temperature range, adjust the refrigerator or freezer temperature control accordingly. If the reading does fall within the desired temperature range, proceed to step 9.3.6.

9.3.4 Allow one hour for the refrigerator or freezer to adjust to the new setting and allow for the thermometer to equilibrate with the environment.

9.3.5 Repeat steps 9.3.3 and 9.3.4 until an appropriate temperature is achieved.

9.3.6 An entire cooling cycle must be observed to make certain that the extremes fall within the designated temperature range. If the designated temperature range cannot be obtained, drug products must be removed immediately and placed in an alternate drug product refrigerator or freezer, and further investigation is required.

9.3.7 All temperature readings must be recorded on the appropriate log sheets.

9.3.8 Each completed temperature calibration log must be filed.

9.4 Maintenance

9.4.1 Maintenance of the drug product refrigerator or freezer must be performed as needed or according to the manufacturer's specifications.

9.4.2 The drug product refrigerator or freezer should be defrosted to prevent build-up of ice on the coils. Refer to manufacturer's owner manual for instructions.

9.43 Check circulating fans for excessive noise and build-up of lint on the blades.

9.4.4 Wipe off the door gasket and inspect for cracks during monthly cleaning.

10.0 ATTACHMENTS

10.1. N/A –Temperatures recorded electronically

11.0 HISTORY

11.1. Original. Brenda Poland. 04-01-2023

11.2. Edited. Amelia Yeh. 04-02-2024

11.3. Reviewed. Amelia Yeh. 11-15-2024

11.4. Edited. Amelia Yeh 08-25-2025

5.004 AUTOCLAVE--USE, CLEANING AND MAINTENANCE OF THE TUTTNAUR EZ10 ELECTRONIC TABLETOP

Authorized by: Shibu John, Amelia Yeh **Date: 7/15/2025**

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for the use, verification and maintenance of the Electronic Tabletop Autoclave at RX COMPOUNDSTORE.

2.0 SCOPE

2.1 This procedure applies to all sterile compounding personnel using the Tuttnauer EZ10 Electronic Tabletop Autoclave at RX COMPOUNDSTORE.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge (PIC) must supervise this procedure and ensure personnel training.

4.0 REFERENCES

4.1 Instruction manual

5.0 FREQUENCY

5.1 An initial verification of each cycle of the autoclave must be performed and documented on the Autoclave Verification Cycle form (F.5.004.1--Attachment 1).

5.2 Re-verification of the autoclave cycles must be performed and documented after any significant event (i.e. moving the equipment or a major repair).

6.0 DEFINITIONS

6.1 LUMAC – Log of Use, Maintenance and Cleaning

7.0 EQUIPMENT AND SUPPLIES

7.1 Tabletop Electronic autoclave capable of achieving and maintaining a minimum temperature of 121 °C and a minimum pressure of 15 psi with the ability to chart and print temperature, pressure, and time increments throughout the cycle

7.2 Distilled or purified water

7.3 Non-abrasive chamber cleaner (Speedclean, Chamber Brite, etc.)

7.4 Mild detergent solution

7.5 Soft cloth or sponge

7.6 Compressed air

7.7 Lint-free wipe

7.8 Equipment LUMAC

7.9 Digital thermometer and/or biological or chemical indicators

8.0 GENERAL INFORMATION

8.1 Personnel using an autoclave must be thoroughly familiar with the sterilization process and the use of the equipment involved. Personnel are responsible for:

8.1.1 Establishing that the equipment is capable of operating within the required parameters.

8.1.2 Establishing that steam sterilization is appropriate for the products or CSP to be sterilized.

8.1.3 Conducting replicate cycles employing actual or simulated product and demonstrating the success of the procedure.

8.1.4 Monitoring the process during routine operation.

8.1.5 Completing all documentation.

8.2 Water used in the autoclave must be free from minerals and deposits that may build up inside the autoclave on the steel surface.

8.3 The autoclave should be installed in conformance with the following parameters:

8.3.1 Verify electrical outlet is appropriate for use.

8.3.2 The unit must be placed on a level, heat and water-resistant surface.

8.3.3 Allow at least 3 inches between the unit and walls on the sides and back for air circulation and allow at least 8 inches between the top of the unit and any objects overhead.

8.3.4 If the unit operates continuously, it must be in an area where steam emissions will not damage equipment or materials.

9.0 PROCEDURE

9.1 Instructions for use:

9.1.1 Remove water reservoir cover and ensure that the water reservoir is filled with distilled water or purified water to the appropriate fill line.

9.1.2 Turn on the rocker switch located below the front panel.

9.1.3 Choose and press the appropriate program button. The light indicator of the selected program is illuminated indicating which program has been selected. The preset data of the program, sterilization temperature, pressure, time, and dry time (if applicable) is displayed.

9.1.4 Load the packaged material to be sterilized into the chamber.

9.1.4.1 Items should be arranged loosely to allow for proper airflow around each item.

9.1.5 Close the door and spin handle until snug ensuring a tight seal between the door gasket and the chamber. Do not over tighten as this may damage the gasket. If the autoclave does not reach the desired temperature and/or pressure, make sure the door is fully sealed.

9.1.6 Press the START key. The "Water Inlet" light is illuminated until the correct volume of water is automatically introduced into the chamber.

9.1.7 Once the water has been filled into the chamber the cycle will begin the sequence of automatic operations. (See operators manual to change the preset cycle parameters).

9.1.8 For any process that includes a drying cycle, the dry cycle begins immediately after the steam exhaust stage. The autoclave is equipped with an air compressor, which draws air through a HEPA filter (0.2μm) during the drying cycle and pushes the air through the heated chamber and out the air outlet valve to remove moisture and facilitate the drying operation. Drying is performed with the door closed.

9.1.9 At the end of a cycle an alarm sounds for approximately five seconds and the "Start" light is no longer illuminated. The air outlet valve is automatically opened to prevent the formation of a vacuum.

9.1.9.1 In the event of a program failure, the exhaust valve is automatically opened to release pressure from the chamber and a continuous buzz will sound for five seconds followed by an interrupted buzz of seven seconds.

9.1.10 Open the door and unload the sterilized material from the chamber. A minimum of 10 minutes must be observed between the end of a cycle and the start of a new cycle. This will prevent overheating of the autoclave.

9.1.11 Once the cycle is complete, attach all printouts to the corresponding formula worksheet (see section 9.5).

9.1.12 When using a biological indicator, follow the manufacturer's instructions for proper incubation process, time, and temperature.

9.2 Verification

9.2.1 Empty-Chamber Verification

9.2.1.1 Prior to initial use for actual sterilization of product, turn on the autoclave to the desired setting, place a chemical indicator in the middle of the chamber, and allow the cycle to run.

9.2.1.2 Once the cycle is complete, remove the indicator.

9.2.1.3 Document the use of the indicator by recording accordingly in Simplifi and monitoring daily.

9.2.2 Filled-Chamber Verification

9.2.2.1 Turn on the autoclave to the desired setting, place a chemical indicator vial in the middle of the load, and allow the cycle to run.

9.2.2.2 Once the cycle is complete, remove the indicator.

9.2.2.3 Document the use of the indicator by recording accordingly in Simplifi and monitoring daily.

9.3 Cleaning/Maintenance

9.3.1 Daily

9.3.1.1 Check water level and add distilled or purified water as needed.

9.3.1.2 Clean the exterior of the unit with a soft cloth.

9.3.2 Weekly

9.3.2.1 Clean the air jet by inserting a pen or similar object into the loop and move wire in and out a minimum of ten times.

9.3.2.2 Clean the water sensor in the rear of the chamber with a damp cloth or sponge.

9.3.2.3 Clean and descale the chamber, copper tubes and the reservoir using non-abrasive chamber cleaner.

9.3.2.4 The following must be completed without interruption.

9.3.2.4.1 When the autoclave chamber is cooled, remove instruments and trays from the autoclave.

9.3.2.4.2 Open the door and apply the non-abrasive chamber cleaner.

9.3.2.4.3 Never use bleach, steel wool, a steel brush, or anything abrasive to scrub or clean the chamber.

9.3.2.4.4 Select and start the steam only cycle, no dry time

9.3.2.4.5 At the end of the exhaust cycle, drain the water from the reservoir.

9.3.2.4.6 Fill the water reservoir with distilled water.

9.3.2.4.7 Repeat a steam sterilization cycle without the chamber cleaner to remove any excess debris in the pipes.

9.3.2.4.8 Select and start the steam only cycle, no dry time

9.3.2.4.9 At the end of the exhaust cycle, drain the water from the reservoir.

9.3.2.4.10 Turn the autoclave off and allow chamber to cool.

9.3.2.4.11 Remove the tray holder frame, rinse, and wipe the interior of the chamber with a damp cloth.

9.3.2.4.12 Fill the reservoir with distilled or purified water

9.3.2.4.13 Remove the tray holder and trays and clean with a detergent or a non-abrasive stainless-steel cleaner and water, using a cloth or sponge. Rinse the tray holder and trays immediately with water to avoid staining the metal.

9.3.3 Monthly

9.3.3.1 Put a few drops of oil on the 2 door pins and door tightening bolt.

9.3.3.2 Clean and check the safety valve.

9.3.3.3 Clean strainer.

9.3.4 Semi-annually—consult the maintenance department before proceeding

9.3.4.1 Replace the air filter as needed.

9.3.4.2 Clean the fan grid with compressed air from the inside outward.

9.3.4.3 Examine and replace the door gasket as needed.

9.4 Sterilization Cycle Printouts/Records

9.4.1 After each sterilization cycle, the printout(s) of each cycle for CSPs sterilized must be attached to the associated formula worksheet.

9.5 Autoclave- Incompatible Materials

9.5.1 There are several materials that should never be placed into the autoclave. A list of known incompatible materials are as followed:

9.5.1.1 Acids, bases and organic solvents.

9.5.1.2 Chlorides and sulfates.

9.5.1.3 Alcohol

9.5.1.4 Seawater.

9.5.1.5 Chlorine, hypochlorite, bleach.

9.5.1.6 Non-stainless steel.

9.5.1.7 Polystyrene (PS).

9.5.1.8 Low-density (LDPE) and high-density polyethylene (HDPE).

9.5.1.9 Polyurethane.

9.5.1.10 Flammable, reactive, corrosive, toxic, or radioactive materials.

9.5.1.11 Paraffin-embedded tissue

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

11.1 Original. Brenda Poland. 04-01-2023

11.2 Reviewed. Shibu John. 03-25-2025

11.3 Edited. Amelia Yeh. 03-15-2025

5.006 INCUBATORS--USE, CLEANING AND MAINTENANCE

Authorized by: Shibu John, Amelia Yeh **Date: 7-15-2025**

1.0 PURPOSE

1.1 The purpose of this procedure is to outline the use, cleaning and maintenance of incubators at RX COMPOUNDSTORE.

2.0 SCOPE

2.1 This procedure applies to all aseptic processing and in-house testing personnel at RX COMPOUNDSTORE.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge (PIC) must supervise this procedure and ensure personnel training.

4.0 REFERENCES

4.1 Instruction manual

5.0 DEFINITIONS

5.1 LUMAC – Log of Use, Maintenance and Cleaning

5.2 Incubator—an enclosed apparatus providing a controlled temperature.

6.0 FREQUENCY

6.1 Monitoring to be completed once daily during normal business hours while in use.

6.2 Cleaning is to be completed once monthly.

6.3 Calibration verification is to be completed annually or whenever there is a noted temperature shift in the daily monitoring.

6.4 Maintenance must be performed as needed.

7.0 EQUIPMENT & SUPPLIES

7.1 Incubators (2)

7.1.1 Incubator 1: Controlled room temperature 20-25C– Boekel Scientific

7.1.2 Incubator 3: 30-35C – Boekel Scientific

8.0 GENERAL INFORMATION

8.1 Incubators at RX COMPOUNDSTORE are used for incubating media samples of CSPs for in-house testing by aseptic processing personnel during the sterilization step.

8.2 Incubators at RX COMPOUNDSTORE are used for incubating media samples of agar plates for in-house environmental monitoring (EM) and in-house personnel monitoring (PM).

8.2.1 Surface sampling of the controlled environment

8.2.2 Gloved fingertip testing of aseptic processing personnel

9.0 POCEDURE

9.1 Use/Monitoring

9.1.1 Assemble unit as outlined in the instruction manual.

9.1.2 Place unit in a clear, draft free environment.

9.1.3 Ensure that all ventilation holes in the incubator are not blocked.

9.1.4 Turn the "Power" switch to the ON position.

9.1.5 Use the temperature control knob to set the desired temperature.

9.1.6 Calibration/verification must be performed using a non-digital, mercury thermometer. See section 9.2 of this SOP. When placing or removing items the door should not be open for extended periods of time.

9.1.7 A thermometer must be positioned in the geometric center of the incubator.

9.1.8 Optimal temperature range can change depending on the required incubation temperature. The temperature will be verified per the calibration procedure when the set point is changed.

9.1.9 Daily readings must be recorded on the daily temperature log.

9.1.10 If the temperature of the incubator falls out of the optimal temperature range, items must be removed immediately and placed in an alternate drug products incubator. Temperature drop is to be recorded on daily temperature log.

Corrective action is to be taken immediately. Once temperature has reached acceptable range, it is to be recorded on the daily temperature log sheet

9.1.11 Items that are damaged by the variation in temperature must be discarded.

9.1.12 Place the log in the quality assurance file once complete.

9.2 Calibration/Verification

9.2.1 A calibrated thermometer of the proper range must be positioned in the middle of one of the incubator shelves. Allow one hour for the thermometer to equilibrate with the environment.

9.2.2 At the end of the hour, read the thermometer. If the reading does not agree with the temperature desired, adjust the incubator temperature control accordingly.

9.2.3 Allow one hour for the incubator to adjust to the new setting and the thermometer to equilibrate with the environment.

9.2.4 At the end of the hour, read the thermometer. Repeat this process until the desired temperature is achieved.

9.2.5 Readings must be recorded electronically on the temperature log in Simplifi.

9.2.6 Place the log in the quality assurance file once complete.

9.3 Cleaning

9.3.1 NEVER use 70% isopropyl alcohol on the plexiglass doors. It will cause the material of the door to crack. It may be wiped with a lint free towel wetted with distilled water and wiped dry.

9.3.2 The metal exterior can be cleaned using 70% isopropyl alcohol.

9.3.3 Remove any materials that may be harmed by 70% isopropyl alcohol or the temperature change that will occur when the door is open for cleaning.

9.3.4 The interior bottom, sides and shelves of the unit can be cleaned using 70% isopropyl alcohol.

9.3.5 Allow to dry thoroughly before re-starting unit.

9.4 Maintenance

9.4.1 Check circulating fans for excessive noise and buildup of lint on the blades.

9.4.2 Wipe off door gasket and inspect for cracks or defects.

8.4.3 Lubricate door hinges as needed.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

11.1 Original. Brenda Poland. 04-01-2023

11.2 Reviewed. Shibu John. 03-25-2025

11.3 Edited. Amelia Yeh 03-15-2025

5.007 pH METER—USE, CLEANING, AND MAINTENANCE

Authorized by: Shibu John, Amelia Yeh **Date: 7/15/2025**

1.0 PURPOSE

1.1 The purpose of this procedure is to outline the use, calibration, and maintenance of the Apera pH700 benchtop pH meter at RX COMPOUNDSTORE.

2.0 SCOPE

2.1 This procedure applies to all personnel using the Apera pH700 benchtop pH meter at RX COMPOUNDSTORE.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge (PIC) shall supervise this procedure and ensure proper personnel training.

4.0 REFERENCES

4.1 Instruction manual

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 Calibration must be performed daily when in use

6.1.1 Recalibration must occur if the unit has been turned off

6.2 Replace the sensor as needed.

7.0 EQUIPMENT & SUPPLIES

7.1 pH buffer 4.0 standard solution

7.2 pH buffer 7.0 standard solution

7.3 pH buffer 10.0 standard solution

7.4 Distilled water

7.5 Lint-free wipes

7.6 70% isopropyl alcohol (IPA)

8.0 GENERAL INFORMATION

8.1 Do not expose the pH meter to direct sunlight.

8.2 Do not use organic solvents to clean the pH meter.

9.0 PROCEDURE

9.1 Operation

9.1.1 Calibration must be performed daily before using the pH meter, or if the unit has been turned off.

9.1.2 Rinse the sensor thoroughly with sterile water before and after testing. Remove the protective screw cap as needed.

9.1.3 Upon completion of pH testing, turn the pH meter off. Rinse the sensor with sterile water.

9.1.4 Refer to the instruction manual as needed

9.2 Calibration

9.2.1 Press the power (on/off) button to turn on or off as needed

9.2.2 Press "CAL/MEAS" button to enter calibration mode.

9.2.3 CAL1 icon will flash in the upper right corner of the LCD. 7.00 pH will flash in the lower right corner of the LCD, reminding you to use pH 7.00 buffer to conduct 1st point of calibration.

9.2.4 Use sterile water to rinse off electrode. Dip it into pH 7.00 buffer solution, stir gently and let it stand still and wait for the reading to become stable. In the lower right corner of LCD, the process of auto recognizing the buffer solution will be displayed. Pressing "ENTER" before the buffer is recognized will generate Er2 (please refer to table 5 in the manual).

9.2.5 When the meter locks 7.00 pH in the lower right corner, stable "SMILEY FACE" icon displays on LCD. Then press "ENTER" key to calibrate the meter. End icon appears after calibration is done. The 1st point calibration is finished.

9.2.5.1 Meanwhile, CAL2 will flash at the upper right corner, and 4.00 pH & 10.01 pH will flash alternately at the bottom right, indicating using pH4.00 or pH10.01 buffer solution to make the 2nd point calibration.

9.2.6 Take out the pH electrode, rinse it in sterile water, dry it, and dip it into pH 4.00 buffer solution. Stir the solution gently and let stand still in the buffer solution until a stable reading is reached. The meter's display will show the recognition process of calibration buffer solution at the lower right corner. When the meter recognizes 4.00 pH, stable "SMILEY FACE" icon displays on LCD. Press "ENTER" key to calibrate the meter. End icon and electrode slope of acidity range will be displayed after calibration is done.

9.2.6.1 Meanwhile, CL3 will flash at the upper right corner of the LCD, and 10.01 pH will flash at the lower right, indicating using pH10.01 buffer solution to make the 3rd point calibration.

9.2.7 Take out pH electrode, rinse it in distilled water, dry it, and dip it into pH 10.01 buffer solution. Stir the solution gently and let it stand still in the buffer solution until a stable reading is reached. The meter's display will show recognition process of calibration buffer solution at the bottom right of LCD. When the meter recognizes 10.01 pH, stable "SMILEY FACE" icon displays on LCD. Press "ENTER" key to calibrate the meter. End icon and electrode slope of alkalinity range display after calibration is done.

9.2.8 The meter returns to the measurement mode, the calibration icons L M H will be displayed. During the calibration process, press "CAL/MEAS" key to exit from the calibration mode.

9.2.9 The meter can perform one-point, two-point and three-point calibration. Calibration guide icons appear on LCD.

9.3 Cleaning and Maintenance

9.3.1 Clean the outside of the pH meter's benchtop unit daily with 70% IPA and a soft cloth to remove any solutions or particulates.

9.3.2 Replace the sensor as needed.

9.3.3 Upon completion of maintenance, and before use, the pH meter must be calibrated.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

11.1 Original. Brenda Poland. 04-01-2023

11.2 Reviewed. Shibu John. 03-25-2025

11.3 Edited. Amelia Yeh. 03-15-2025

5.013 DRY HEAT OVEN—USE, CLEANING, MAINTENANCE

Authorized by: Shibu John, Amelia Yeh **Date: 7/15/2025**

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for the use, verification, and maintenance of the Cole Palmer Dry-Heat Oven.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel using the Cole Palmer Dry-Heat Oven at RX COMPOUNDSTORE.

3.0 RESPONSIBILTY

3.1 The Pharmacist-in-Charge (PIC) must supervise this procedure and ensure proper personnel training.

4.0 REFERENCES

4.1 Instruction manual

4.2 SOP 1.040 "Use and Control of LUMACs"

5.0 FREQUENCY

5.1 Initial verification of temperature consistency must be performed and documented on the Cole Palmer Dry-Heat Oven Verification Log (Attachment 1).

5.2 Additional verification must be performed and documented after any significant event (equipment move, major repair, etc.).

6.0 DEFINITIONS

6.1 LUMAC – Log of Use, Maintenance and Cleaning

7.0 EQUIPMENT AND SUPPLIES

7.1 Dry-Heat Oven capable of maintaining a temperature of 250°C for sterilization and depyrogenation

7.2 A non-digital glass or handheld thermometer for calibration.

8.0 GENERAL INFORMATION

8.1 Dry heat sterilization is usually done as a batch process in an oven designed for sterilization. Heated filtered air must be evenly distributed throughout the chamber by a blower device.

8.2 The oven should be equipped with a system for controlling temperature and exposure.

8.3 Sterilization by dry heat requires higher temperatures and longer exposure times than does sterilization by steam.

8.4 Dry heat must be used only for those materials that cannot be sterilized by steam, when either the moisture would damage the material, or the material is impermeable.

8.5 During sterilization sufficient space must be left between materials to allow for good circulation of the hot air.

8.6 The dry heat sterilization conditions and durations for specific CSPs must be included in written documentation in the CSP formula.

8.7 The effectiveness of dry heat sterilization must be verified using appropriate Bis of bacillus subtilis and other confirmation methods such as temperature sensing devices and sterility tests.

8.8 Personnel involved in terminal sterilization via the use of a dry-heat oven should be thoroughly familiar with the sterilization process and the equipment involved. Personnel are responsible for:

8.8.1 Establishing that the equipment is capable of operating within the required parameters.

8.8.2 Establishing that dry-heat sterilization is appropriate for the products to be sterilized.

8.8.3 Conducting replicate cycles employing actual or simulated product and demonstrating the success of the procedure.

8.8.4 Monitoring the process during routine operation.

8.8.5 Completing all documentation.

9.0 PROCEDURE

9.1 Use

9.1.1 Turn the unit on using the rocker switch.

9.1.2 Entering a Display Offset

9.1.2.1 Press MENU, the display indicates CAL.

9.1.2.2 Press and hold the SET key to view the present offset value.

9.1.2.3 To change the display offset, press and hold the SET key. Press INCREASE or DECREASE until the display indicates the desired offset.

9.1.2.4 Release the SET key.

9.1.2.5 Press MENU once to return to normal temperature control.

9.1.3 Prior to use, place a thermometer in the chamber so that it can be externally read and turn on the oven to the desired temperature. Allow sufficient time for the temperature to be reached. Do not depend upon the oven dial to set the temperature.

9.1.4 When preparing the product for dry-heat sterilization, if a liquid (such as oil) is being sterilized, prepare a container of the liquid and place in the oven chamber so that the thermometer can be inserted into the liquid and externally read (generally, the liquid should be in the center of the oven).

9.1.5 Place the items to be sterilized in the oven, evenly distributed with ample space for heated airflow between them.

9.1.6 Close the door and observe the temperature on the thermometer placed in the liquid. Start timing for the sterilizing process only after the desired temperature has been reached in the liquid in which the thermometer is placed.

9.1.7 Continue the sterilization process until the complete time has elapsed.

9.1.8 Turn off the heat and allow the oven to cool.

9.1.9 Open the door and remove the items.

9.1.10 Clean the oven and close the door.

9.2 Verification

9.2.1 Empty-Chamber Verification

9.2.1.1 Prior to use, place a thermometer in the chamber so that it can be externally read and turn on the oven to the desired temperature. Allow sufficient time for the temperature to be reached.

9.2.1.2 After the temperature is reached, record the temperature on the Cole Palmer Dry-Heat Oven Verification Log (Attachment 1) at 15-minute intervals for a minimum of 2 hours.

9.2.1.3 Turn the oven off and allow it to cool down.

9.2.1.4 Complete the Cole Palmer Dry-Heat Oven Verification Log (Attachment 1).

9.2.2 Filled-Chamber Verification

9.2.2.1 Prepare a container with simulated product, place a thermometer in the simulated product so that it can be externally read and seal the container with aluminum foil.

9.2.2.2 Place the sealed container in the center of the oven chamber and turn on the oven to the desired temperature.

9.2.2.3 After the temperature is reached, record the temperature on the Cole Palmer Dry-Heat Oven Verification Log (Attachment 1) at 15-minute intervals for a minimum of 2 hours.

9.2.2.4 Turn the oven off and allow it to cool down.

9.2.2.5 Open the door and remove the items.

9.2.2.6 Complete the Cole Palmer Dry-Heat Oven Verification Log (Attachment 1).

9.3 Cleaning/Maintenance

9.3.1 The exterior of the oven can be kept clean by periodically wiping with a cloth dampened with purified water or alcohol.

9.3.2 Clean immediately if soiling or leakage of product occurs.

9.3.3 Perform maintenance as required per equipment manual.

9.3.3.1 Replace the door gasket, hinges, and/or handle as needed.

9.3.4 When not in use, the oven must remain off.

9.4 All pertinent information must be documented in the appropriate equipment LUMAC.

10.0 ATTACHMENTS

10.1 Attachment 1 – F.5.017.1 Dry Heat Sterilization Cycle Monitoring Log

10.2 Attachment 2 – F.5.017.2 COLE PALMER DRY-HEAT OVEN VERIFICATION LOG

11.0 HISTORY

11.1 Original. Brenda Poland. 04-01-2023

11.2 Reviewed. Shibu John. 03-25-2025

11.3 Edited. Amelia Yeh. 03-15-2025

5.017 Monitoring Device Certification

Authorized by: Amelia Yeh **Date Effective: 7/14/2025**

1.0 PURPOSE

1.1 The purpose of this procedure is to ensure all environmental and equipment monitoring devices used at RX COMPOUNDSTORE are properly certified, calibrated, and maintained to guarantee accuracy and compliance with applicable regulatory standards

2.0 SCOPE

2.1 This procedure applies to all personnel responsible for monitoring, using, or maintaining temperature, pressure, particle count, and other environmental monitoring devices at RX COMPOUNDSTORE..

3.0 RESPONSIBILITY

3.1 The Pharmacist in Charge (PIC) must supervise this procedure and is responsible for personnel training and documentation review.

3.2 Designated QA staff are responsible for ensuring calibration records are maintained and devices are serviced per the required schedule.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Nonsterile Preparations"

4.2 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.3 USP Current Version <800> "Safe Handling of Hazardous Drugs in the Healthcare Setting"

4.4 NIST Calibration Standards

5.0 DEFINITIONS

5.1 Calibration – The comparison of a measurement device to a known standard to ensure accuracy.

5.2 NIST – National Institute of Standards and Technology; provides traceable standards for calibration.

6.0 FREQUENCY

6.1 Calibration must be performed at least annually or per manufacturer's specifications.

6.2 Certification must be obtained upon new equipment installation and retained thereafter.

6.3 Out-of-specification devices must be removed from use immediately, and recalibrated before being returned to service.

6.4 Device inventory should be reviewed quarterly to verify certification status.

7.0 EQUIPMENT & SUPPLIES

7.1 Monitoring devices (e.g., temperature probes, pressure gauges, particle counters)

7.2 Calibration certificates

7.3 Device inventory log

7.4 Third-party calibration vendor contact information

8.0 GENERAL INFORMATION

8.1. Only certified and calibrated monitoring devices may be used for any activity that involves environmental or product monitoring.

8.2. Certification must be traceable to a national standard (e.g., NIST).

9.0 PROCEDURE

9.1 Device Certification and Calibration

- 9.1.1 Maintain an inventory of all monitoring devices, including serial numbers, locations, and calibration due dates.
- 9.1.2 Each device must have a valid calibration certificate on file, issued by a qualified vendor.
- 9.1.3 Upon receipt of a new device, confirm the device is calibrated and certified before use.
- 9.1.4 When calibration is due, schedule service with a qualified calibration vendor.
- 9.1.5 Calibration certificates must indicate:
  - 9.1.5.1 Device identification
  - 9.1.5.2 Calibration date
  - 9.1.5.3 Calibration results
  - 9.1.5.4 Technician name
  - 9.1.5.5 Traceable standard used
- 9.1.6 File certificates in the designated quality assurance system and update the device inventory log.

9.2 Handling Out-of-Tolerance Devices

- 9.2.1 Devices showing erratic or out-of-range readings must be removed from service immediately.
- 9.2.2 Label as "Out of Service – Do Not Use" until calibration is completed.
- 9.2.3 Investigate any impact the inaccurate readings may have had on product integrity.
- 9.2.4 Document corrective actions taken.

9.3 Periodic Review and Documentation

- 9.3.1 Device calibration due dates must be reviewed at least quarterly.
- 9.3.2 Maintain a log of all calibration events, including due dates and results.
- 9.3.3 Retain all calibration and certification records for a minimum of three years.

10.0 HISTORY

10.1 Original. Amelia Yeh 7/14/2025

6.003 ADVERSE EVENTS REPORTING

Authorized by: Shibu John, Amelia Yeh **Date Effective: 7/14/2025**

1.0 PURPOSE

1.1 The purpose of this standard operating procedure (SOP) is to provide guidance on adverse events associated with the quality of a compounded sterile preparation (CSP) or compounded nonsterile preparation (CNSP) prepared by RX COMPOUNDSTORE.

2.0 SCOPE

2.1 This procedure applies to all personnel at RX COMPOUNDSTORE.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge or the Quality Control Officer shall supervise this procedure and ensure proper personnel training and compliance.

3.2 All personnel at RX COMPOUNDSTORE are responsible for following this procedure.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Nonsterile Preparations"

4.2 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.3 USP Current Version <800> "Safe Handling of Hazardous Drugs in the Healthcare Setting"

4.4 SOP 6.017 Corrective Action and Preventative Action (CAPA)

4.4.1 Form F.6.017 CAPA Plan

4.5 SOP 6.009 Complaint Handling

4.5.1 Form F.6.009.1 Customer Complaint Form

4.6 SOP 6.015 Recalls, Quarantine, and Audit Trail of Compounding

4.6.1 Form F.6.015.1 Recall Report

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 As needed.

7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

8.1 FDA. What is a Serious Adverse Event? 2/1/16. Retrieved on 04-15-2021.

8.1.1 An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported to FDA when the patient outcome is:

8.1.1.1 Death

8.1.1.1.1 Report if you suspect that the death was an outcome of the adverse event and include the date if known.

8.1.1.2 Life-threatening

8.1.1.2.1 Report if suspected that the patient was at substantial risk of dying at the time of the adverse event or use or continued use of the device or other medical product might have resulted in the death of the patient.

8.1.1.3 Hospitalization (initial or prolonged)

8.1.1.3.1 Report if admission to the hospital or prolongation of hospitalization was a result of the adverse event.

8.1.1.3.2 Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious medically important event).

8.1.1.4 Disability or Permanent Damage

8.1.1.4.1 Report if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life

functions, i.e., the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life.

8.1.1.5 Congenital Anomaly/Birth Defect

8.1.1.5.1 Report if you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.

8.1.1.6 Required Intervention to Prevent Permanent Impairment or Damage (Devices)

8.1.1.6.1 Report if you believe that medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, either situation suspected to be due to the use of a medical product.

8.1.1.7 Other Serious (Important Medical Events)

8.1.1.7.1 Report when the event does not fit the other outcomes, but the event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes. Examples include allergic bronchospasm (a serious problem with breathing) requiring treatment in an emergency room, serious blood dyscrasias (blood disorders) or seizures/convulsions that do not result in hospitalization. The development of drug dependence or drug abuse would also be examples of important medical events.

8.2 Additional Resources

8.2.1 Report a Serious Medical Product Problem Online

8.2.2 Report Dietary Supplements and Tobacco Product Problems Online

8.2.3 Form FDA 3500 - Voluntary Reporting

8.3 Adverse events may or may not occur because of an error.

8.4 A preventable adverse event is described as an adverse event where the care falls below the standard expected or that results from an error or systems failure.

8.5 As it relates to sterile compounding, any adverse events associated with the quality of a CSP should be reported to the applicable regulatory body, such as the State Board of Pharmacy, State Department of Health, the FDA MedWatch Program for Human Drugs, or use of the FDA Form 1932a for animal drugs, in keeping with RX COMPOUNDSTORE's risk management SOPs (not included in the Sterile Compounding SOP and Form Templates).

8.6 Adverse events are likely to be reported to RX COMPOUNDSTORE as a complaint from a physician, nurse, patient, or family and are handled according to SOP 6.009 Customer Complaints.

8.7 As a result, the investigation into the root cause of the adverse event is performed according to SOP 6.017 Corrective Action and Preventive Action and recalls are performed according to SOP 6.015 Recalls and Quarantine and Audit Trail.

9.0 PROCEDURE

9.1 Action to be taken for potential adverse event

9.1.1 The person who receives the notification of a possible adverse event completes the F6.009.1 *Customer Complaint Form.*

9.1.2 Since these types of complaints are considered quality-related (not service-related), the Designated Person is notified immediately.

9.1.3 The Designated Person (who may be part of the quality group) reviews the complaint and initiates a *CAPA Plan; F.6.017.1*

9.1.4 If it is determined from the CAPA plan that a recall is required, See SOP 6.015 Recalls and Quarantine and Audit Trail.

9.1.5 Report the adverse event to the applicable regulatory body by completing the appropriate form.

9.1.6 Within 24 hours of notification of a potential adverse event, RX COMPOUNDSTORE:

9.1.6.1 determines if the potential adverse event is applicable to other CSPs produced for its customers; and

9.1.6.2 determines what level of recall action needs to be taken

9.1.7 RX COMPOUNDSTORE immediately notifies the prescribers who serve patients receiving CSPs related to the potential adverse event.

9.1.8 Adverse Events related to vaccine administration must be reported to: Vaccine Adverse Event Reporting System (VAERS) at: www.vaers.hhs.gov

9.1.8.1 Patients must be instructed to

9.1.8.1.1 Contact their healthcare provider

9.1.8.1.2 Report the Adverse Event using VAERS online form or the downloadable pdf form

9.1.9 Vaccination errors must be reported to the Institute for Safe Medicine via Vaccination Error Reporting Program (VERP).

9.1.9.1 The reporting system asks for detailed information about the occurrence, including:

9.1.9.1.1 A description of what went wrong

9.1.9.1.2 Identification of any known causes or contributing factors

9.1.9.1.3 How the event was discovered or intercepted

9.1.9.1.4 Outcome for patient(s) involved

9.2 Documentation Elements

9.2.1 Each patient affected will have a separate CAPA plan completed.

9.2.2 Any remediation of personnel or changes in practice due to the outcome of the investigation and taken to prevent future occurrences are to be documented.

10.0 ATTACHMENT

10.1 N/A

11.0 HISTORY

11.1 Original. Brenda Poland. 04-01-2023

11.2 Reviewed. Shibu John. 03-25-2025

11.3 Edited. Amelia Yeh 03-15-2025

6.006 POTENCY, STABILITY AND BEYOND-USE DATING TESTING FOR COMPOUNDED PREPARATIONS

Authorized by: Shibu John, Amelia Yeh **Date: 7/14/2025**

1.0 PURPOSE

1.1 The purpose of the standard operating procedure (SOP) is to describe the general procedure for testing compounded preparations for potency and stability at RX COMPOUNDSTORE.

2.0 SCOPE

2.1 This procedure applies to compounding personnel at RX COMPOUNDSTORE.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge (PIC) must supervise this procedure and is responsible for employee training.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Nonsterile Preparations"

4.2 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.3 USP Current Version <800> "Safe Handling of Hazardous Drugs in the Healthcare Setting"

4.4 SOP 4.030 Deviations

5.0 DEFINITIONS

5.1 BUD—Beyond Use Date-Either the date, or the hour and date, after which a CSP must not be used. The BUD is determined from the date and time that the preparation initiated. Applies to all compounded preparations.

5.2 CSP—Compounded Sterile Preparation

5.3 CNSP—Compounded Nonsterile Preparation

5.4 QM—Quality Management

6.0 FREQUENCY

6.1 Ongoing as needed for stability testing of non-sterile compounded preparations

7.0 EQUIPMENT & SUPPLIES

7.1 Appropriate reference materials—Formula worksheet, Compounding Record, Master Formulation Record

7.2 Prescription Data Reports from pharmacy software

7.3 Submission Forms

7.4 Third-Party testing lab(s)

- 7.4.1 ARL—Analytical Research Labs, Oklahoma City, OK
- 7.4.2 Eagle—Analytical testing lab in Houston, TX
- 7.4.3 CIAL—Compounders International Analytical Lab in Castle Rock, CO
- 7.4.4 DynaLabs—Analytical testing of compounded preparations in St. Louis, MO

8.0 GENERAL INFORMATION

8.1 Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded. This is the BUD

8.2 The BUD is the date after which a compound preparation must not be used and is determined from the date when the preparation is compounded.

8.3 Compounded preparations are intended for administration immediately or following short term storage, their BUDS are assigned based on criteria different from those applied to assigning expiration dates to manufactured products.

8.4 BUDs must be assigned conservatively.

8.5 Compounding personnel who assigned BUDs to CSPs when lacking direct chemical assay results must critically interpret and evaluate the most appropriate available information sources to determine a conservative and safe BUD.

8.6 When assigning a BUD, compounding personnel must consult and apply all drug specific and general stability documentation and literature when available and should consider:

8.6.1 the nature of the drug and its degradation mechanism

8.6.2 the dosage form and its components

8.6.3 the potential for microbial proliferation in the preparation

8.6.4 the container in which it's packaged

8.6.5 the expected storage conditions

8.6.6 the intended duration of therapy

8.7 When a manufactured product is used as a source of the API for a nonsterile compounded preparation, the product expiration date cannot be used solely to assign A BUD for the compound preparation. Instead, the compounder must refer to the manufacturer for stability information and to the literature for applicable information on stability, compatibility, and degradation of ingredients; must consider stability factors as outlined in USP Chapter <1191>; And must use his or her compounding education and experience.

8.8 All stability data must be carefully interpreted in relation to the actual compound formulation.

8.9 At all steps in the compounding, dispensing, and storage process, compounding personnel must observe the compounded drug preparation for signs of instability.

8.10 For specific details of some of the common physical signs of deterioration see USB chapter <1191> Observing Products for Evidence of Instability.

8.9.1 it must be understood that excessive chemical degradation and other drug concentration loss due to reactions maybe invisible more often than visible.

9.0 PROCEDURE

9.1 In the *absence of stability information* that is applicable to a specific drug and preparation, the following criteria presents maximum BUDs recommended for compounded nonsterile preparations that are packaged in tight, light resistant containers and stored at controlled room temperature, unless otherwise indicated. Drugs or chemicals known to be the label to decomposition will require shorter BUDs.

9.1.1 For Non-Aqueous Formulations: The BUD is not later than the time remaining until the earliest expiration date of any API or six months, whichever is earlier.

9.1.2 For Water-Containing Oral Formulations: The BUD is not later than 14 days when stored at controlled room temperature. (20--25°C)

9.1.3 For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations: The BUD is not later than 30 days

9.2 Susceptible preparation should contain suitable antimicrobial agents to protect against bacteria, yeast, and mold contamination inadvertently introduced during or after the compounding process. When antimicrobial preservatives are contraindicated in such

compounded preparations, storage of the preparation at controlled cold temperature is necessary.

9.2.1 Appropriate patient instruction and consultation is essential to ensure proper storage and handling of such compound in preparations by the patient or caregiver.

9.2.2 Anti-microbial preservative should not be used as a substitute for good compounding practices.

9.2.3 Assurance of sterility in a compounded sterile preparation is mandatory. Compounding and packaging of sterile drugs requires strict adherence to guidelines presented in USP chapter <797> and in the manufacturers labeling instructions.

9.3 BUDs for compounded preparations are usually assigned based on professional experience, which should include careful interpretation of appropriate information sources for the same or similar formulations. See Stability Criteria and Beyond-Use Dating under Pharmaceutical Compounding-- Non-sterile Preparations USP chapter <795>.

9.4 The majority of CSPs are aqueous solutions in which hydrolysis of dissolved ingredients is the most common chemical degradation reaction. The extent of hydrolysis and other heat catalyzed degradation reactions at any time point in the life of the CSP represents the thermodynamic some of the exposure temperatures and durations.

9.4.1 Personnel who prepare, dispense, and administer CSPs must store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs. When CSPs are known to have been exposed to temperatures warmer than the warmest labeled limit or to temperatures exceeding 40 degrees C for more than four hours such CSP should be discarded unless direct assay data or appropriate documentation confirms their continued stability.

9.5 BUD's and expiration dates are not the same. Expiration dates are for the chemical and physical stability of manufactured products determined from results of rigorous analytical and performance testing, and they are specific for a particular formulation in its container an at stated exposure conditions of illumination and temperature.

9.5.1 When CSPS deviate from conditions in the approved labeling of manufactured products contained in CSPS, compounding personnel may consult the manufacturer of products for advice on assigning beauties based on chemical and physical stability parameters.

9.5.2 BUD's for CSP's that are prepared strictly in accordance with manufacturers product labeling must be those specified in the labeling or from appropriate literature sources or direct testing. BUDS for CSP's that lack justification from either appropriate literature sources or by direct testing evidence must be assigned as described in Stability Criteria and Beyond-Use Dating under Pharmaceutical Compounding—Non-sterile Preparations USP chapter <795>.

9.5.3 Compounding personnel may refer to applicable publications to obtain relevant stability, compatibility, degradation information regarding the drug or its congeners.

9.6 When assigning BUDs, compounding personnel should consult and apply drug specific and general stability documentation and literature where available and they should consider the nature of the drug and its degradation mechanism, the container which is packaged, the expected to storage conditions, and the intended duration of therapy.

9.7 Stability information must be carefully interpreted in relation to the actual compound formulation and conditions for storage and use.

9.8 Stability testing provides the pharmacy the ability to accurately assign beyond-use-dates/ expiration dates to compounded medications. When testing for stability, both strength and stability can be determined, but not all strength testing can determine stability.

9.9 Stability testing includes method development, method validation, and a stability study.

9.10 Stability is the extent to which a product remains, within specified limits and throughout its period of storage and use, the same properties and characteristics that is possessed at the time of compounding.

9.11 Time intervals for testing should be initially, 14 days, 30 days, 60 days, 90 days and finally 180 days until or unless failed.

9.12 The sample to be tested must be submitted in the final dispensing container or a container of the same material.

- 9.12.1 Each dosage form made at RX COMPOUNDSTORE should be submitted for testing
- 9.12.2 Each compounder at RX COMPOUNDSTORE should prepare testing samples of various dosage forms to validate processes
- 9.12.3 Samples to be tested should be tested at intervals of initially, followed by every three months for one year for each compounder and dosage form.
  - 9.12.3.1 RX COMPOUNDSTORE's QM Team must determine which preparations, dosage forms, and which personnel are to be tested so that all dosage forms and each compounder are tested annually.
    - 9.12.3.1.1 A report of RX COMPOUNDSTORE's most frequently compounded preparations must be run every six months.
    - 9.12.3.1.2 Approximately twenty percent of the most frequently compounded preparations must be tested over the next six-month period.
    - 9.12.3.1.3 QM must ensure that each compounder is tested on each dosage form at least annually validating both processes and personnel at RX COMPOUNDSTORE.

9.13 Samples to be tested must be stored and tested under the same storage conditions for dispensation and that will protect the preparation.

- 9.13.1 Storage conditions to be considered—light protective, refrigerated, frozen, room temperature, etc.

9.14 Testing results must be reviewed by a pharmacist and any changes in formulation needed, implemented.

9.15 Highest risk preparations are preservative free and/or sterilized via filtration.

9.16 In the absence of stability information, the following guidelines set forth in USP Chapter <795> must be followed.

- 9.16.1 Beyond-Use Dates (BUDs) should be assigned conservatively. When assigning a BUD, compounders must consult USP Chapter <795> and apply drug-specific and general stability documentation and literature and should consider the following.
  - 9.16.1.1 The nature of the drug and its degradation mechanism
  - 9.16.1.2 The dosage form and its components
  - 9.16.1.3 The potential for microbial proliferations in the preparation
  - 9.16.1.4 The container in which it is packaged
  - 9.16.1.5 The expected storage conditions
  - 9.16.1.6 The intended duration of therapy

9.16.2 When a manufactured product is used as the source of the API for a nonsterile compounded preparation, the product expiration cannot be used solely to assign a BUD for the compounded preparation. The following must be considered.
- 9.16.2.1 Manufacturer stability information
- 9.16.2.2 Literature for applicable stability information
- 9.16.2.3 Compatibility and degradation of ingredients
- 9.16.2.4 Stability factors in USP Chapter <1191>
- 9.16.2.5 Professional judgement

9.16.3 All stability data must be carefully interpreted in relation to the actual compounded formulation.

9.16.4 BUD by type of formulation.
- 9.16.4.1 Non-aqueous formulations--the BUD is not later than the time remaining until the earliest expiration date of any API or 6 months whichever is earlier
- 9.16.4.2 Water-containing oral formulations—the BUD is not later than 14 days when stored at controlled cold temperature
- 9.16.4.3 Water-containing topical/dermal and mucosal liquid and semisolid formulation—The Bud is not later than 30 days.

9.16.5 Extension of a beyond-use date is supported by the following.
- 9.16.5.1 Method Suitability Test
- 9.16.5.2 Container Closure Integrity Test
- 9.16.5.3 Stability Studies

9.16.6 Shorter dating must be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

11.1 Original. Brenda Poland. 04-01-2023

11.2 Reviewed. Shibu John. 03-25-2025

11.3 Edited. Amelia Yeh. 03-15-2025

6.015 AUDIT TRAIL AND RECALL OF COMPOUNDED PREPARATIONS

Authorized by: Shibu John, Amelia Yeh
Date: 7/15/2025

1.0 PURPOSE

1.1 The purpose if this standard operating procedure (SOP) is to establish requirements for recalling a conventionally manufactured drug product or a compounded preparation that is defective or otherwise unsafe at RX COMPOUNDSTORE.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at RX COMPOUNDSTORE.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge (PIC) must supervise this procedure and ensure proper personnel training.

3.1.1 The Quality Management Team (QMT) is responsible for developing and implementing the recall process.

3.1.2 A Designated Person is responsible for notifying prescribers and patients about recalls.

3.1.3 The Director of Operations is responsible for handling customer inquiries regarding recalls.

3.1.4 The Quality Manager is responsible for the physical handling of recalled products or preparations.

4.0 REFERENCES

4.1 N/A

5.0 DEFINITIONS

5.1 A recall of a commercial product is a notification issued when a product does not comply with the Food and Drug act or code of Federal Regulations. Recalls involving misbranded or adulterated products may include the physical removal of the marketed product by the manufacturer.

5.2 A recall of a compounded preparation is a notification issued when a preparation poses a safety risk or fails to meet minimum standards. Decisions regarding the recall of compounded preparations are made by the PIC and/or Quality Management Team (QMT).

6.0 FREQUENCY

6.1 As needed

7.0 EQUIPMENT & SUPPLIES

7.1 RX COMPOUNDSTORE pharmacy software's report or audit of formulations and prescriptions

7.2 Formulation compounding worksheet

7.3 Test results from third party laboratory (if applicable)

7.4 Product samples

7.5 In-house testing kits (if applicable)

7.6 Applicable records (lot numbers, facility name, patient names, etc.)

8.0 GENERAL INFORMATION

8.1 Th intention of recalling potentially harmful products or preparations is to protect consumers from harm and to maintain the integrity of RX COMPOUNDSTORE's reputation.

8.2 All employees who are involved in the recall process must be trained on this SOP.

8.3 The recall process must be executed in a timely and efficient manner.

8.4 The recall process should be audited annually to ensure it is effective and efficient

8.5 The product manufacturer, in cooperation with the FDA, usually initiates a product recall. The FDA has no authority to initiate or order a recall of a compounded preparation, however, it can request a firm to recall a product. The FDA has established guidelines for manufacturers to follow in recalling distributed products. The guidelines categorized all recalls into one of three classes according to the level of hazard involved. The classes are as follows:

8.5.1 Class 1: dangerous and effective products that predictably could cause serious health problems or death. Examples of products that could fall into this category or label mix up on a lifesaving drug or a defective artificial heart valve.

8.5.2 Class 2: products that might cause a temporary health problem or pose only a slight threat of a serious nature. An example is a drug that has less potency than stated but is not used to treat life threatening situations.

8.5.3 class 3: products that are unlikely to cause any adverse health reactions but violate FDA regulations. An example is a bottle of aspirin that contains 90 tablets instead of 100 as stated on the label.

8.6 RX COMPOUNDSTORE may initiate an internal recall to remove from use conventionally manufactured products if it is deemed necessary. An example of an internal recall is a problem that has been reported involving a specific lot of components used in a finish compound in preparation, an RX COMPOUNDSTORE has determined the facility should not use the product even though the manufacturer has not initiated a recall.

8.7 Depending on the type of class of recall, the action level may be:

8.7.1 Wholesale or distributor only: not applicable to RX COMPOUNDSTORE; No action necessary.

8.7.2 Retail: applicable to RX COMPOUNDSTORE facility; Action required to remove any affected products from facility inventory.

8.7.3 Hospital: applicable to RX COMPOUNDSTORE facility; Action necessary to remove any affected product from facility inventory or administration offices.

8.8 An audit trail is necessary in the event of a recalled compounded preparation.

8.8.1 All compounded preparations are traced with a prescription number.

8.8.2 Formulas used for prescription compounding are traced with a lot number

9.0 PROCEDURE

9.1 Any personnel who become aware of a defective component or unsafe product/preparation must immediately report it to their supervisor.

9.1.1 Any employee who fails to report a defective component or unsafe product/preparation may be subject to disciplinary action.

9.2 Upon notification of a manufacturer recall, take appropriate action to remove the items from inventory. Also, remove any finished CPs stored at RX COMPOUNDSTORE or delivered and stored at other locations such as patient homes or offices where CPs are administered.

9.3 Check all incoming inventory related to the recall for the next 30 days from the date of the initial recall notice to ensure affected lot numbers are not brought back into inventory.

9.4 Place recalled items into the "Quarantine Area". Label any quarantine product clearly and conspicuously with the following message: Recalled Product: DO NOT USE."

9.5 As directed by the QMT of RX COMPOUNDSTORE, retrieve all recalled items from RX COMPOUNDSTORE inventory in any finished CPS that contain recalled component from finished RX COMPOUNDSTORE inventory awaiting delivery or any finished CPs already delivered to patient locations and awaiting use with patient. Inspect all records created since the recalled item was received. Those records may include but not limited to:

9.5.1 compounding documents including compounding record, master formulation record, prescription or orders,

9.5.2 inventory forms

9.5.3 shipping and delivery tickets

9.5.4 equipment maintenance logs

9.5.5 equipment validations

9.5.6 environmental monitoring records

9.6 Hold recalled items for return to manufacturer for vendor for credit, replacement, or disposal according to manufacturer or vendor or RX COMPOUNDSTORE instruction

9.7 Recall notices are signed and dated with quantity and lot number and documentation of action taken.

9.8 Recall notices received for products not in use at RX COMPOUNDSTORE bear a note directly on the recall notice that all inventory was examined, and recall is not applicable.

9.9 Retain recall notices of all inventories that applied to RX COMPOUNDSTORE inventory used.

9.10 RX COMPOUNDSTORE maintains a recall file where notices and documentation of action taken are filed in chronological order period

9.10.1 Recall Plan documents the steps taken in the event of a recall

9.10.2 Recall Notice notifies customers of the recall

9.10.3 Return Tracking documents the return and quarantine of recalled products

9.11 In the event of a recall for compounded preparations, the Quality Manager must investigate the preparation in question and determine the scope of the recall.

9.11.1 Identify the problem

9.11.2 Assess the risk

9.11.3 Determine course of action

9.11.4 Determine the scope of the recall

9.11.5 Notify consumers

9.11.6 Retrieve and quarantine affected products

9.11.7 Investigate probable cause

9.11.8 File report with appropriate agencies and cooperate fully

9.11.9 Dispose of affected products appropriately

9.12 The following documentation must be completed and maintained for all recalls

9.12.1 A copy of the recall notice

9.12.2 A list of all consumers who were notified of the recall

9.12.3 A record of customer inquiries regarding the recall

9.12.4 A record of all the recalled units of preparation that were returned to RX COMPOUNDSTORE

9.13 A positive sterility test unit or exceeded endotoxin levels immediately trigger the following actions:

9.13.1 Notation of critical identifying data such as:

9.13.1.1 Date positive sterility tests or exceeded endotoxin levels were observed

9.13.1.2 Type of test performed

9.13.1.3 The type of media that demonstrated growth

9.13.1.4 Date affected batch and lot was prepared

9.13.1.5 Assigned lot number

9.13.1.5.1 Released or the total batch units put into inventory to be dispensed

9.13.1.5.2 not released

9.13.1.6 Name of RX COMPOUNDSTORE management team member notified

9.13.1.7 Time and date of notification of RX COMPOUNDSTORE management team member

9.13.2 The required action steps are also documented and include:

9.13.2.1 The affected lot record is removed from where it is filed and reviewed.

9.13.2.2 Units from the affected lot still located in RX COMPOUNDSTORE internal unreleased inventory are located, counted, and quarantined.

9.13.2.3 Any of the affected lot that was destroyed due to in-house expiry are identified, if applicable.

9.13.2.4 Accounting for the total number of units in the affected lot is mandatory.

9.13.2.4.1 The number of units affected in the lot placed in inventory equals the sum of the number of units in RX COMPOUNDSTORE inventory plus number of units dispensed to patients plus number of units destroyed due to expiry.

9.14 Next, if any CSPs have been dispensed, each affected patient and their prescriber must be notified of the required recall. RX COMPOUNDSTORE works to ensure the following steps are completed:

9.14.1 Identification of the specific patients to whom the affected lot was dispensed immediate quarantine of unused inventory still present at RX COMPOUNDSTORE, administration office, or patient home

9.14.2 Identification of the number of CSP units in question at each patient received

9.14.3 Any entity in possession of the affected lot is advised not to destroy the preparation.

9.14.4 Clients including prescribers, patients, caregivers shall be advised that the affected sterility test samples were sent for microbiological examination by an independent lab.

9.14.4.1 Clients should be reminded about the extensive environmental sampling program; Personnel training and competency evaluation, and strict hand hygiene, garbing, cleaning, and staging practices employed at RX COMPOUNDSTORE.

9.14.5 RX COMPOUNDSTORE will immediately replace the recalled CSP inventory with inventory made from unaffected components. The goal is to avoid disruption of treatment to patients receiving therapy.

9.14.5.1 Documentation for replacement inventory must be such that clients are not double billed.

9.14.6 All information collected during the investigation is documented as part of the CAPA plan.

9.14.7 RX COMPOUNDSTORE shall contact the prescribers who wrote the prescription for patients identified at risk. The prescribers are informed regarding the positive sterility tests or exceeded endotoxin levels and asked to advise RX COMPOUNDSTORE if the patient is exhibiting any signs or symptoms of infection or fever that may be related to the recall.

9.14.8 A final disposition report, including any impacted patients, is documented as part of the CAPA plan.

9.14.9 Additionally, the following activities must occur immediately after identification of the positive sterility test unit or exceeded endotoxin results, while awaiting results from the microbiological examination:

9.14.9.1 a review of cleaning, surface sampling, viable air sampling, and temperature and pressure monitoring documentation is completed by RX COMPOUNDSTORE's sterile department manager or QM to identify potential adverse trends or instances where practice deviated from facility SOPs

9.14.9.2 if any instances are identified where SOPs and performance deviate, appropriate remediation in terms of additional staff training, competency measurement, and observation is initiated

9.14.9.3 if any situation is identified where the physical facility is not operating as designed, appropriate action is taken and documented.

9.14.9.4 A thorough monthly cleaning of the entire clean room facility is performed and documented.

9.14.9.5 Basic competencies of the person who compounded the lot in question must be reviewed, measured, and verified by the Sterile Department Manager and documented.

9.15 If a compounded preparation is suspected or confirmed to have caused patient harm, was compounded incorrectly, or needs to be recalled for any other reason, all prescribers, facilities and/or patients that received the preparation must be notified immediately.

9.16 A comprehensive list of all lot numbers affected shall be retrieved using all available data devices (formulation records, testing results, retained samples, hard copy files, Pharmacy Software, etc.).

9.17 The nature of the recall shall be explained by the Pharmacist-in-charge or applicable designee and a request will be made to check the affected lot numbers.

9.18 A comprehensive list of all lot numbers and other identifiable data shall be used to determine the reach of the recall. All data sources available shall be used (e.g., software, formulation records, testing results, retained samples, hard copy files, etc.) All facilities and/or patients that received the recall item must be notified immediately and the nature of the recall shall be explained. This contact must be documented.

9.19 A formal recall letter shall be written, detailing the nature of the recall, affected lot numbers, and dates of dispensing to the facility and/or the patient. <See F.1.009.1 Recall Letter Template>

9.20 The Pharmacist-in-charge or designated person shall ensure that all preparations that were dispensed are accounted for and/or that no harm was done to patients. The Pharmacist-in-charge or designee shall complete the recall record.

9.21 RX COMPOUNDSTORE will require all recalled preparations be returned to RX COMPOUNDSTORE via prepaid delivery devices.

9.22 All recalled products and/or preparations shall be accounted for and documented.

9.23 Upon receipt of recalled product, RX COMPOUNDSTORE will quarantine the product for further analytical testing and evaluation of process malfunctions.

9.24 Any deficiencies shall be addressed, problems shall be resolved and/or investigated, and a formal explanation of the outcome of the recall will be documented.

9.25 Any training and/or education required to prevent process deficiencies from occurring in the future will be initiated immediately.

9.26 A copy of the investigation, the recall letter, quarantine records and distraction records shall be filed along with the recall records in a quality assurance file.

9.27 Documentation Elements

9.27.1 F.6.025.1 Recall Form

9.27.2 Each patient affected will have a separate CAPA plan completed

9.27.3 Each prescriber would receive a recall letter if RX COMPOUNDSTORE was required to retrieve any CP or CSP from their location

9.27.4 Any remediation of personnel or changes in practice due to the outcome of the investigation and taken to prevent future positive sterility tests or exceeded endotoxin level current is already documented.

10.0 ATTACHMENTS

10.1 Attachment 1 -F.6.015.1 Recall Letter Template

10.2 Attachment 2 – F.6.015.2 Recall Record

11.0 HISTORY

11.1 Original. Brenda Poland. 04-01-2023

11.2 Reviewed. Shibu John. 03-25-2025

11.3 Edited. Amelia Yeh. 03-15-2025

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6.019 INCIDENT REPORTING

Authorized by: Shibu John, Amelia Yeh **Date: 7-15-2025**

1.0 PURPOSE

1.1 The purpose of the standard operating procedure (SOP) is to describe the general procedure for reporting incidents at RX COMPOUNDSTORE.

2.0 SCOPE

2.1 All personnel are responsible for being able to recognize, handle, and document any incidents at RX COMPOUNDSTORE.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge (PIC) must supervise this procedure and is responsible for employee training.

4.0 REFERENCES

4.1 N/A

5.0 DEFINITIONS

5.1 Incident—any unforeseen and inappropriate event

5.2 CAPA—Corrective And Preventative Action

5.3 Corrective Action—action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation to prevent recurrence.

5.4 Preventative Action—Action taken to eliminate the cause of potential nonconformity, defect or other undesirable situation in order to prevent its occurrence.

5.4.1 Preventative action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

6.0 FREQUENCY

6.1 With each occurrence

7.0 EQUIPMENT

7.1 Incident Report Form

8.0 FREQUENCY

8.1 Ongoing as needed for all incidents.

9.0 GENERAL INFORMATION

9.1 Any incident that occurs must be documented and investigated fully.

9.2 This SOP is applicable to all events and incidents which can affect the safety, identity, strength, purity and/or quality of the product. Following are potential factors

9.2.1 Equipment or machine breakdown related

9.2.2 Facility related

9.2.3 Storage related

9.2.4 Production related or having occurred during processing

9.2.5 Sampling or testing related

9.2.6 Delivery or dispensing related

9.2.7 Confirmed failures out of repeat analysis and out of specification (OOS) investigations

9.2.8 Unplanned deviations from approved procedures or SOPs without prior authorization and documentation

9.3 Pharmacy supervisor or manager must investigate the incident, evaluate the impact on quality of the preparation, and prepare the incident investigation report.

10.0 PROCEDURE

10.1 The incident report form will be used to document any actual or potential unexpected and inappropriate event that occurred regarding patient care. Examples include, but are not limited to, the following.

10.1.1 Workplace accident or injury

10.1.1.1 Slip and fall
10.1.1.1.1 Improper ladder use
10.1.1.1.2 Marked or unmarked wet floor
10.1.2 Loss/Breakage
10.1.3 Patient/caregiver reports article missing from home after home visit
10.1.4 Staff involved in damage/breakage of patient's personal belonging or equipment
10.1.5 Staff discovery of personal belongings or equipment missing

10.2 Any untoward event dealing with equipment or devices:
10.2.1 Lack of equipment
10.2.2 Equipment failure or malfunction
10.2.3 Any injury resulting from the use of the equipment or medical device

10.3 An event that may endanger the staff while providing care/service:
10.3.1 Verbal abuse
10.3.2 Physical abuse
10.3.3 The patient is unwilling to accept or follow appropriate instructions.

10.4 Any problem or error dealing with the completion of a procedure or protocol:
10.4.1 Failure to follow a procedure
10.4.2 Care performed outside the scope of practice of the clinician

10.5 Any untoward outcomes related to drug administration or treatment modality:
10.5.1 Adverse or toxic drug reactions
10.5.2 Anaphylaxis

10.6 Noncompliance by the patient/caregiver that results in emergency intervention or hospitalization.

10.7 Any medication error including the patient's failure to follow the physician/nurse/pharmacist instructions as well as delays in the administration sequence or failure of the patient to receive a dose.

10.8 An incident report will be initiated by the person who first becomes aware that an incident has occurred.

10.8.1 The incident report must be completed accurately and no later than 24 hours after the discovery of the occurrence.
10.8.2 All sections of the report are to be completed, leaving no blanks.
10.8.3 If a section does not apply, the words "not applicable" should be written in the space.

10.9 If the incident requires treatment by a physician or an emergency room visit, this must be included in the documentation.

11.0 ATTACHMENTS

11.1 F.6.019.1 INCIDENT REPORT

12.0 HISTORY

12.1 Original. Brenda Poland. 04-01-2023
12.2 Reviewed. Shibu John. 03-25-2025
12.3 Edited. Amelia Yeh 03-15-2025

6.020 BEYOND-USE DATING FOR COMPOUNDED PREPARATIONS

Authorized by: Shibu John, Amelia Yeh **Date Effective: 7/15/2025**

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for determining a beyond-use date (BUD) for compounded preparations at RX COMPOUNDSTORE.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at RX COMPOUNDSTORE.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge (PIC) must supervise this procedure and ensure proper personnel training.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.3 USP Current Version <1150> "Pharmaceutical Stability"

5.0 DEFINITIONS

5.1 BUD – Beyond-use date

6.0 FREQUENCY

6.1 This procedure must be performed for each compounded preparation.

7.0 EQUIPMENT & SUPPLIES

7.1 Appropriate reference materials

8.0 GENERAL INFORMATION

8.1 All compounded preparations must have an appropriate and conservative BUD.

8.2 The BUD is the date after which a compound preparation must not be used in this determined from the date when the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their BUDs are assigned on basis of criteria different from those applied to assigning expiration dates to manufacture products.

8.3 BUDs must be assigned conservatively. When assigning A BUD, compounder must consult and apply drug specific and general stability documentation and literature when available and should consider:

- 8.3.1 the nature of the drug in its degradation mechanism
- 8.3.2 the dosage form and its components
- 8.3.3 the potential for microbial proliferation in the preparation
- 8.3.4 the container in which it's packaged
- 8.3.5 the expected storage conditions

8.3.6 the intended duration of therapy

8.4 BUDs and expiration dates are not the same. Expiration dates are for the chemical and physical stability of manufactured products are determined from result of rigorous analytical and performance testing, and they are specific for a particular formulation in its container an ad stated exposure conditions of illumination and temperature.

8.5 When a compounded preparations deviate from conditions in the approved labeling of manufactured products contained in CSPs, compounding personnel may consult the manufacturer of particular product for advice when assigning BUDs based on chemical and physical stability parameters.

8.6 BUDs for compounded preparations that are performed strictly in accordance with manufacturers product labeling must be those specified in the labeling or from appropriate literature sources or direct testing. BUDs for compounded preparations that lack justification from either appropriate literature sources or by direct testing evidence must be assigned as described in USP Chapter <795> Pharmaceutical Compounding—Non-sterile Preparations under Stability Criteria and Beyond-Use Dating.

9.0 PROCEDURE

9.1 All stability data must be carefully interpreted in relation to the actual compounded formulation.

9.2 All steps in the compounding, dispensing, and storage processes of the compounded preparation must be observed by compounding personnel

9.3 BUDs must be assigned based on current drug stability information and sterility considerations.

9.4 Consideration must be given to all aspects of the finished product including drug reservoir, concentration, and storage conditions.

9.5 A reliable method for determining BUDs must be established, including laboratory testing of product stability, pyrogenicity and chemical content when necessary.

9.5.1 Physical stability of the compounded preparation must signify that the preparation has retained the original physical properties of the preparation, such as appearance, palatability, uniformity, dissolution and suspendability.

9.5.2 Chemical stability of the compounded preparation must signify that each active ingredient has retained its chemical integrity and labeled potency within specified limits.

9.5.3 Microbiological stability of the compounded preparation must signify that sterility or resistance to microbial growth has been retained according to the specified requirements. Antimicrobial agents that are present must retain their effectiveness within the specified limits.

9.5.4 Additional factors that affect the stability of the final preparation, and must be considered, include pH, temperature, solvent, light, air, humidity, particle size, ionic strength, dielectric constant, polymorphism, crystallization, vaporization and absorption.

9.6 In the absence of stability information that is applicable to a specific drug and preparation, the following maximum BUDs are recommended for non-sterile compounded preparations packaged in tight, light-resistant containers and stored at controlled room temperature (unless otherwise indicated):

9.6.1 **For non-aqueous formulations**-the BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.

9.6.2 **For Water-Containing Oral Formulations**—The BUD is not later than 14 days when stored at controlled cold temperature.

9.6.3 **For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations**—The BUD is not later than 30 days.

9.7 Susceptible preparations should contain suitable anti-microbial agents to protect against bacteria, yeast, and mold contamination inadvertently introduced during or after the compounding process.

9.8 When anti-microbial preservatives are contraindicated in such compounded preparations, storage of the preparation at controlled cold temperature is necessary.

9.8.1 To ensure proper storage and handling of such compounded preparations by the patient or caregiver, appropriate patient instruction and consultation is essential.

9.8.2 Anti-microbial preservatives should never be used as a substitute for good compounding practices.

9.9 Assurance of sterility in a compounded sterile preparation is mandatory. Compounding and packaging of sterile drugs requires strict adherence to guidelines presented in USP chapter 797 Pharmaceutical Compounding—Sterile Preparations

9.10 Applicable publications must be referenced to obtain relevant stability, compatibility and degradation information regarding a drug or its congeners.

9.10.1 A compounding pharmacy reference library will be available for compounding laboratory personnel so they may access critical information in a timely manner.

9.10.2 Referenced publications must be available for compounding personnel. The reference library may include, but not be limited to, the following publications:

9.10.2.1 Facts and Comparisons

9.10.2.2 Handbook on Injectable Drugs (ASHP)

9.10.2.3 Handbook on Injectable Drugs (Trissel)

9.10.2.4 Handbook of Pharmaceutical Excipients

9.10.2.5 International Journal of Pharmaceutical Compounding

9.10.2.6 Internet access to PubMed for literature searches

9.10.2.7 Martindale: The Extra Pharmacopoeia

9.10.2.8 Micromedex Electronic Drug Reference

9.10.2.9 Pharmaceutical Calculations

9.10.2.10 Pharmaceutical Dosage Forms and Drug Delivery Systems

9.10.2.11 Policies and procedures

9.10.2.12 Principles of Sterile Product Preparation (ASHP)

9.10.2.13 Quality Control/Assurance documentation logs

9.10.2.14 Remington: The Science and Practice of Pharmacy

9.10.2.15 State law books and guidelines regarding compounding

9.10.2.16 The Merck Index

9.10.2.17 United States Pharmacopeia or USP Pharmacists' Pharmacopeia--monographs

9.10.3 All periodical subscriptions that pertain to compounding pharmacy must be kept in the reference library.

9.11 RX COMPOUNDSTORE may choose to perform potency assays on products with a narrow therapeutic index, where close monitoring or dose titration is required to ensure

therapeutic effectiveness and to avoid toxicity, where a theoretically established BUD is supported by only marginal evidence or where significant margin of safety cannot be verified.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

11.1 Original. Brenda Poland. 04-01-2023

11.2 Reviewed. Shibu John. 03-25-2025

11.3 Edited. Amelia Yeh. 03-15-2025

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6.025 BEYOND-USE DATING FOR STERILE COMPOUNDED PREPARATIONS

Authorized by: Shibu John Date: 4/1/2023

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for determining a beyond-use date (BUD) for compounded sterile preparations (CSPs) at RX COMPOUNDSTORE.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at RX COMPOUNDSTORE.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge must supervise this procedure and ensure proper personnel training and compliance.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.3 USP Current Version <1150> "Pharmaceutical Stability"

5.0 DEFINITIONS

5.1 Administration: The direct application of a sterile medication to a single patient by injection, infusing, or otherwise instilling a sterile medication in its final form

5.2 BUD – Beyond-use date: The date and time after which a CSP must not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.

5.3 CRT—Controlled Room Temperature

5.4 CSP—Compounded Sterile Preparations

5.5 **Immediate-Use CSP:** A CSP is for direct and immediate administration within 4 hours after preparation.

5.6 **Category 1 CSP:** A CSP that is assigned a BUD of 12 h or less at controlled room temperature or 24 h or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in this chapter.

5.7 **Category 2 CSP:** A CSP that may be assigned a BUD of greater than 12 h at controlled room temperature or greater than 24 h refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in this chapter.

5.8 **Category 3 CSP:** A CSP that may be assigned a BUD exceeding the limits in Table 13 for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter.

5.9 **Component:** Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.

5.10 **Compounded sterile preparation (CSP):** A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.

5.11 **Conventionally manufactured product:** A pharmaceutical dosage form, usually the subject of an FDA approved application, and manufactured under current good manufacturing practice conditions.

5.12 **Immediate Use CSP:** CSP aseptically compounded outside of ISO classified air for direct and immediate administration to a single patient with a maximum BUD of 4 hours from the initiation of compounding.

5.13 **Stability:** The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.

6.0 FREQUENCY

6.1 This procedure must be performed for each compounded preparation.

7.0 EQUIPMENT & SUPPLIES

7.1 Appropriate reference materials

8.0 GENERAL INFORMATION

8.1 All compounded preparations must have an appropriate and conservative BUD.

8.2 Per USP Chapter <797> BUD limits are intended to help prevent patient harm resulting from microbial proliferation and contamination of CSPs. BUDs are determined by evaluating the chemical stability of the CSP components or formulation, storage conditions, starting components (sterile vs. non-sterile), sterile processing approach, and type of sterile compounding area where the CSP is prepared.

8.3 Expiration dates and BUDs are not interchangeable terms or concepts and medication administration terms cause confusion around the definition and application of BUDs assigned to compounded sterile preparations.

8.3.1 **Expiration date** is the time during which a manufactured product can be expected to meet the requirements of the USP–NF monograph, if one exists, or maintain expected quality provided it is kept under the specified storage conditions; applies to all conventionally manufactured products, active pharmaceutical ingredients (API), and added substances.

8.3.2 **BUD** is the date, or hour and date, after which the administration of a CSP cannot begin. BUDs are not intended to limit administration time; applies to all CSPs and stock solutions made by Compounding Personnel.

8.3.3 **Hang time or administration time** refers to the amount of time during which a CSP or conventionally manufactured product (e.g. pre-mix, large volume parenteral solution) may by be infused before which the tubing or medications needs to be changed due to stability

8.4 This policy denotes the BUD assignment for all CSPs compounded at RX COMPOUNDSTORE.

8.4.3 Refer to USP Chapter <797> for the procedures and further information about the requirements and definition of Category 1 CSPs

8.4.3.1 ≤ 12 hours at CRT

8.4.3.2 ≤ 24 hours in a refrigerator

8.4.4 Refer to USP Chapter <797> for the procedures and further information about the requirements and definition of Category 2 CSPs.

8.4.5 Category 2 CSPs will be compounded at RX COMPOUNDSTORE

8.4.5.1 Aseptically processed, no sterility testing, only sterile starting component(s)

8.4.5.1.1 4 days at CRT (20° C to 25° C)

8.4.5.1.2 10 days in a refrigerator (2° C to 8° C)

8.4.5.1.3 45 days in a freezer (-25 ° to -10° C)

8.4.5.2 Aseptically processed, no sterility testing, one or more nonsterile starting component(s)

8.4.5.2.1 1 day at CRT (20° C to 25° C)

8.4.5.2.2 4 days in a refrigerator (2° C to 8° C)

8.4.5.2.3 45 days in a freezer (-25 ° to -10 ° C)

8.4.5.3 Aseptically processed, passed sterility testing

8.4.5.3.1 30 days at CRT (20° C to 25° C)

8.4.5.3.2 45 days in a refrigerator (2° C to 8° C)

8.4.5.3.3 60 days in a freezer (-25 ° to -10 ° C)

8.4.5.4 Terminally sterilized, no sterility testing

8.4.5.4.1 14 days at CRT (20° C to 25° C)

8.4.5.4.2 28 days in a refrigerator (2° C to 8° C)

8.4.5.4.3 45 days in a freezer (-25 ° to -10 ° C)

8.4.5.5 Terminally sterilized, passed sterility testing

8.4.5.5.1 45 days at CRT (20° C to 25° C)

8.4.5.5.2 60 days in a refrigerator (2° C to 8° C)

8.4.5.5.3 90 days in a freezer (-25 ° to -10 ° C)

8.4.6 Only Category 3 CSPs will be compounded at RX COMPOUNDSTORE

8.4.6.1 Aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs

8.4.6.1.1 60 days at CRT (20° C to 25° C)

8.4.6.1.2 90 days in a refrigerator (2° C to 8° C)

8.4.6.1.3 120 days in a freezer (-25 ° to -10° C)

8.4.6.2 Terminally processed, sterility tested, and passing all applicable tests for Category 3 CSPs

8.4.6.2.1 90 days at CRT (20° C to 25° C)

8.4.6.2.2 120 days in a refrigerator (2° C to 8° C)

8.4.6.2.3 180 days in a freezer (-25 ° to -10° C)

8.5 BUDs are assigned by Compounding Personnel with consideration for factors that could impact the CSP quality or sterility including, but not limited to:

- 8.5.1 Chemical and physical stability of the components and/or formulation
- 8.5.2 Container closure system and compatibility with the final preparation and storage conditions
- 8.5.3 Compounding environment in which the CSP is prepared
- 8.5.4 Aseptic processing and sterilization method
- 8.5.5 Sterility of starting components
- 8.5.6 Whether or not sterility testing is performed (if applicable)
- 8.5.7 Storage conditions

8.6 When the chemical or physical stability of the CSP is shorter than the maximum BUD, the most conservative dating becomes the BUD.

- 8.6.1 Chemical stability is based on available manufacturer's data, published literature, and industry references.

8.7 Packaging is selected for the CSP to preserve sterility, chemical stability, and potency.

8.8 CSPs stored under or moved to different storage conditions before they are used assume the new shorter BUD of the storage condition(s) which does not to exceed the original BUD placed on the CSP at the time of preparation

- 8.8.1 BUDs are not additive; administration is initiated before the BUD is exceeded or the CSP is promptly and appropriately discarded
- 8.8.2 Once a CSP has been stored under a new storage condition requiring a shorter BUD, the CSP is used within the shortened timeframe

8.9 Storage conditions per **USP <659> Packaging and Storage Requirements:**

- 8.9.1 Controlled Room Temperature: 20°C to 25°C
- 8.9.2 Refrigerated: 2°C to 8°C
- 8.9.3 Frozen: -25°C to -10°C

8.10 Multiple-dose CSPs, including topical ophthalmic CSPs, meet the following criteria:

- 8.10.1 Prepared as Category 2
- 8.10.2 Preserved unless prepared specifically for a sterile topical application (including ophthalmic use). Preservatives are appropriate for the dosage form, intended patient population, and route of administration.
- 8.10.3 Non-preserved topical CSPs are only prepared for a single patient and labeled with a Discard by Date (or "in-use" date)
- 8.10.4 Dispensed in a multi-dose container closure system that has been evaluated for and conforms with container closure integrity testing (per USP <1207>; except for sterile multi-dose topical applicators such as eye droppers)
- 8.10.5 Assigned a maximum BUD per USP <797> (see Section 2.2) and labeled with a Discard by Date as follows:

Multi-Dose CSPs		
	Maximum BUD (from compounding date)	Discard By Date (or "in-use" time once opened)
Nonaqueous multi-dose CSPs	Per USP <797> BUDs (see Section 2.2)	No longer than 28 Days* or the Labeled BUD (whichever is shorter)

Multi-Dose CSPs		
	Maximum BUD (from compounding date)	Discard By Date (or "in-use" time once opened)
Preserved aqueous multi-dose CSPs *with* passing USP <51> compliant antimicrobial effectiveness testing	Per USP <797> BUDs (see Section 2.2)	No longer than 28 Days* or the Labeled BUD (whichever is shorter)
Non-preserved aqueous multi-dose CSPs for topical use	Per USP <797> BUDs (see Section 2.2)	No longer than: 24 hours stored at room temp OR 72 hours if stored refrigerated

*28 Days at room temperature or storage temperature per manufacturer's specifications

8.11 Conventionally manufactured sterile products or components used in the preparation of CSPs adhere to the following BUDs, use and storage requirements:

Conventionally Manufactured Products & Components		
	Expiration Date	Use and Storage Conditions
Single-dose containers	12 hours	• Punctured and entered within an ISO Class 5 PEC • Stored per labeled storage conditions
Ampule (or open plastic luer lock vials)	Discard immediately after use	• Punctured and entered within an ISO Class 5 PEC
Multi-dose containers	28 days (unless otherwise specified by manufacturer's labeling)	• Punctured and entered within an ISO Class 5 PEC • Stored per labeled storage conditions
Pharmacy bulk packages	Per manufacturers labeling	• Punctured and entered within an ISO Class 5 PEC • When manufacturer provides a shorter expiration time after puncture or entry, use the shorter dating and clearly label on packaging
Proprietary bag & vial systems	• Docking and activation for immediate use – is NOT considered compounding (no BUD assignment required) and can be performed in a non-classified area. • Docking for future activation and use – performed in an ISO Class 5 PEC and assigned a BUD that does not exceed the BUD specified in the manufacturer's labeling.	

8.12 CSPs compounded as components for use in other CSPs are initially assigned BUDs per USP <797> (see Section 2.2) and adhere to the following BUDs, use, and storage conditions once entered or punctured for use in a Final CSP; the BUD of the Final CSP is not impacted by the component CSP.

CSPs Compounded as a Component in a Final CSP			
	BUD of Component CSP Once Punctured	BUD of Final CSP Using Component	Use and Storage Conditions of Component
Preserved multi-dose Component CSP	No longer than 28 Days or the Component BUD (whichever is shorter)	Per USP <797> (not impacted by the Component BUD)	• Punctured and entered within an ISO Class 5 PEC • Stored per conditions intended for the initial BUD
Single-Dose & CSP Stock Solutions	≤ 12 Hours or the Component BUD (whichever is shorter)	Per USP <797> (not impacted by the Component BUD)	• Punctured and entered within an ISO Class 5 PEC • Stored per conditions intended for the initial BUD • Remainder is discarded

8.13 Roles & Responsibilities

8.13.1 The Designated Person(s):

8.13.2 Ensures all CSPs compounded at RX COMPOUNDSTORE are assigned the correct and appropriate BUD by careful consideration and research pertaining to component and final CSP stability, sterility of components and sterilization method used (if appropriate), container closure system, and compounding conditions

8.13.3 Ensures Master Formula Records (MFRs) and/or IV Workflow Systems have the correct BUD, CSP storage, and drug stability information and instructions

8.13.4 Ensures Compounding Personnel are educated on how to accurately determine and document BUDs and storage conditions for CSPs and conventionally manufactured and compounded components used in compounding Final CSPs

8.13.5 Ensures individuals (e.g., practitioners, patients, caregivers, other support staff) transporting, storing, or administering mediations understand how to interpret and/or adjust BUDs if conditions warrant

8.14 Compounding Personnel

8.14.1 Determine and properly record the BUD on the immediate product label and affix all appropriate auxiliary labels confirming required storage conditions

8.14.2 Conduct all aseptic manipulations in an ISO 5 and store CSPs and components appropriately

9.0 Procedure

9.1 Category 1 Compounded Sterile Preparations

9.1.1 Determine the appropriate BUD for Category 1 CSPs (refer to Section 2.2 adapted from Table 12 of USP <797>). Category 1 CSPs meet the following criteria:

9.1.1.1 Compounded in a Segregated Compounding Area (SCA)

9.1.1.2 Compounded in a certified ISO Class 5 Primary Engineering Control (PEC)

9.1.1.3 Compounded aseptically by qualified Compounding Personnel

9.1.1.4 Compounded using only sterile starting components

9.1.1.5 Stored in conditions associated with the assigned BUD

9.1.2 At the direction and discretion of the Designated Person(s), assign Category 1 CSP BUDs to preparations made in a sterile compounding suite under the following circumstances including:

9.1.2.1 Assign Category 1 BUDs to all CSPs prepared in a sterile suite when facilities and/or environmental conditions are out-of-specification.

9.1.3 Sterility and endotoxin testing is not required for Category 1 CSPs

9.2 Category 2 Compounded Sterile Preparations

9.2.1 Determine and assign the appropriate BUD for Category 2 CSPs (refer to Section 2.2 adapted from Table 13 of USP <797>). Category 2 CSPs meet the following criteria:

9.2.1.1 Compounded in a cleanroom suite
9.2.1.2 Compounded in an ISO Class 5 PEC located in ISO Class 7 Buffer Room
9.2.1.3 Compounded aseptically by qualified Compounding Personnel
9.2.1.4 Aseptically processed utilizing sterile and/or non-sterile starting components
9.2.1.5 Undergo aseptic or terminal sterilization of the final CSP (if appropriate)

9.2.2 Category 2 CSPs are eligible for longer BUDs (refer to Section 2.2) when USP <71> compliant sterility testing is performed and passed.

9.2.3 Category 2 CSPs assigned longer BUDs and compounded from nonsterile starting ingredients require Bacterial Endotoxin Testing that meets USP <85> requirements to validate endotoxin levels do not surpass established or calculated maximum limits based on route of administration

9.2.4 Refer to the **Sterilization and Depyrogenation** policy for aseptic and terminal sterilization requirements and procedures.

9.2.5 Refer to the **Sterility and Bacterial Endotoxin Testing** policy for related requirements and procedures.

9.3 ***The following section is for informational purposes only. RX COMPOUNDSTORE will not prepare Category 3 CSPs.*** **Category 3 Compounded Sterile Preparations: Maximum BUDs**

9.3.1 Determine and assign the appropriate BUD for Category 3 CSPs. Category 3 CSPs meet the following criteria:

9.3.1.1 All of the requirements for Category 2 BUDs
9.3.1.2 Increased personnel competency, garbing, environmental monitoring, and cleaning requirements per USP <797> at met at all times.

Refer to the **Category 3 CSP** policy for related requirements.

9.3.1.3 Category 3 BUDs are supported by stability data obtained via a stability-indicating analytical method able to distinguish APIs from their degradants and impurities as well as quantify APIs present in each unique formulation and container closure system

9.3.1.4 Prepared according to the exact formulation and procedures from which the stability data is derived

9.3.1.5 Packaged and stored in container closure systems of the same materials of composition as those used in the referenced stability study

9.3.1.6 Stability data collection method(s) used are validated based on characteristics and parameters described in USP <1225> - Validation of Compendial Articles

9.3.2 All Category 3 CSPs undergo sterility testing that meets the requirements of USP <71> or a validated and non-inferior method

9.3.3 Category 3 CSPs require endotoxin testing that meets USP <85> requirements if compounded from one or more non-sterile starting component(s) to validate endotoxin levels do not surpass established or calculated maximum limits based on route of administration

9.3.4 Each Category 3 CSP formulation for injectables undergoes USP <788> compliant particulate matter testing once with acceptable results

9.3.5 Each Category 3 CSP formulation for ophthalmic solutions undergo USP <789> compliant particulate matter testing once with acceptable results

9.3.6 Refer to **Sterilization and Depyrogenation** policy for aseptic and terminal sterilization requirements and procedures.

9.3.7 Refer to policy **Sterility and Bacterial Endotoxin Testing** for endotoxin testing requirements and procedures.

9.4 Preserved Multi-dose CSPs:

9.4.1 If a multi-dose CSP meets the requirements of antimicrobial effectiveness testing per USP <51>, the maximum BUD does not exceed the assigned BUD or 28 days from initial puncture, whichever is shorter.

9.5 Topical Ophthalmic CSPs (and other non-preserved topical CSPs):

9.5.1 Preserved topical ophthalmic CSPs with proven antimicrobial effectiveness testing results per USP <51> are assigned a maximum BUD of 28 days.

9.5.2 Non-preserved topical ophthalmic CSPs are assigned a maximum BUD of 28 days but must carry the following BUD adjustment labeled on the CSP container: "Discard 24 hours after first opening when stored at controlled room temperature or after 72 hours when stored under refrigeration".

9.6 CSPs Compounded as a Component or Stock Solution:

9.6.1 When the CSP component or stock solution is stored according to its originally assigned BUD and only punctured or entered in an ISO 5 PEC for use in a Final CSP:

9.6.1.1 Preserved, multi-dose component CSPs can be used for up to 28 days

9.6.1.2 Single-dose (non-preserved) component CSPs or stock solution can be used for up to 12 hours or the originally assigned BUD, whichever is shorter. Any remaining CSP from the original component or stock solution is discarded.

9.6.2 Final CSPs compounded from multi-dose, single-dose, or stock solution CSPs are assigned BUDs consistent with USP <797> (refer to Section 2.2); the BUD of the component CSP does not affect the determination of the BUD for the Final CSP.

9.7 Epidural, intrathecal and intraventricular CSPs:

9.7.1 Due to the highly sensitive nature and potential life-threatening impacts of medication administered via these routes, CSPs prepared for administration do not exceed the following:

Epidural, intrathecal, or intraventricular CSPs	Controlled Room Temperature [20°C - 25°C]	Refrigerated Temperature [2°C- 8°C]	Frozen Temperature [-25°C - -10°C]
Epidural or Intrathecal	{{*[< 24 hours]*}}	{{*[< 24 hours]*}}	NA
Intraventricular	{{*[< 8 hours]*}}	{{*[< 8 hours]*}}	NA

9.8 Proprietary bag and vial systems:

9.8.1 Docking of proprietary bag and systems for FUTURE activation and administration is considered compounding and is compounded in an ISO Class 5 PEC. BUD assignment does not exceed the BUD stated in the manufacturer's labeling.

9.8.2 Docking and activation of proprietary bag and vial systems for IMMEDIATE administration is not considered sterile compounding and is not assigned a BUD.

9.9 Conventionally Manufactured Products, APIs, and Components used in CSPs

9.9.1 BUDs for entered or punctured commercially manufactured products used to compound a CSP do not exceed the values listed in Section 2.9.

9.9.2 Inspect for damage or visible defects to the packaging or the product prior to use.

9.9.3 Puncture or enter in an ISO Class 5 PEC.

9.9.4 Commercially manufactured products are stored per the labeled instructions. When storage temperature and/or

condition deviations are known or suspected, consult with the Designated Person(s) or the manufacturer's healthcare support line. Discard the product if data validating the safety and stability of the medication under the excursion conditions cannot be attained.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

11.1 Original. Brenda Poland. 04-01-2023

11.2 Reviewed. Amelia Yeh. 03-29-2024

11.3 Reviewed. Amelia Yeh. 04-01-2025

4TT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: [redacted] ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: St. Luke Compounding Pharmacy

Physical Address: 9338 Little Rd.

City: New Port Richey State: FL Zip: 34654

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 727-416-2006 Toll Free # (NAC 639.708, NRS 639.23286): 877-310-5668

Fax: 727-416-2007 Contact Email: admin@stlukecompounding.com

Website: www.stlukecompounding.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Andrew Mesiha

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24829

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Andrew Mesiha	NV Pharmacist Registration #: 24829
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): St. Luke Lab LLC

Corporation/Organization Name: St. Luke Compounding Pharmacy

Mailing Address: 9338 Little Rd.

City: New Port Richey State: FL Zip: 34654

Telephone: 727-416-2006 Email: admin@stlukecompounding.com

Contact Person Name: Andrew Mesiha

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for St. Luke Compounding Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Andrew Mesiha

Print Name of Authorized Person

Andrew Mesiha

Original signature of Authorized Person (copies or stamps not accepted)

12/10/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Mesiha

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Andrew Mesiha

Original signature of Authorized Person (copies or stamps not accepted)

12/10/2025

Date

Board Use Only	Date Received: 12/15/25	Amount: $500-cc

DC HEALTH | PHARMACEUTICAL CONTROL DIVISION

2201 SHANNON PLACE SE
WASHINGTON, DC 20020

Please see the list below of corporate officers for St. Luke Lab, LLC dba St. Luke Compounding Pharmacy.

Name	Title	DOB	Mailing Adress	Telephone
Andrew Mesiha	CEO/PIC	[redacted]		
Shady John	CFO			
Emad Goun	Vice President			
Michael Shaker	President			

Please see the list below of stockholders for St. Luke Lab, LLC dba St. Luke Compounding Pharmacy.

Name	Title	% of Ownership	DOB	Mailing Adress	Telephone
Andrew Mesiha	CEO/PIC	25	[redacted]		
Shady John	CFO	25			
Emad Goun	Vice President	25			
Michael Shaker	President	25			

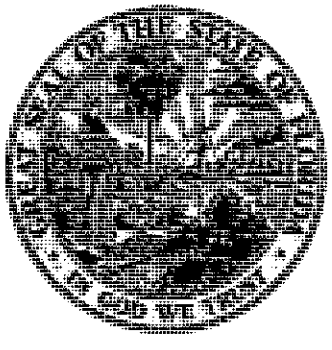
State of Florida
Department of State

I certify from the records of this office that ST.LUKE LAB, LLC is a limited liability company organized under the laws of the State of Florida, filed on November 8, 2019, effective November 11, 2019.

The document number of this limited liability company is L19000279144.

I further certify that said limited liability company has paid all fees due this office through December 31, 2025, that its most recent annual report was filed on March 15, 2025, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Ninth day of September, 2025



Secretary of State

Tracking Number: 4695660316CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunhiz.org/Filings/CertificateOfStatus/CertificateAuthentication

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler St Luke Compounding Pharmacy

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 9338 Little Rd.

City New Port Richey State FL Zip 34654

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 727-416-2006 Website www.stlukecompounding.com

Licensing Company Email Admin@stlukecompounding.com

Section 2: Personal Information

First Andrew Middle _____ Last Mesiha

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Azab High School			2003-2006	
Address		City	State	Zip
Egypt				
Diploma/Degree obtained, if any				
General Curriculum				
School Name			From - To (MM/YY – MM/YY)	
Tanta University School of Pharmacy			2006-2011	
Address		City	State	Zip
Egypt				
Diploma/Degree obtained, if any				
Bachelor of Pharmaceutical Science				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
01/2018-Current				
From - To (MM/YY – MM/YY)				
02/2015-01/2018				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
St. Luke Compounding Pharmacy			09/2023-Current	
Business Address		**City**	**State**	**Zip**
9338 Little Rd.		New Port Richey	FL	34654
Phone	**Title**		**Number of Employed Hours**	
727-416-2006	CEO/PIC		4680	
Description of Duties				
Responsible for ensuring the pharmacy's compliance with state and federal pharmacy laws and regulations, overseeing pharmacy operations and staff, maintaining required records, ensuring proper handling of RX drugs and Controlled Subs				

Business Name			From - To (MM/YY – MM/YY)	
Trust Pharmacy			01/2021-09/2023	
Business Address		**City**	**State**	**Zip**
36515 US Highway 19 N		Palm Harbor	FL	34654
Phone	**Title**		**Number of Employed Hours**	
	Pharmacist		5547	
Description of Duties				
Reviewed and dispensed prescriptions, performed drug utilization review, provided patient counseling, maintained records, ensured proper handling of prescription drugs and controlled substances, and complied w/ state and federal regs				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Andrew Mesiha, **certify that as the designated representative for**

St. Luke Compounding Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. A.M. I am at least 21 years of age;
3. A.M. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. A.M. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. A.M. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. A.M. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. A.M. I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Andrew Mesiha

Print Name (First, Last)

Andrew Mesiha

Original Signature (electronic, copies or stamps not accepted)

12/20/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Mesiha
Print Name (First, Last)

Andrew Mesiha
Original Signature (electronic, copies or stamps not accepted)

12/20/2025
Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pasco

I, Andrew Mesiha, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Andrew Mesiha
Original Signature

12/20/2025
Date

Subscribed and Sworn to before me this 20 day of December, 2025.

Notary Public Signature

MICHAEL CHAMBERS
Notary Public - State of Florida
Commission # HH 697300
My Comm. Expires Jul 11, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site St. Luke Compounding Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 9338 Little Rd.

City New Port Richey State FL Zip 34654

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 727-416-2006 Website www.stlukecompounding.com

Licensing Company Email admin@stlukecompounding.com

Section 2: Personal Information

First Andrew Middle _____ Last Mesiha

Alias(es, nicknames, name changes, etc.) [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Tanta university school of pharmacy		09/06 - 05/11	
Address	**City**	**State**	**Zip**
EL Geish street	Tanta - EGypt		
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
EL SALAM High school		09/03 - 05/06	
Address	**City**	**State**	**Zip**
EL Geish street	Tanta - Egypt		
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/18 - Current	[redacted]			
12/15 - 04/18				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
St. Luke Compounding pharmacy	09/24 - Current

Business Address	City	State	Zip
9338 Little Rd	New Port Richey	FL	34654

Phone	Title
727-416-2006	PIC

Description of Duties: pharmacist in charge

Business Name	From - To (MM/YY – MM/YY)
Trust pharmacy LTC	01/19 - 09/24

Business Address	City	State	Zip
36515 US 19	Palm Harbor	Fl	34684

Phone	Title
727-781-7400	pharmacist

Description of Duties: Verify prescriptions

Business Name	From - To (MM/YY – MM/YY)
Walgreens homosassa	04/18 - 01/19

Business Address	City	State	Zip
9427 S Suncoast Blvd	Homosassa	FL	34446

Phone	Title
352-382-0520	

Description of Duties:

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties:

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties:

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Mesiha

Print Name (First, Last)

Andrew Mesiha

Original Signature (electronic, copies or stamps not accepted)

12/10/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pasco

I, Andrew Mesiha, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Andrew Mesiha

Original Signature

12/10/2025

Date

Subscribed and Sworn to before me this 10 day of December.

Courtney

Notary Public Signature

COURTNEY VALENTAS
Notary Public - State of Florida
Commission # HH 615168
My Comm. Expires Nov 20, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site St. Luke Compounding Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 9338 Little Rd.

City New Port Richey State FL Zip 34654

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 727-416-2006 Website www.stlukecompounding.com

Licensing Company Email admin@stlukecompounding.com

Section 2: Personal Information

First Shady Middle _____ Last John

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pharmacy School Cairo University, Egypt		9/1999 – 6/2006	
Address	City	State	Zip
Diploma/Degree obtained, if any			
Bachelor Degree			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
3/2013 – 10/2025	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Trust Pharmacy 2 LLC			From - To (MM/YY – MM/YY): 10-2018 — Current	
Business Address: 9340 Little RD	City: New Port Richey	State: FL	Zip: 34654	
Phone: 727-233-6400	Title: owner			
Description of Duties: RPH / Manager				

Business Name: ST Philo LLC			From - To (MM/YY – MM/YY): 1-2019 / Current	
Business Address: 4127 Mariner BLVD	City: Spring Hills	State: FL	Zip: 34609	
Phone: 352-556-2509	Title: owner			
Description of Duties:				

Business Name: ST Luck Compounding LLC			From - To (MM/YY – MM/YY): 1-2021 – Current	
Business Address: 9338 Little RD	City: New Port Richey	State: FL	Zip: 34654	
Phone: 727-416-2006	Title: owner			
Description of Duties:				

Business Name: Trust Pharmacy			From - To (MM/YY – MM/YY): 1-2013 # 10-2018	
Business Address: 36515 US 19 Hwy	City: Palm Harbor	State: FL	Zip: 34684	
Phone: 727-781-9400	Title: RPH			
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:	State:	Zip:	
Phone:	Title:			
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shady John

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10-29-2025

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pasco

I, Shady John, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10-29-2025

Date

Subscribed and Sworn to before me this 29 day of October 2025

Notary Public Signature

COURTNEY VALENTAS
Notary Public - State of Florida
Commission # HH 615168
My Comm. Expires Nov 20, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: St. Luke Compounding Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 9338 Little Rd.

City: New Port Richey State: FL Zip: 34654

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 727-416-2006 Website: www.stlukecompounding.com

Licensing Company Email: admin@stlukecompounding.com

Section 2: Personal Information

First: Emad Middle: _____ Last: Goun

Alias(es, nicknames, name changes, etc.): _____

[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Helwan university			10-97 // 10-2003	
Address: 1034 Helwan ST	City: Helwan		State: EGYPT	Zip:
Diploma/Degree obtained, if any: Bachelor				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2012 Now	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Trust Pharmacy			From - To (MM/YY – MM/YY): 2/2015 – Now
Business Address: 4127 Mariner BLVD	City: Spring Hills	State: FL	Zip: 34609
Phone: 352-556-2509	Title: owner / Manager		
Description of Duties: owner/ Manager			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Emad Goun

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-5-25

Date

Please have this section completed in the presence of a Notary Public.

State of FLORIDA, ss. County of PASCO

I, EMAD Goun, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11-5-25

Date

Subscribed and Sworn to before me this 5 day of NOV. 2025

Notary Public Signature

NICOLE L. BOWERS
Notary Public, State of Florida
Commission# HH 420356
My comm. expires July 11, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site St. Luke Compounding Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 9338 Little Rd.

City New Port Richey State FL Zip 34654

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 727-416-2006 Website www.stlukecompounding.com

Licensing Company Email admin@stlukecompounding.com

Section 2: Personal Information

First Michael Middle _____ Last Shaker

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Cairo University		9-1998 – 10/2005	
Address	City	State	Zip
125 Cairo ST	Cairo	Egypt	
Diploma/Degree obtained, if any			
Bachelor Degree			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
11-2014 – Now				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Trust pharmacy			10/2010 – Now	
Business Address		**City**	**State**	**Zip**
38515 US 19 Hwy		palm Harbor	FL	34684
Phone	**Title**			
727-781-6400	owner/ RPH			
Description of Duties				
owner/ Manager				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Shaker

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/31/25

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pinellas

I, Michael Shaker, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/31/25

Date

Subscribed and Sworn to before me this 31 day of October 2025

R. Heyner

Notary Public Signature

ROBIN HEYNER
Notary Public - State of Florida
Commission # HH 221818
My Comm. Expires Jan 30, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: St. Luke Compounding Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): PH32747

Physical Address: 9338 Little rd

City: New Port Richey State: Fl Zip: 34654

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 727-416-2006 Toll Free # (NAC 639.708, NRS 639.23286): 877-310-5668

Fax: 727-416-2007 Contact Email: admin@stlukecompounding.com

Website: www.stlukecompounding.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Andrew Mesiha

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24289

Name of Designated Person(s) as defined by revised USP-797 guidelines: Andrew Mesiha

Email of Designated Person(s): admin@stlukecompounding.com

Telephone of Designated Person(s): 727-416-2006

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 07/03/2025 and 09/16/2025 for BSC

6. What is the frequency of the recertification for the ISO classified areas? every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? monthly

10. Will you be performing sterile hazardous drug compounding? ■ Yes No

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Sermorelin 3 mg/mL Injection Solution Preserved (5 mL)
Methylcobalamin 5000 mcg/mL Sterile Solution for Injection
Nicotinamide Adenine Dinucleotide (NAD+) 200mg/mL Sterile Injectable Solution (Preserved)
LIPO C (Methionine 25mg - Inositol 100mg - Choline Chloride 50mg - L-carnitine 50 mg - Cyanocobalamin 1mg /mL Sterile Solution for Injection
TIRZEPATIDE/NIACINAMIDE 20MG/2MG/ML INJECTION SOLUTION
SEMAGLUTIDE/PYRIDOXINE 5MG/10MG/ML (2ML) INJECTABLE SOLUTION
SEMAGLUTIDE/PRYRIDOXINE 2.5MG/10MG/ML (2ML) INJECTABLE SOLUTION
Ascorbic Acid 550mg/mL Sterile Solution for Injection
Methionine (L) 15mg - Choline Chloride 50mg - Carnitine(L) 50mg - Dexpanthenol 5mg /mL Sterile Solution for Injection
TESTOSTERONE CYPIONATE INJECTABLE SOLUTION 200MG/ML (SESAME OIL) (5ML)
Glutathione 200 mg/mL Injection (Solution) 30 ml
Prednisolone Phosphate 1% - Moxifloxacin 0.5% - Bromfenac 0.09% Ophthalmic Solution

12. What laboratory performs your sterility or endotoxin testing?

Name: Pharmetric Laboratory

Address: 7265 Ulmerton Rd.

City: Largo State: Fl Zip: 33716

Telephone: 727-209-5778

13. What is your procedure for visual inspection of compounded sterile products?

1. Container IntegrityInspect vials/syringes for cracks, chips, leaks, or closure defects.Confirm proper seal and absence of residue.2. Solution InspectionUnder appropriate lighting and both white and black backgrounds, verify:No visible particulate matterNo cloudiness, precipitation, crystallization, discoloration, or phase separationAny abnormality results in product quarantine and investigation.3. Label VerificationConfirm correct drug, strength, volume, BUD, lot number, and storage instructions.Compare label to the prescription and formulation record.4. DocumentationInspection findings are recorded on the batch record with date and inspector initials.Product cannot be released until all criteria are met.

14. How often do you perform glove fingertip and medial fill testing?

every 6 month

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Initial and Ongoing Training Program for Sterile Compounding Personnel Completion of didactic training on USP <797>, aseptic technique, contamination control, and facility SOPs Hands-on training in garbing, gowning, hand hygiene, cleaning, and aseptic manipulations Successful completion of media-fill testing and gloved fingertip/thumb sampling prior to independent compounding Demonstration of competency in equipment use, environmental monitoring, labeling, documentation, and workflow procedures Annual (or more frequent) requalification, including media fills, gloved fingertip testing, and observational competency assessments Ongoing training when new equipment, procedures, or formulations are introduced Continuous performance monitoring with corrective action and retraining if deviations are observed

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

ISO 5 areas (LAFWs/BSCs) require the most frequent disinfection with sterile 70% IPA:Beginning of each shift Before each batch At least every 30 minutes during continuous compounding Before critical manipulations After spills (post-decontamination)When contamination is suspected Policy covers ISO 7 buffer rooms, ISO 7/8 anterooms, SCAs, and PECs. Applies to non-hazardous and hazardous compounding (HD procedures require additional steps per HD SOP).Leadership selects cleaning agents based on compatibility, effectiveness, and residue safety.Daily and monthly cleaning uses EPA-registered, sterile bactericidal/sporicidal one-step agents for PECs and room surfaces.A fungicidal agent is used weekly; additional rotation is not required due to low cleanroom bioburden.Sterile water is used to dilute disinfectants for ISO 5 use (if applicable) to avoid bioburden introduction.General preparation areas, though not ISO-classed, are included in the cleaning schedule.Daily cleaning occurs at day's end to prevent overnight microbial growth; no cleaning is performed during compounding. Monthly cleaning occurs in the 4th week of each month, following a top-to-bottom sequence; may extend over several days as long as daily cleaning continues. Only trained personnel may perform cleaning; required competencies:Hand hygiene/garbing + three successful gloved fingertip tests Cleaning & disinfecting competency assessment Cleaning agents:EPA-registered surfactant-containing agents onlyPeridox RTU® (sterile) used for daily and monthly cleaning and material handling HD decontamination uses Peridox RTUS

17. Who performs the sterile compounding process at your facility?

Sahar Mikhail - Sterile Pharmacy Technician

18. Who is responsible and accountable for the sterile compounding process at your facility?

Andrew Mesiha

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

All compounded sterile and temperature-sensitive products are shipped using validated cold-chain packaging to maintain required temperatures throughout transit with indicators. Refrigerated items (2–8°C) are shipped with gel packs/ice bricks and insulated containers to ensure stability until delivery. Ambient-stable products are shipped in protective packaging.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding:)

1. What type of primary engineering controls will you be using in your facility?
biological safety cabinet class AII

2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	■ Yes	No

9. If yes, list the name of the device:
USP <800>-compliant Closed System Transfer Device (e.g., BD® PhaSeal™, Equashield®, or Tevadaptor®)

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?
Information Provided to Patients on Handling and Disposal of Hazardous Drug Products Written counseling materials instruct patients to handle hazardous drugs with care, avoiding direct skin or mucosal contact. Patients are advised to wash hands before and after handling the medication or containers. Guidance is provided on using protective gloves (if appropriate) when handling the drug, especially if tablets/capsules are not unit-dose sealed. Instructions emphasize not to crush, open, or split hazardous drug capsules or tablets. Patients are advised to store the medication securely, away from children, pets, food, and household items. Disposal instructions direct patients to return unused medication and contaminated supplies to a pharmacy, medical facility, or take-back program—never to place them in household trash or wastewater. Patients are instructed to place contaminated materials (e.g., gloves, wipes) in a sealed plastic bag until proper disposal. Contact information for the pharmacy is provided for questions about safe handling or disposal.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Initial Training Process for Employees Prior to Compounding Sterile Hazardous Drugs Completion of didactic training on USP <797> and USP <800>, hazardous drug risks, PPE use, and contamination prevention. Instruction on facility SOPs covering HD handling, storage, engineering controls, cleaning, and spill management. Demonstration and supervised practice of proper garbing, hand hygiene, and use of CSTDs. Hands-on training in negative-pressure PEC workflow and safe aseptic technique specific to HDs. Successful completion of gloved fingertip testing and media fill testing before performing any independent HD compounding. Assessment of competency in decontamination, waste disposal, labeling, and documentation requirements. New employees must complete all training and competency evaluations before being permitted to handle or compound hazardous drugs.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?		
6. What is the frequency for using sporicidal agents?		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Mesiha

Name of Person who Completed the Form

CEO

Title

Andrew Mesiha

Signature (copies or stamps not accepted)

12/10/2025

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

www.FloridaHealth.gov

File # 26858
Insp # 199614

NAME	PERMIT NUMBER	DATE OF INSPECTION
st luke lab	32747	07/22/2025
DOING BUSINESS AS		
ST LUKE COMPOUNDING PHARMACY		
STREET ADDRESS	**TELEPHONE #**	**EXT**
9336 Little Rd	727-437-9538	
CITY	**COUNTY**	**STATE/ZIP**
NEW PORT RICHEY	PASCO	FL/34654

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 9am - 5pm
Monday Y	Monday Hours 9am - 5pm
Tuesday Y	Tuesday Hours 9am - 5pm
Wednesday Y	Wednesday Hours 9am - 5pm
Thursday Y	Thursday Hours 9am - 5pm
Friday Y	Friday Hours 9am - 5pm
Saturday N	Sunday N
Saturday Hours CLOSED	Sunday Hours CLOSED

Registered Pharmacist / Intern / Tech

License # PS51531	Licensee Name Shady John
License Type Registered Pharmacists	
License # PS59672	Licensee Name Andrew Mesiha
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # [redacted]	

License Relations

Pharmacy Affiliate

GOUN, EMAD MAHROUS	License # 40648
JOHN, SHADY MAHROUS	License # 51531
MESIHA, ANDREW EMIL MAKRAM HANNA	License # 59672
SHAKER, MICHAEL M	License # 44495

RX DPT MGR/COR/POR

MESIHA, ANDREW EMIL MAKRAM HANNA	License # 59672

Special Sterile Compounding

ST. LUKE LAB LLC	License # 35628

INV 359 - Community Requirements

Signage Requirements Section

INV359 - Community Requirements

Insp # 199614 st luke lab File # 26858

Signage stating the hours the pharmacy department is open. [64B16-28.1081(2), F.A.C.]	Yes
"Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109, F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] [64B16-28.1035, F.A.C.]	Yes

Community Requirements General Section

Outdated medications removed from active stock. [64B16-28.110, F.A.C.] [64B16-28.1191, F.A.C.]	Yes
Prescription Department is open for a minimum of 20 hours per week. [64B16-28.1081(1), F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c), F.S.] [21CFR1306.05]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d), F.A.C.]	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102(5)(a), F.A.C.]	Yes
Technicians properly identified. [64B16-27.100(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.410, F.A.C.] [64B16-27.420, F.A.C.]	Yes
Legend drugs properly stored within confines of pharmacy department and maintained at appropriate temperature to preserve therapeutic activity. [64B16-28.118, F.A.C.]; [64B16-28.120, F.A.C.]; [64B16-28.102, F.A.C.]	Yes
Documentation of destruction or return of controlled substances. [64B16-28.303, F.A.C.] *EcoPharm*	Yes
Generic equivalent sign is posted. [465.025(7), F.S.]	Yes

Additional Community Requirements

Prescription department is operating under clean, sanitary, and uncrowded health conditions. [64B16-28.102, F.A.C.]	Yes
Prescription department has a sink with running water easily accessible to the prescription counter. [64B16-28.102, F.A.C.]	Yes
Pharmacist is on the premises and on duty when the prescription department is open. [64B16-28.109, F.A.C.]	Yes
Pharmacy maintains a written policy and procedure manual regarding the number of registered pharmacy technician positions and the pharmacy operates within the established ratio as defined by rule. [64B16-27.410(2)(a), F.A.C.]	Yes
Pharmacists, technicians, and interns are licensed in the State of Florida. [465.015(1)(a), F.S.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication is properly labeled for dispensing to patient. [64B16-28.108, F.A.C.]	Yes
Unclaimed prescriptions are maintained in stock for no more than one year past dispensing date. [64B16-28.1191, F.A.C.] *Compounding facility (No return to stock)*	N/A
Manufacturer containers are properly labeled. [499.003(26), F.S.]	Yes
Customized medication packages are labeled properly with beyond use date of not more than 120 days from the date of preparation but not later than the beyond use date for any of the medications in the package. [64B16-28.108(6)9., F.A.C.]	N/A
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality-Related Events are available for inspection. [64B16-27.300, F.A.C.] [766.101(1)(a)(l), F.S.] *December 11th, 2024, March 25th, 2025 Reviewed.*	Yes
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.] *Pharmetika*	Yes
Compounding records include compounding date, lot number, expiration date, name and manufacturer of ingredients, package size, number of units, technician compounding and pharmacist verifying the final compound. [64B16-28.140(4), F.A.C.]	Yes
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005, F.S.] [61N-1.012, F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005(14), F.S.] *AmerisourceBergen*	Yes
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility. [64B16-27.700(3)(g), F.A.C.]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek follow-up care from his or her primary care physician. [465.1895(9), F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S.]	Yes

Requirements for Dispensing Controlled Substances

Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] *March 4th, 2025 Close of Business*	Yes
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2), F.S.] [21CFR 1305.13(e)] [21CFR1305.22(g)]	Yes
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [465.022(12)(a), F.S.] [64B16-28.140, F.A.C.] [21CFR1306.22] [21CFR1304.04]	N/A
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b), F.S.] [465.022(11)(b), F.A.C.]	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4)(3)(a), F.S.]	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

INV359 - Community Requirements

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Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	
Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Pharmacy engages in Centralized Prescription Filling [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197(3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

HIV Infection Prevention Drugs

Pharmacists are screening, ordering or dispensing HIV postexposure prophylaxis drugs under a written Collaborative Practice Agreement. [465.1861, F.S.]	
An access-to-care plan has been submitted to the board office and is in place to assist patients in gaining access to appropriate care settings when they present to a pharmacist for HIV screening and indicate that they lack regular access to primary care. [465.1861, F.S.]	

Remarks:

Routine inspection completed with Shady John. Operating requirements met.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

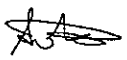
HODGES, PETER



Date:7/22/2025

Representative:

Andrew Mesiha



Date:7/22/2025

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797 USP Sterile Compounding

www.FloridaHealth.gov

File # 30333
Insp # 203292

NAME	PERMIT NUMBER	DATE OF INSPECTION
St. Luke Lab LLC		03/05/2025
DOING BUSINESS AS		
ST. LUKE COMPOUNDING PHARMACY		
STREET ADDRESS	**TELEPHONE #**	**EXT**
9338 Little Road	727-416-2006	
CITY	**COUNTY**	**STATE/ZIP**
NEW PORT RICHEY	PASCO	FL/34654

Additional Information

Business Operation Hours

M-T-W-TH-F N	Monday Y
Monday Hours 9:00 am to 5:00 pm	Tuesday Y
Tuesday Hours 9:00 am to 5:00 pm	Wednesday Y
Wednesday Hours 9:00 am to 5:00 pm	Thursday Y
Thursday Hours 9:00 am to 5:00 pm	Friday Y
Friday Hours 9:00 am to 5:00 pm	Saturday N
Saturday Hours Closed	Sunday N
Sunday Hours Closed	

Registered Pharmacist / Intern / Tech

License # PS59672	Licensee Name Andrew Mesiha
License Type Registered Pharmacists	
License # RPT98211	Licensee Name Sahar Mikhail
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # [redacted]	

License Relations

Pharmacy Affiliate

GOUN, EMAD	License #
JOHN, SHADY MAHROUS	License # 51531
MESIHA, ANDREW EMIL MAKRAM HANNA	License # 59672
SHAKER, MICHAEL M	License #

RX DPT MGR/COR/POR

MESIHA, ANDREW EMIL MAKRAM HANNA	License # 59672

Special Sterile Compounding

ST LUKE LAB	License # 32747

DESIGNATED PERSON: A designated person(s) is identified who is responsible and accountable for the performance and operation of the facility and personnel involved in the preparation of CSPs. [USP 797 Section 1.1.3] *Designated Person: Andrew Mesiha- has training in Critical Point around June to Nov 2024, and Medisca LP3 class*	Yes
IMMEDIATE USE COMPOUNDING: When preparing immediate use preparations, written SOPs are in place for all requirements and all criteria are met including 1. aseptic technique, processes, and procedures; and, 2. personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and SOP's, 3. the preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs, 4. the preparation involves not more than 3 different sterile products, 5. Any unused starting component from a single-dose container is discarded, 6. Administration begins within 4 hours following the start of preparation and, 7. Unless directly administered by the preparer or administration is witnessed by the preparer, the CSP is labeled with the names and amounts of all active ingredients, the name or initials of the preparer and the 4 hour period within which administration must begin. [USP 797 Section 1.3] *Cleanroom Suite, hazardous and non-hazardous and non-sterile compounding suite*	N/A
BAG & VIAL SYSTEM: Docking of vial and bag systems for future activation and administration is performed in an ISO 5 environment and BUDs are not longer than those specified in the manufacturer's labeling. [USP 797 Section 1.4]	N/A
REPACKAGING: Repackaging of sterile products or preparations from its original container into another container are prepared according to all applicable USP 797 requirements. [USP 797 Section 1.1.2]	N/A

B. COMPONENT BUDs (Single and Multi-dose Containers) – ALL CATEGORIES

SINGLE DOSE CONTAINERS (SDCs): SDCs are entered or punctured only in an ISO Class 5 or cleaner air and are used up to 12 hours after initial entry or puncture if the labeled storage requirements during that 12-hour period are maintained. [USP 797 Section 15.1] *Not currently compounding, will be per Policy 6.1 'Beyond Use Date'*	N/A
AMPULES: Opened SINGLE DOSE AMPULES are used immediately and not stored for any time period. [USP 797 Section 15.1]	Yes
MULTIDOSE CONTAINERS (MDCs): Upon initially entering or puncturing a conventionally manufactured MDC, the MDC is not used for more than 28 days unless otherwise specified by the manufacturer on the labeling. [USP 797 Section 15.2] *Not currently compounding- Example will be with Glutathione Inj*	N/A
PHARMACY BULK PACKAGES: Conventionally manufactured pharmacy bulk packages are entered or punctured only in an ISO Class 5 PEC and must be used according to the manufacturer's labeling. [USP 797 Section 15.3] *Facility has Policy 6.1 'Beyond Use Date' per manufacturers labels*	Yes
SINGLE DOSE COMPONENT CSPs & STOCK SOLUTIONS: When single-dose CSPs or CSP stock solutions are used as a component to compound additional CSPs, the original compounded single-dose component CSP or CSP stock solution is entered or punctured in ISO Class 5 or cleaner air and is stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). Once punctured, the component CSP is used for sterile compounding for up to 12 hours or its assigned BUD, whichever is shorter, and any remainder is discarded. [USP 797 Section 16.2] *Policy 6.1 'Beyond Use Date' Section 7*	N/A

C. CSP LABELING – ALL CATEGORIES

CSP LABEL REQUIREMENTS: CSP Immediate container label prominently and legibly displays 1) assigned internal identification number; 2) active ingredient(s) and their amount(s), or concentration(s); 3) storage conditions if other than controlled room temperature; 4) BUD; 5) dosage form; 6) total amount or volume; 7) statement if CSP is a single dose container (when space permits) or multi-dose container. Labeling of CSP displays 1) route of administration, 2) special handling instructions, 3) warning statements, and the compounding facility name and contact information if the CSP is sent outside of the facility in which it was compounded. [USP 797 Section 13] *Please add dosage form on label-example solution, Label does not state 'Discard 28 days after first use' of if vial is a multi-dose container.*	No
ADDITIONAL REQUIREMENTS FOR A CLASS II OR III FACILITY: 1) Identification of responsible compounding personnel and/or dispensing pharmacist;2) labels for batch-prepared CSPs must also include: Control or lot number, auxiliary labeling (including precautions); and device-specific instructions. Patient specific medications must also include patient's name, location the medication is to be delivered to and directions for use. [USP 797 Section 13] [F.A.C.64B16-28.108(10)] *Facility is a retail establishment*	N/A
LABELING SOP: SOPs describe labeling procedures and are followed to prevent labeling errors and CSP mix-ups. [USP 797 Section 13] *SOP 6.12 requires the dosage form to be stated on sample label of Glutathione inj. Sodium Bicarbonate 8.4% inj does state solution on label. Please be consistent. Per SOP 6.12 'Labeling of CSP', dosage form is required.* *Per USP <797>, 2023 version, "The label on each immediate container of the CSP must, at a minimum, display prominently and legibly the following information: Assigned internal identification number (e.g., barcode, prescription, order, or lot number)* *Active ingredient(s) and their amount(s), activity(ies), or concentration(s)* *Storage conditions if other than controlled room temperature BUD* *Dosage form"*	No
LABEL VERIFICATION: CSP labels are verified to ensure that they conform with the prescription or medication order, MFR (if required), and the CR. [USP 797 Section 13] *Has not actively compounded or dispensed at this time.* *Will be in Si software from Pharmetric*	N/A

D. PERSONNEL PREPARATION & OBSERVATION – ALL CATEGORIES

UNNECESSARY ITEMS: Personnel remove outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests); cosmetics, and all hand, wrist, and other exposed jewelry, including piercings that may interfere with effectiveness of garbing. Items not necessary for compounding (e.g., food, drinks, mints, gum, earbuds, headphones) are not introduced into the compounding environment. Accommodations are documented. [USP 797 Section 3.1]	Yes
NAILS: Nails are clean and trimmed. Nail products (e.g., polish, artificial nails, and extenders) are not worn. Personnel clean under nails under warm running water with a disposable nail cleaner. Hands and forearms are washed with soap and water for at least 30 seconds prior to entering a compounding area. [USP 797 Section 3.2]	Yes
REQUIRED PPE GARBING ORDER & STORAGE: Personnel garb (don and doff) in an order that reduces risk of contamination per SOP. Required garb, manner of storage, and order or garbing is documented in SOP's. The minimum required PPE when preparing CSPs includes a garment with sleeves that fit around wrists and enclosed neck, shoe covers, head/facial hair cover, face mask, and sterile powder-free gloves. All PPE is low lint for Category 1 & 2 compounding or sterile if Category 3. Gowns and other garb are stored in a manner that minimizes contamination (e.g., away from sinks) and within a classified area or SCA. [USP 797 Section 3.3] *Gerbing was done using 3XL Coverall-incorrect size and RPt needs to be re-educated on proper donning so as to avoid touching the wrist part of the sleeves.*	No
INAPPROPRIATE HAND HYGIENE PRACTICES: Brushes and hand dryers are not used, and soap containers are not refilled or topped off. [USP 797 Section 3.2] *RPt observed proceeded to perform hand hygiene using brush bristles on hands.*	No
ALCOHOL-BASED HAND RUB: Hands are sanitized with alcohol-based hand rub prior to donning gloves. Handrub is used prior to donning garb when hand hygiene is done outside of a classified area. [USP 797 Section 3.3] *Hands free Avagard*	Yes

STERILE GLOVES USED: Sterile gloves are donned in classified room or SCA. Skin is not exposed inside ISO 5 PEC (e.g., gloves are not donned or doffed). [USP 797 Section 3.3] *Contec Critigear ASTM 6978 sterile gloves*	Yes
SANITIZATION OF STERILE GLOVES: Sterile 70% IPA is applied to gloves prior to compounding and regularly throughout the compounding process. [USP 797 Section 3.3]	Yes
SANITIZATION OF ITEMS INTRODUCED INTO PEC: Items are wiped with sterile 70% IPA and sterile low-lint wipers just prior to being introduced into the PEC and allowed to dry before use. [USP 797 Section 8.2]	Yes
CRITICAL SITES (e.g., vial stoppers, ampule necks, and intravenous bag septum's) are wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA is allowed to dry before personnel enter or puncture stoppers and septum's or break the necks of ampules. [USP 797 Section 8.3] *Pharmacist Choice gamma sterilized alcohol wipes*	Yes
MATERIALS AND EQUIPMENT DISINFECTION: Before any item is introduced into the clean side of anteroom(s), placed into pass-through chamber(s), or brought into the SCA, it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. Dwell time is followed. [USP 797 Section 8.1 & 9.1] *As observed when passing goggles into cleanroom*	Yes

E. EQUIPMENT, SUPPLIES, & COMPONENTS – ALL CATEGORIES

DAILY ACD ACCURACY ASSESSMENT: An accuracy assessment is conducted for Automated Compounding Devices (ACDs) or similar equipment before the first use and again each day the equipment is used to compound CSPs. A daily record of accuracy measurements is maintained. Corrective actions are implemented if accuracy measurements are outside of manufacturer's specifications. [USP 797 Section 9.1] *2 Baxter Repeater pumps dedicated to each compounding environment per SOP 6.9 'Operation, Cleaning, and Maintenance of Baxter Repeater Pump'. Documentation will be maintained in 797 tools software.*	Yes
EQUIPMENT SOPs: Written SOPs for the calibration, maintenance, cleaning, and use of equipment are established and are based on the manufacturer's recommendations. Procedures are followed and records are maintained. [USP 797 Section 9.1] *Per SOP* *FL Biomedical Associates Repair calibrated the following equipment on Oct 24, 2024:* *Yamato Dry Heat Oven Model DKN602C SN BG300052* *Tuttnauer Autoclave- Model: 2540EA SN* *3 Incubators SN 0201-1616, SN L-16933, SN L-16932* *Insignia Fridge SN 24F06C00241* *Armens calibrated the 3 Ohaus Weighing scales SN AX223/E and Greystone EM monitoring Device SN CR3C (total of 6 monitoring devices in 6 cleanrooms) March 1, 2025* *2 Repeater pumps calibrated by Plexus Oct 23, 2024* *Medrep certified cleanroom suite, PEC's SEC's Jan 2025* *In-house Viable air sampling device Qualisair MicroBio SN 30152581591 last calibrated Oct 28, 2024* *Guardian 5000 hot plate stirrer purchased calibrated from Medisca 9-16-24* *PH meter came calibrated 2-13-25* *Autoclave SN 215754 validated with 11 Attest BI's and a positive control by Pharmetric 3-3-25* *Dry Heat Oven Depryogenation Validation Report from Pharmetric using Endosafe PTS Cartridges demonstrated a 5.3 log reduction in endotoxins per 3-3-25 report*	Yes

F. SEGREGATED COMPOUNDING AREA: Category 1

CATEGORY 1 MAXIMUM BUDs & COMPOUNDING AREA REQUIREMENTS: Category 1 CSPs are compounded in an ISO class 5 PEC located within a SCA and are assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less when refrigerated. [USP 797 Section 1.5, 4.2.1]	
DEDICATED AREA FOR SCA: The SCA is separated from areas not directly related to compounding, and all surfaces (walls, floors, counters, and equipment) are clean, uncluttered, and dedicated to compounding. [USP 797 Section 4.2.1]	
SCA LOCATION: The SCA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC. SCA is not located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality of the PEC within the SCA. A sink is not located within 1 meter of PEC. [USP 797 Section 4.2.1]	
ITEMS WITHIN SCA: Only furniture, equipment, and other materials necessary for performing compounding activities are located within the SCA. [USP 797 Section 4.2.1]	

G. FACILITIES & SECONDARY ENGINEERING CONTROLS – Categories 2 and 3

STERILE SUITE CONSTRUCTION: The ISO-classified anteroom and buffer room are separated from the surrounding unclassified areas of the facility by fixed walls and doors, and controls are in place. [USP 797 Section 4.2.1]	Yes
HEPA FILTERED AIR: Air supplied to the cleanroom suite is introduced through HEPA filters located in the ceiling of the buffer room and anteroom. [USP 797 Section 4.2.1]	Yes
AIR RETURNS: Air returns in the cleanroom suite are low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow. [USP 797 Section 4.2.1] *Low wall vent returns*	Yes
LINE OF DEMARCATION: The anteroom has a line of demarcation to separate the clean side from the dirty side. [USP 797 Section 4.2.1]	Yes
SURFACES & WALLS: The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area are smooth, impervious, free from cracks and crevices, and non-shedding. Walls are constructed of/or covered with durable material. [USP 797 Section 4.3.1] *3 inch insulated polyvinyl material*	Yes
CEILINGS & FLOORS: Inlaid panels of ceilings are caulked around each panel to seal them to the support frame. Junctures between the ceiling and the walls and between the walls and the floor are sealed to eliminate cracks and crevices where dirt can accumulate. Floors include coving to the sidewall, or the juncture between the floor and the wall are caulked. [USP 797 Section 4.3.1] *Flushed epoxy juncture where floor meets wall*	Yes
LEDGES & OVERHANGS: Overhangs and ledges are easily cleanable, and the exterior lens surface of ceiling light fixtures are smooth, mounted flush, and sealed. [USP 797 Sections 4.3.1]	Yes
FURNITURE, EQUIPMENT, & MATERIALS: Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. Tacky mats are not placed within ISO-classified areas. Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels. [USP 797 Sections 4.2.1 & 4.5] *Steel bench for garbing in garbing room*	Yes

TEMPERATURE & HUMIDITY MONITORING: Temperature and humidity in the cleanroom suite are controlled through a heating, ventilation, and air conditioning (HVAC) system. The temperature and humidity are monitored in each room of the cleanroom suite each day that compounding is performed, either manually or by a continuous recording device. They are documented at least once daily or stored in the continuous recording device and are retrievable and are reviewed as described in the facility's SOP. [USP 797 Section 4.2] *See clipboard for monthly log 'Sterile Compounding Area Environment Monitoring Log'*	Yes
PRESSURE DIFFERENTIATION MONITORING & DOCUMENTATION: Facility maintains a minimum differential positive pressure of 0.020-inch water column between the nonhazardous buffer room to anteroom and anteroom to unclassified area. A pressure differential monitoring device is used to continuously monitor the pressure differentials. Quantitative results from the pressure monitoring device are reviewed and documented at least daily on the days when compounding is occurring. [USP 797 Sections 4.2.5] *On this log, pressure is expressed in mm water column*	Yes
PEC LOCATION: PECs are located in a buffer room in a manner that minimizes conditions that could increase the risk of microbial contamination (strong air currents, personnel traffic, or air streams from HVAC system(s)) and allows for cleaning around the PEC. [USP 797 Sections 4.2.2 & 4.2.3]	Yes
INTEGRATED VERTICAL LAMINAR FLOW ZONES: IVLFZ is separated from ISO Class 7 area with a physical barrier and there is full coverage of HEPA filters above the work surface. [USP 797 Section 4.2.3]	N/A

H. CERTIFICATION AND RECERTIFICATION – ALL CATEGORIES

PEC & SEC CERTIFICATION: PECs are certified initially and every 6 months to meet ISO Class 5 or better conditions, during dynamic operating conditions. SECs are certified initially and every 6 months to meet ISO Class 7 or 8 or better conditions, during dynamic operating conditions (including presterilization activities if applicable). Anterooms providing access to positive-pressure buffer rooms are at least ISO 8 and at least ISO 7 for anterooms providing access to negative-pressure buffer rooms. ISO Class 7 rooms maintain a minimum of 30 total HEPA-filtered ACPH during dynamic operating conditions, at least 15 ACPH come from the HVAC through HEPA filters located in the ceiling. ISO Class 8 rooms maintain a minimum of 20 total HEPA-filtered ACPH during dynamic operating conditions; 15 ACPH must come from the SEC. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH are documented on the certification report. HEPA filter integrity testing for both SECs & PECs is conducted initially and every 6 months as part of total particle testing. Classified areas are recertified when changes occur that could affect airflow or air quality [USP 797 Sections 4.1, 4.2.4, 4.2.6, & 5.0] *Dec 30, 31, and repeated by Medrep Jan 2 & 8, 2025 due to initial failure of Hepa filter leak test. Dynamic for hoods.* *Non-HD suite: + pressure sterile prep room (ISO 8-ACPH of 21.13), + pressure ante gown-in room with bench(ISO 7-ACPH of 36.96), + pressure buffer room (ISO 7-ACPH of 50.51)* *HD suite: + pressure gown in room (ISO 7 ACPH of 57.55), - pressure buffer room (ISO 7-ACPH of 60.86)* *PT#1 -between non-HD prep and non-HD buffer (ISO 7), PT#2- between HD prep and HD buffer room (ISO 7)* *PEC's: Air Science Purair Horizontal flow hood SN HLF000645 (ISO 5)- certified Nov 5, 6, 2024 certified under dynamic conditions* *Esco Class II A2 Vertical flow BSC SN 2024-204033 (ISO 5)*	Yes
DOCUMENTATION OF PERSONNEL PRESENT DURING CERTIFICATION: The number of personnel present in each PEC and SEC during total particle counts and dynamic airflow smoke-pattern tests is documented on the certification report. [USP 797 Section 5.0] *Per Medrep documentation no personnel present for all certifications from Nov 5,6, 2024, Dec 30,31, 2024 and Jan 2, 8, 2025*	No
PEC DYNAMIC SMOKE PATTERN TEST: Smoke pattern tests are performed under dynamic conditions initially to demonstrate minimal disruption in airflow and repeated if equipment is placed in a different location. Smoke pattern tests are performed under dynamic conditions every 6 months to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s). [USP 797 Section 5.0] *Single vial simulated to withdraw contents with a needle to transfer is not considered dynamic. Please redo smoke study in the future to demonstrate in situ air pattern over simulated vials close to what you are producing.* *Recorded smoke study Jan 17, 2025.*	No
ROBOTICS / ROBOTIC ENCLOSURES: Robotic enclosures used as a PEC or placed within a PEC have a dynamic airflow smoke pattern test is performed initially and at least every 6 months that confirms 1) the robotic device is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the DCA(s). [USP 797 Section 4.2.3]	N/A
MONITORING DEVICE CERTIFICATION: Temperature and humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. [USP 797 Section 4.2] *Armens calibrated the Greystone EM monitoring Device SN CR3C (total of 6 monitoring devices in 6 cleanrooms) March 1, 2025*	Yes
CONTAINMENT DEVICES USED FOR PRESTERILIZATION PROCEDURES: CVEs, BSCs, or CACIs used for presterilization procedures are certified at least once every 6 months. Presterilization procedures do not adversely affect the required air quality of the SEC as demonstrated during certification under dynamic operating conditions. [USP 797 Section 4.2.6] *Jan 8, 2025*	Yes
CERTIFICATION REPORT REVIEW BY DESIGNATED PERSON: All certification and recertification records are reviewed by the designated person(s). A corrective action plan is implemented and documented in response to any out-of-range results on certification report and data reviewed to confirm that the actions taken have been effective. [UPS 797 Section 5.0] *No document provided clarifying that the Designated Person has reviewed all 3 certification reports from Nov, Dec, Jan.*	No

I. RABS

LOCATION: If used to prepare Category 2 or Category 3 CSP's RABS are located in a cleanroom suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom. [USP 797 Section 4.2.3]	
RECOVERY TIME: When a RABS is used, the recovery time after opening the transfer chamber to achieve ISO Class 5 air is documented and internal procedures are developed to ensure that adequate recovery time is allowed after opening and closing the RABS. [USP 797 Section 4.2.3]	
STERILE GLOVES: are worn over gloves attached to RABS sleeves. [USP 797 Section 3.3]	

J. CATEGORY 2 CSPs WITHOUT STERILITY TESTING

CATEGORY 2 COMPOUNDING ENVIRONMENT: Category 2 CSPs are compounded in an ISO class 5 PEC located within an ISO classified anteroom and buffer room. [USP 797 Sections 4.1 & 14.3] *Pharmacy qualifies for sterile to sterile Cat 2 compounding*	Yes
CATEGORY 2 BUDs FROM STERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from all sterile starting components and in the absence of sterility testing do not exceed the following BUDs: 4 days room temperature, 10 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *Not currently compounding, but future plans for Gentamicin and Amikacin compounding possibly from sterile to sterile for dispensing patient-specific for institutional and home infusion dispensing. (See SPE permit)*	N/A
CATEGORY 2 BUDs FROM NONSTERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from one or more nonsterile starting components and in the absence of sterility testing do not exceed the following BUDs: 1 day room temperature, 4 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *See table in Section 5 B of SOP 6.1 'Beyond Use Dates'*	N/A

K. CATEGORY 2 EXTENDED BUD REQUIREMENTS

CATEGORY 2 BUDs FOR ASEPTICALLY PROCESSED CSPs WITH STERILITY TESTING: Category 2 CSPs compounded aseptically, and which have passed sterility testing do not exceed the following BUDs: 30 days room temperature, 45 days refrigerated, or 60 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *New business, review of Glutathione MFR, demonstrates a refrigerated BUD of 45 days at 2-8C. See SOP 6.1 'Beyond Use Date'*	N/A
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITHOUT STERILITY TESTING: Category 2 CSPs terminally sterilized and in the absence of sterility testing do not exceed the following BUDs: 14 days room temperature, 28 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *At this time pharmacy does not have plans to terminally sterilize CSP's*	N/A
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITH STERILITY TESTING: Category 2 CSPs terminally sterilized, and which have passed sterility testing do not exceed the following BUDs: 45 days room temperature, 60 days refrigerated, or 90 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3]	N/A
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmics) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1] *Has not been completed for Glutathione Inj-pharmacy has not initiated testing at this time-please ensure this is completed prior to release*	N/A
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved CSPs), container integrity testing is performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5] *Required for all container closures compounded by the firm -nothing released yet*	N/A
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are assigned are prepared as a Category 2 CSP, for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5] *SOP 6.1 'Beyond Use Date' Section 5.6.1*	N/A
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1] *New Business -has not initiated compounding, but is contracted with Pharmetric*	N/A
OUTSOURCED STERILITY TESTING: Sterility testing is performed for all Category 2 CSPs assigned a BUD requiring sterility testing according to USP <71> or a validated alternative and noninferior method. Membrane Filtration as described in USP <71> is the preferred method when the formulation allows. [USP 797 Section 12.2] *Will be per Pharmetric as supported by policy*	N/A
INHOUSE STERILITY TESTING: Sterility testing is according to USP <71> or a validated alternative and noninferior method. Membrane filtration is used if appropriate and filters are rinsed according to USP <71>. Direct inoculation is done only when membrane filtration cannot be carried out. Volume inoculated does not exceed 10% of the culture media volume. Growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP <71>. TSB or SCD is incubated at 20-25C for 14 days; FTM is incubated at 30-35C for 14 days. (2 incubators present).	N/A
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method. [USP 797 Section 12.2] *Policy 6.1 -to be done with eech formulation using Pharmetric lab. Has not initiated at this time.*	N/A
MAXIMUM BATCH SIZE: The maximum batch size for all CSPs requiring sterility testing is 250 final yield units. [USP 797 Section 12.2] *Has not exceeded 70 vials of simulation of media fill representing Glutathione 100mg/ml 10ml vials. Has not initiated compounding for release.*	Yes
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2] *SOP 8.2 'Responding to Out of Specification test'*	N/A
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2] *SOP 6.11 'Sterility'. Has not initiated compounding yet.*	N/A
ENDOTOXIN TESTING: Category 2 Injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing are tested for bacterial endotoxins. [USP 797 Section 12.3] *Has not initiated compounding. Policy 6.11 "Sterility" requires Endotoxin testing.*	N/A
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3] *SOP 6.11 'Sterility'*	N/A

L. CATEGORY 3 CSPs, BUDs, & RELATED REQUIREMENTS

CATEGORY 3 REQUIREMENTS: All requirements associated with Category 3 compounding (e.g., garbing, cleaning, environmental monitoring) apply to all personnel entering the buffer room where Category 3 CSPs are compounded and always apply regardless of whether Category 3 CSPs are compounded on a given day. [USP 797 Section 14.4.2]	
STERILE/SINGLE USE GARB: When compounding Category 3 CSPs, skin is not exposed in buffer room (i.e., face and neck are covered) and all low lint outer garb is sterile, including sterile sleeves over RABS gauntlet sleeves. Disposable garb items are not reused. [USP 797 Section 3.3]	
STERILIZED/REUSABLE GARB: Non-disposable garb is not reused without being laundered and resterilized with a validated cycle. Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment. [USP 797 Section 3.3]	
CATEGORY 3 BUDs FOR ASEPTICALLY PROCESSED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 60 days room temperature, 90 days refrigerated, or 120 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for aseptically processed CSPs. [USP 797 Section 14.4.3]	
CATEGORY 3 BUDs FOR TERMINALLY STERILIZED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 90 days room temperature, 120 days refrigerated, or 180 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for terminally sterilized CSPs. [USP 797 Section 14.4.3]	
MAXIMUM BATCH SIZE: Category 3 CSP batch sizes do not exceed 250 final yield units. [USP 797 Section 12.2]	

STABILITY INDICATING ASSAYS: All Category 3 CSP formulations are supported by data obtained using a validated stability-indicating analytical method that can distinguish active ingredients from degradants and impurities and quantify the amount of active ingredient. CSPs are prepared according to the exact formulation, components, and packaged in a container closure system of the same materials of composition. Facilities have documentation of the stability study, its results, and the method validation available for review. [USP 797 Section 14.3.3]	
STERILITY TESTING: All category 3 CSPs and batches undergo sterility testing performed according to USP <71> or a validated alternative and noninferior method. [USP 797 Sections 12.2 & 14.4.4]	
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method for each formulation. [USP 797 Section 12.2]	
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	
ENDOTOXIN TESTING: Category 3 injectable CSPs compounded from one or more nonsterile component(s) are tested for bacterial endotoxins. [USP 797 Section 12.3]	
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	
PARTICULATE MATTER TESTING: Category 3 injectable CSPs undergo USP <788> (Particulate Matter in Injections) and ophthalmic solutions undergo USP <789> (Particulate Matter in Ophthalmic Solutions) test once per formulation with acceptable results. [USP 797 Section 14.3.3]	
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmic) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1]	
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved multi-dose CSPs), container closure integrity testing is also performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are prepared for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1]	

M. PERSONNEL TRAINING & COMPETENCIES - ALL CATEGORIES

TRAINING PROGRAM & SOP: Facility maintains a written training program and corresponding SOP which defines required trainings, frequency of training and the process for evaluating the performance of individuals who compound, have direct oversight of compounding personnel, perform in-process checks, final verification and dispensing of CSP's. The training program equips personnel with the appropriate knowledge and training in the required skills necessary to perform their assigned tasks. [USP 797 Section 2] *per SOP 4.2 "Training, Conduct and Competency of Sterile Compounding Personnel"*	Yes
INITIAL DIDACTIC TRAINING & SKILLS ASSESSMENT: Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel complete training and can demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions. [USP 797 Section 2.1] *Critical Point modules completed for SM, RPt and AM*	Yes
INITIAL GLOVED FINGERTIP & HAND HYGIENE/GARBING COMPETENCY: Before beginning to compound independently or have direct oversight of compounding personnel, personnel successfully complete an initial gloved fingertip (GFT) competency no fewer than 3 separate times, with a documented visual audit while performing hand hygiene and garbing procedures. GFT samples are collected before applying sterile 70% IPA to gloves. [USP 797 Section 2.2] *Initial GFT for AM and SM started on 12-12-24, completed on 12-19-24. This is a future Cat 2 compounder. Completed 3 separate times using Hardy TSA with L&T plates P34 refrigerated, 3 separate times, but consecutive. Pharmacy is not planning of starting off as a Cat 3 compounder.*	Yes
INITIAL MEDIA FILL & ASEPTIC TECHNIQUE ASSESSMENT: Before beginning to compound independently or have direct oversight of compounding personnel, personnel who compound or have direct oversight of compounding successfully complete an initial aseptic manipulation competency evaluation which consists of a visual observation, media-fill testing followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area. [USP 797 Section 2.3] *Using GM3000 kit packets from QI Medical TSB. Available for vial formulation. completed for AM and SM. Initial media fill completed for 70 vials simulating vials needed for Method Suitability, however does not simulate bags(ex Sodium Bicarbonate 8.4%), only vials (Glutathione 100mg/ml 10ml vials).* *Furthermore, more than one sterilizing filter Pal supor 0.22 microns was used as each is stated to have a volume capacity of 200ml, whereas 700ml were intended to be filtered into 10ml vials.* *According to USP <797>, 2023 version, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process."* *Media fill does not demonstrate 4 filters used.*	No
GFT & MEDIA FILL INCUBATION: Documentation includes the name of the person evaluated, evaluation date and time, media and components used to include their manufacturer or supplier, expiration dates and lot numbers, starting temperature for each interval of incubation; dates of incubation, the results, and the names or other identification of the observer and the person who reads end documents the results. [USP 797 Section 2.3] *Per Tacy 797 tools each interval of incubation is documented*	Yes
ONGOING CATEGORY 1 AND 2- GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency evaluation and GFT every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2] *New Business-Has not hit 6 months as Cat 2 compounder-Initial testing was 12-19-24*	N/A
ONGOING CATEGORY 1 AND 2- MEDIA FILL & ASSESSMENT: After initial aseptic manipulations competency evaluations, compounding personnel complete aseptic technique competency, media fill, GFTs, and surface sampling of DCA every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete media fill every 12 months. GFTs and surface samples are appropriately incubated. [USP 797 Section 2.3] *New Business-Has not hit 6 months as Cat 2 compounder-Initial testing was 12-19-24*	N/A

ONGOING KNOWLEDGE & COMPENTENCY OF CORE SKILLS: Training and knowledge assessment of sterile compounding principles or core skills is completed at least every 12 months. [USP 797 Section 2.1] *New Business Critical Point and Observational forms*	N/A
FAILED COMPETENCY INVESTIGATION: Initial and ongoing competency assessment failures are investigated, remediated, and documented in a Corrective Action Plan. [USP 797 Sections 2.2 & 2.3]	N/A
STAFF TRAINING IN VIABLE AIR AND SURFACE SAMPLING: Personnel are trained and competent in air and surface sampling procedures to ensure accurate and reproducible sampling. [USP 797 Section 6.1] *Initially taught by Critical Point and consultant, and there is a competency assessment for training of VAS and SS*	Yes
CLEANING PERSONNEL: Cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures. Cleaning personnel demonstrate knowledge and competency of core skills related to cleaning, disinfection, and maintenance of environmental conditions initially and at least once every 12 months. [USP 797 Sections 7 & 2.1] *Nov and Dec 2024*	Yes

FACILITY COMPOUNDS CATEGORY 3

ONGOING CATEGORY 3 GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency and GFT every 3 months for Category 3 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2]	
ONGOING CATEGORY 3 ASEPTIC PROCESSING COMPETENCY: Aseptic competency is repeated at least one time every 3 months for personnel compounding Category 3 CSPs. The simulation must capture elements that could potentially affect the sterility of the CSP. Immediately following the media-fill test, gloved fingertip and thumb sampling is performed on both hands and surface sampling of the direct compounding area. Direct oversight personnel who do not compound must complete media fill every 12 months. [USP 797 Section 2.3]	

N. MICROBIOLOGICAL AIR AND SURFACE MONITORING: ALL CATEGORIES

ENVIRONMENTAL MONITORING PROGRAM & SOPs: The microbiological air and surface monitoring program is clearly described in the facility's SOPs, which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that trigger corrective action. [USP 797 Section 6] *SOP 2.3 "Viable Air Sampling' and SOP 2.31 'Operation and Maintenance of MicroBio MB1 Bioaerosol Sampler'*	Yes
VIABLE AIR SAMPLING: Volumetric active air sampling using an impaction air sampler collecting at least 1000L of air is conducted in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions and is completed at least every 6 months. [USP 797 Section 6.2] *Dates of collection: Feb 21, 2025*	Yes
AIR IMPACTION DEVICE: Device is serviced and calibrated according to the manufacturer's recommendations. [USP 797 Section 6.1] *In-house Viable air sampling device Qualisair MicroBio SN 30152581591 last calibrated Oct 28, 2024*	Yes
SURFACE SAMPLING: Microbiological surface sampling is conducted in all classified areas and pass-through chambers under dynamic operating conditions and performed at least once monthly. [USP 797 Section 6.3] *New Business-so far SS date 2-20-25-see map posted*	Yes
GROWTH MEDIA: A general microbiological growth media that supports the growth of bacteria and fungi is used and a COA from the manufacturer is available. Growth media used for surface sampling contains neutralizing agents (e.g., lecithin and polysorbate 80). [USP 797 Sections 6.2 & 6.3] *Hardy TSA with L&T plates P34*	Yes
MEDIA INCUBATION: Samples are incubated at 30°C - 35°C for 48 hours and 20°C - 25°C for an additional 5 days; if dual growth media are used, incubate one media device at 30°C - 35°C for 48 hours and the second media device at 20°C - 25°C for 5 days. The incubator temperature is monitored during incubation, either manually or by a continuous recording device, and results are reviewed and documented as described in the facility's SOPs. Incubators are placed in a location outside of the sterile compounding area. [USP Sections 6.2.2 (Box 5) & 6.3.2 (Box 6)] *Per SOP 4.4 'Glove Fingertip Sampling' Section 6.4.4. Pharmacy has 3 incubators*	Yes
ENVIRONMENTAL MONITORING TREND ANALYSIS: Regular review of sampling data is performed to detect trends and review of trending data is documented. [USP 797 Section 6.1] *New business*	N/A
CORRECTIVE ACTION: When microbial growth exceeds action levels, the cause is investigated, and corrective action is taken; corrective actions taken are reviewed for effectiveness. An attempt to identify microorganisms at the genus level is made. [USP Sections 6.2.3 & USP 6.3.3]	N/A

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-VIABLE AIR SAMPLING: Volumetric air sampling is completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.Air sampling sites are selected in all classified areas. [USP 797 6.2.1]	
CATEGORY 3-SURFACE SAMPLING: Surface sampling for any Category 3 CSPs, is completed in all classified areas, and pass-through chambers connecting to classified areas, prior to assigning a BUD longer than BUD limits for Category 2 CSPs (defined in Table 13 of USP 797) and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. [USP 797 6.2.2]	
CATEGORY 3-BATCH SURFACE SAMPLING: Surface sampling is conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used. When a self-enclosed robotic device is used as the PEC, surface sampling is conducted at least once daily at the end of compounding operations before cleaning and disinfection occurs. [USP 797 Section 6.3.2]	

O. CLEANING AND DISINFECTING: ALL CATEGORIES

CLEANING SOPS: The frequency, method(s), documentation requirements, and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants are described in written SOPs; use of agents is in accordance with manufacturer's instructions, procedures, and in adherence with minimum wet contact times. SOPs describe the time period during which, once opened, sterile cleaning and disinfecting agents, supplies, and sterile 70% IPA may be reused. Sterile water is used to dilute concentrated cleaning agents used inside of PECs (if applicable). Cleaning and disinfecting agents are EPA-registered. If a one-step disinfectant cleaner is not used, surfaces are cleaned prior to being disinfected. [USP 797 Section 7] *Policy SOP 3.5 'Sanitization of Sterile Compounding Environments'*	Yes
DAILY PEC CLEANING & DISINFECTION WITH STERILE AGENTS: Equipment and all interior surfaces of the PEC are cleaned and disinfected daily on days when compounding occurs and when surface contamination is known or suspected. Sterile 70% IPA is applied after cleaning, disinfecting, or after one-step disinfectant cleaner or sporicidal agent application to remove residue. [USP 797 Section 7] *As documented in Tacy 797 tool-using sterile Peridox (dwell time of 3 mins) and Sterile SIPA*	Yes
CATEGORY 1 AND 2-MONTHLY PEC SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, are cleaned with a sporicidal agent monthly. [USP 797 Section 7] *Documented in Tacy's 797 tool as completed on 2/13/25*	Yes

DAILY SEC & SCA CLEANING & DISINFECTION: Work surfaces, floors, sink surfaces, and pass-through chambers are cleaned and disinfected daily on days when compounding occurs. [USP 797 Section 7]	Yes
CATEGORY 1 AND 2 -MONTHLY PEC, SEC & SCA SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings*, walls, doors, and doors frames at least once monthly. SCA ceilings (if applicable) are only cleaned, disinfected, and have sporicidal agents applied when visibly soiled and when surface contamination is known or suspected. [USP 797 Section 7] *Documented in Tacy's 797 tool as completed on 2/13/25. Task states cleaned under work surface of BSC.*	Yes
PEC SANITIZATION WITH STERILE 70% IPA: Sterile 70% IPA is applied to the horizontal work surface, including removable trays, immediately before initiating compounding and at least every 30 minutes. If a compounding process takes more than 30 minutes, the work surface is disinfected immediately after the end of the compounding process. Sterile 70% IPA is allowed to dry. [USP 797 Section 7]	Yes
CLEANING SUPPLIES & TOOLS: All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads), except for tool handles and holders, are low lint. Supplies used inside PECs are sterile. [USP 797 Section 7.1.2] *Noted sterile dedicated lint free wipes inside each hood*	Yes
REUSABLE CLEANING TOOLS: Reusable cleaning tools (e.g., mop frames) are made of cleanable materials and are cleaned and disinfected before and after each use. Reusable tools are dedicated for use in the classified areas or SCA and are not removed. Mops used in HD compounding areas, are dedicated for use only in thosa areas. [USP 797 Section 7.1.2] *Separate mops for the different suites*	Yes

FACILITY COMPOUNDS CATEGORY 3

WEEKLY SPORICIDAL CLEANING OF PECs & SECs: Weekly cleaning using a sporicidal agent is performed on all internal surfaces of PEC and equipment in PEC's, on work surfaces outside the PEC, pass-through chambers, and floors. [USP 797 Section 7]	
MONTHLY SEC SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to storage shelving and bins, equipment outside of PEC's, sink surfaces, ceilings, walls, doors, and doors frames at least once monthly. [USP 797 Section 7]	

P. COMPOUNDING CSPs FROM NONSTERILE COMPONENTS OR SUPPLIES – CATEGORY 2 & 3

PRESTERILIZATION ACTIVITY CONTAINMENT ENCLOSURES: Pre-sterilization procedures, such as weighing and mixing of nonsterile components, occur in ISO Class 8 or better environment (e.g., anteroom or buffer room) and are performed in single-use containment glove bags, CVEs, BSCs, or CACIs. [USP 797 Section 4.2.6] *SOP 6.4 'Compounding non-sterile to sterile' CVE 's are located in ISO 8 rooms*	Yes
LOCATION OF STERILE & NONSTERILE PECs: PECs used for sterile and nonsterile compounding (e.g., pre-sterilization procedures) are placed in separate rooms unless the buffer room can maintain an ISO Class 7 classification during particulate generating activities. Co-located PECs are at least 1 meter apart and particle-generating activities are not performed during sterile compounding processes [USP 797 Section 4.2.1; USP 800 Section 5.3] *Separate CVE's. PEC's are only for compounding Sterile preparation.*	Yes
COMPONENT SOPs: Written SOPs address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components including ingredients and container closures. [USP 797 Section 9.3] *SOP 6.4 Section 4.1 "Preparing Sterile from Non-sterile Components'. Pharmacy has bar code scanning and entry into SI Compounding software.*	Yes
COMPONENT QUALITY & COA: APIs and components comply with the criteria in the USP-NF (if one exists for inactive components) and have a COA including specifications and test results showing the API or component meets expected quality. APIs and other components labeled "not for pharmaceutical use", "not for injectable use", "not for human use", or equivalent are not used in CSPs. [USP 7 Section 9.3.1] *Has not ordered injectable medication API to be compounded until permitted*	N/A
API MANUFACTURERS: APIs are manufactured by an FDA-registered facility in the U.S. or comply with the laws and regulations of the applicable regulatory jurisdictions outside of the U.S. [USP 797 Section 9.3.1]	N/A
COMPONENT STORAGE: Components are handled and stored in a manner that prevents contamination, mix-ups, and deterioration and under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers and/or manufacturers. [USP 797 Section 9.3.4] *No injectable components ordered yet*	N/A
STERILE, DEPYROGENATED SUPPLIES: Supplies in direct contact with CSPs are sterile and depyrogenated. A COA or similar conformance documentation is reviewed. [USP 797 Section 9.3.1] *Beakers, tweezers, cylinders, scissors noted wrapped in Aluminum foil*	Yes
COMPONENT RECEIPT: Upon receipt, the external packaging of components is examined and components of unacceptable quality or showing deterioration are promptly labeled as rejected and segregated from active stock. APIs and components are inspected for a visible manufacturer expiration date. Components lacking expiration dates are assigned an expiration date no more than 1 year after receipt and both the date of receipt and facility assigned expiration date is clearly marked on the component packaging. [USP 797 Section 9.3.2] *Process is to write in sharpie the date opened on the jar and place a bar code on lid*	N/A
STERILIZATION OF INJECTABLES WITHIN 6 HOURS OF COMPLETION: Injectable CSPs containing nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during compounding are sterilized within 6 hours of completion. [USP 797 Section 10] *See sterilization time on CR under Compounding Controls*	N/A

Q. STERILIZATION OF CSPs - CATEGORY 2 & 3

STERILIZING FILTERS: Sterilizing filters used are sterile, depyrogenated, have a nominal pore size of 0.22 µm or smaller, and are appropriate for pharmaceutical use. Sterilizing filters are certified by the manufacturer to retain at least 10,000,000 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area. Filters are chemically and physically compatible with all ingredients in the CSP (e.g., water-miscible alcohols may damage filter integrity); chemically stable at the pressure and temperature conditions that will be used; and have enough capacity to filter the required volumes. [USP 797 Section 10.2] *Pall Supor filter HP1002 25mm Syringe Filter used for demonstrating media fill of 700ml only has a capacity of 200ml, so multiple filters were used. Inadequate capacity of filter to filter required volume.* *This filter when used for Media fill, package insert states Max Operating pressure is 75 psi, however, expected bubble point noted on Media fill record is noted to be 46 with measured outcome of 52 psi bubble point* *This pharmacy will be sterilizing by filtration per SOP 6.11 'Sterility'* *Plan is to use MDI Asepti-Cap KS PES Capsule filter (capable of 1 liter) for aqueous solutions and AseptiVent TF PTFE Capsule filter.-See COA Pall Supor filter used for demonstrating media fill of 700ml only hes a capacity of 200ml, so multiple filters were used. Inadequate capacity of filter to filter required volume.* *Since multiple filters were used, where is it documented that each filter passed the bubble point?* *Per 2023, USP <797>, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process. Filter units used to sterilize CSPs must be subjected to the manufacturers' recommended integrity testing, such as a post-use bubble point test. If multiple filters are required for the compounding process, each of the filters must pass a filter-integrity test."*	No

BUBBLE POINT TESTING: Sterilizing filters are subjected to the manufacturers' recommended integrity testing, such as a post-use bubble point test. If multiple filters are required for the compounding process, each of the filters passes a filter-integrity test. [USP 797 Section 10.2] For failed BP testing, CSP is discarded or, after investigating, refiltered not more than one time. [USP 797 Section 10.2] *Pharmacy used 4 filters to filter 700ml of media fill, however bubble point is not documented for each filter.*	No
CSP PREFILTRATION: When CSPs are known to contain excessive particulate matter, prefiltration is performed using a filter of larger nominal pore size (e.g., 1.2 µm) or a separate filter of larger nominal pore size placed upstream of (i.e., prior to) the sterilizing filter. [USP 797 Section 10.2] *No plans on prefiltration at this time.*	N/A
CSP TERMINAL STERILIZATION SOP includes: 1) A description of CSP terminal sterilization process(es), including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization methods and equipment. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. [USP 797 Section 10] *Pharmacy will not be terminally sterilizing*	N/A
STEAM OR DRY HEAT STERILIZATION CYCLES FOR CSPs: Sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of the CSP to reach and remain at the sterilizing temperature during the duration of the sterilization period. CSPs sterilized vial steam are placed in the autoclave to allow steam to reach CSPs without entrapment of air. CSPs sterilized via dry heat are placed with sufficient space between materials to allow for hot air circulation. Sterilization cycle parameters (e.g., temperature, pressure, and duration) and load configuration(s) are documented. [USP 797 Section 10.3 & 10.4] *No terminal sterilization of CSP plan.*	N/A
BIOLOGICAL INDICATOR USE: The effectiveness of steam or dry heat sterilization of CSPs is verified and documented for each sterilization run or load by using appropriate biological indicators (e.g., Geobacillus stearothermophilus for steam, Bacillus atrophaeus for dry heat) and other confirmation methods. [USP 797 Section 10.3] *Pharmacy had autoclaved the head of the viable air sampler and plans on autoclaving goggles. BI used is Letco's Verify SCBI.* *Other items to be sterilized: Rubber stoppers, utensils (Scissors, tweezers)* *See Autoclave run log Cycle # A021325@1*	Yes
STEAM & DRY HEAT CSP PREFILTRATION: Immediately before filling containers that will be sterilized via steam, or dry heat, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.3]	N/A
CALIBRATED DATA RECORDER: A calibrated data recorder or chart is used to monitor each steam or dry heat sterilization cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure). The calibrated oven is equipped with temperature controls and a timer. [USP 797 Section 10.3 & 10.4] *It cannot be demonstrated from the review of the autoclave run that the duration of the exposure period includes sufficient time for the entire contents of the items to reach the sterilizing temperature.* *Cycle PKG has incorrect units of 255degrees C.* *The date and time of the cycle initiation of the run with the BI is indicated on the run of autoclaved items-ex Air sampler head or utensils, but the log does not indicate the end time to demonstrate that temp of 121C was met for the full 30 minutes as per SOP 3.4 'Autoclave Steam Sterilization'*	No

R. STERILIZATION & DEPYROGENATION OF SUPPLIES & CONTAINER CLOSURE SYSTEMS - CATEGORY 2 & 3

STERILIZATION & DEPYROGENATION SOP's include: 1) A description of sterilization and depyrogenation process(es) used to sterilize and/or depyrogenated compounding supplies and container closure systems, including the temperature, duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. [USP 797 Section 10] *SOP 6.6 'Dry Heat Depyrogenation'* *Pharmacy outsourced the cycle load for depyrogenation to External lab Pharmetric. The depiction of the load is pending from the firm. Inspector clarified largest beaker size was 1 liter.* *See training log in each binder for Pre-Cycle Preparation and Dry Heat Oven Setup and Operation* *Handling and Storage of Depyrogenated items*	Yes
DEPYROGENATION VIA DRY HEAT: Dry heat depyrogenation is used to render glassware, metal, and other thermostable containers and components pyrogen free. The exposure period includes sufficient time for items to reach the depyrogenation temperature; items remain at the depyrogenation temperature for the duration of the depyrogenation period. [USP 797 Section 10.1 & USP 1228.4] *As per 'Dry Heat Oven Monitoring log'* *During walk through observed covered beakers with the run#*	Yes
DEPYROGENERATION VIA RINSING: Non-thermostable items are sterilized via a validated sterilization method and cycle: these items are also depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., Sterile Water for Injection or Sterile Water for Irrigation) and then thoroughly drained or dried immediately before use in compounding. [USP 797 Section 10 & 10.1] *Pharmacy currently does not have any non-thermostable items*	N/A
DEPYROGENATION PROCESS VALIDATION: The effectiveness of the dry heat depyrogenation cycle(s) is established initially and verified annually using Endotoxin Challenge Vials (ECVs) to demonstrate the cycle achieves a greater than or equal to 3-log endotoxin reduction. The effectiveness of the depyrogenation cycle is re-established if there are changes to the cycle parameters . Cycle verifications are documented. [USP 797 Section 10.1] *Dry Heat Oven Depryogenation Validation Report from Pharmetric using Endosafe PTS Cartridges demonstrated a 5.3 log reduction in endotoxins per 3-3-25 report*	Yes
STERILIZATION CYCLE VALIDATION: When performed onsite, the efficacy of sterilization cycles used for supplies or container closure systems are established and documented. Each sterilization run or load is verified and documented by using appropriate biological indicators (e.g., spores of Geobacillus stearothermophilus) and other confirmation methods. [USP 797 Section 9.3.1 & USP 1229] *Autoclave SN 215754 validated with 11 Attest BI's and a positive control by Pharmetric 3-3-25* *Dry Heat Oven Depryogenation Validation Report from Pharmetric using Endosafe PTS Cartridges demonstrated a 5.3 log reduction in endotoxins per 3-3-25 report*	Yes

S. MASTER FORMULATION AND COMPOUNDING RECORDS – ALL CATEGORIES

MASTER FORMULATION RECORD (MFR): A MFR is created for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more then one patient and any changes or alterations to an MFR are approved and documented per facility's SOPs. [USP 797 Section 11.1] *Sample MFR's reviewed for Glutathione 100mg/ml 10ml vials and Sodium Bicarbonate 8.4% bags*	Yes
MFR DOCUMENTATION: An MFR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Identities, amounts of all ingredients, and, if applicable, relevant characteristics of components; 3) Type and size of container closure system(s); 4) Complete instructions for preparing the CSP including equipment, supplies, a description of the compounding steps, and any special precautions; 5) Physical description of the of the final CSP; 6) BUD and storage requirements; 6) Stability reference; 7) Quality control procedures; 8) other information as needed to describe the compounding process and ensure repeatability. [USP 797 Section 11.1 (Box 9)] *Documentation reviewed form MFR in Si Compounding, specifically Formula #68 v.2 does not specify the size of the Depyrogenated beaker.* *No actual stability reference on Glutathione 100mg/ml IM Inj -it refers to Medisca Formula No F 003 861V4-per SOP 3.1 'Formulation Master Record' 3.3.4 requires compatibility and references.*	No

COMPOUNDING RECORD (CR): A CR is created for all Category 1, Category 2, and Category 3 CSPs. A CR is created for immediate-use CSPs prepared for more than one patient. A CR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Date and time of preparation of the CSP; 3) Assigned internal identification number (e.g., prescription, order, or lot number); 4) A method to identify the individuals involved in the compounding process and individuals verifying the final CSP; 5) Name of each component; 6) Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s); 7) Weight or volume of each component; 8) Strength or activity of each component; 9) Total quantity compounded; 10) Final yield; 11) Assigned BUD and storage requirements; 12) Results of QC procedures. And, if applicable, 13) MFR reference for the CSP; and 14) Calculations made to determine and verify quantities and/or concentrations of components. [USP 797 Section 11.2] *No sample CR at this time. Pharmacy has not compounded for release or testing.*	No
STERILIZATION CYCLE DOCUMENTATION: The date, run, and load numbers of the steam or dry heat sterilizer used to sterilize a CSP are documented on the CR if applicable. [USP 797 Sections 10.3 & 10.4] *Unable to determine as there is no sample CR*	No

T. RELEASE INSPECTION AND TESTING – ALL CATEGORIES

RELEASE TESTING PROCEDURES: All release testing procedures (e.g., visual inspections and testing) are included in facility documentation such as MFRs and SOPs. [USP 797 Section 12] *SOP 3.1 'Formulation Record (Master Formula), SOP 6.5 'Visual Inspection"*	Yes
VISUAL INSPECTION: CSPs are visually inspected before release and dispensing to determine whether the 1) physical appearance of the CSP is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects), 2) container closure integrity is intact (e.g., checking for leakage, cracks in the container, or improper seals), 3) CSP and its labeling match the prescription or medication order. [USP 797 Section 12.1] *Pharmacy has not compounded for testing or release. SOP 6.5 'Visual Inspection' -covered under Quality Verificetion on MFR*	Yes
DELAYED DISPENSING VISUAL INSPECTION: When CSPs are not released or dispensed on the day of preparation, a visual inspection is conducted immediately before its release to ensure the CSP is free from any defects such as precipitation, cloudiness, or leakage, which could develop during storage. [USP 797 Section 12.1] *No indication that this is a requirement prior to release after quarantine from Formula #68 v.2 under 'Verification list' of the record for Glutethione inj. Nothing has been released. This question is really an N/A*	No
CSP REJECTION & QUARANTINE: CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock. [USP 797 Section 12.1] *N/A Nothing released*	Yes
INVESTIGATION OF OOS RESULTS: Out-of-specifications results and defects indicating sterility or stability problems are investigated to determine the root cause and a corrective action plan is implemented and documented per facility SOPs. [USP 797 Section 12 & 12.1] *This is an N/A nothing tested or released.*	Yes

U. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, & TRANSPORT – ALL CATEGORIES

STORAGE AREA TEMPERATURE MONITORING: Temperature in CSP & component storage areas is monitored at least once daily and recorded on a log on days when the facility is open or by a continuous temperature recording device; temperature data is readily retrievable. Monitoring equipment is calibrated or verified for accuracy as recommended by the manufacturer or every 12 months. When CSPs have been exposed to temperature excursions above or below storage temperature limits for the CSP, a Designated Person determines whether the CSP has retained its integrity or quality. [USP 797 Sections 9.3 & 19.1]	Yes
CSP PACKAGING: CSP packaging and shipping materials are selected to protect CSPs from damage, leakage, contamination, degradation, adsorption and prevent inadvertent exposure to transport personnel. [USP 797 Section 19.2] *Has not selected shipping materials yet. Plans on using U-line double insulated containers.*	N/A
SHIPPING & TRANSPORTING: Modes of transport are selected that are expected to deliver properly packaged CSPs in an undamaged, sterile, and stable condition. Special handing instructions are provided and/or affixed to the exterior of the container when applicable. [USP 797 Section 19.2] *Will plan on using UPS*	N/A

V. STERILE QUALITY PROGRAM, SOP's & DOCUMENTATION- ALL CATEGORIES

QA/QC PROGRAM & SOPs: A Quality Assurance (QA) and Quality Control (QC) program is documented in facility SOPs and formally establishes a system of 1) adherence to procedures, 2) prevention and detection of errors and other quality problems, 3) evaluation of complaints and adverse events, and 4) appropriate investigations and corrective actions. The QA/QC SOPs describe the roles, duties, and training of personnel responsible for each aspect of the QA program. [USP 797 Section 18] *SOP 8.1 'Continuous Quality Improvement'* *See Attachment 1 for QRE data*	Yes
INVESTIGATIONS & CAPAs: A designated person(s) follows up to ensure investigations are conducted and corrective actions are taken if problems, deviations, failures, or errors are identified or when complaints or adverse reactions are reported. A complete record of each reported complaint and adverse reaction is created and retained. Investigations and corrective actions are documented. [USP 797 Sections 17, 18.2, & 18.3] *SOP 8.2 'Responding to OOS tests'*	Yes
ADR & COMPLAINT DOCUMENTATION: A complete record of each reported complaint and adverse reaction is created and retained per USP 797. [USP 797 Section 18.1] *SOP 8.1 CQI*	Yes
RECALL PROCEDURES & SOP: If CSPs are dispensed or administered before the results of release testing are known, procedures are in place to immediately notify the prescriber of a failure of specifications with a potential to cause patients harm; determine the severity of the problem and urgency for implementation/completion of recall; identify patients (or other points of distribution) who have received affected CSP; recall any unused dispensed CSPs; quarantine remaining stock in the pharmacy; investigate if other lots are affected and recalled if needed; conduct investigation and document reason for the failure. Recalls are reported to the appropriate regulatory body as required by the laws and regulations of the applicable regulatory jurisdiction. [USP 797 Section 18] *SOP 8.3 'Recalls'*	Yes
ANNUAL SOP & QA/QC COMPLIANCE REVIEW: Facility sterile compounding SOPs are reviewed every 12 months by the Designated Person(s); the review is documented. Changes to SOP are made only by the Designated Person and documented. Acknowledgement of revisions to SOP's are communicated to all personnel. The overall QA/QC Program is reviewed at least once every 12 months by the Designated Person(s); the review is documented, and corrective actions are taken if needed. [USP 797 Section 17 & 18] *Each SOP is signed and Table of Contents has the date of reviewed*	Yes

W. HAZARDOUS DRUG HANDLING & COMPOUNDING – ALL CATEGORIES

DESIGNATED PERSON: The entity has a Designated Person who is qualified and trained to be responsible for implementing appropriate HD procedures, overseeing compliance with USP 800 requirements, ensuring environmental control of the storage and compounding areas, monitoring HD facility operations, testing, and acting on results. [USP 800 Section 4] *Designated Person: Andrew Mesiha- has training in Critical Point around June to Nov 2024, and Medisca LP3 class*	Yes

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HAZARD COMMUNICATION PROGRAM (HCP): Facility has SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of HDs and use of Safety Data Sheets. The HCP and HD SOPs include a written plan describing 1) how USP 800 requirements are implemented, 2) HD chemical container labeling with the identity of the material and appropriate hazard warnings, 3) readily accessible location of HD chemical SDSs known and accessible by all personnel, 4) HD risk training and information provided to all personnel with HD exposure risk before initial HD handling work assignment and whenever hazard changes, 5) personnel of reproductive capability written acknowledgement of understanding of HD handling risks. [USP 800 Section 8] *SOP 7.0 'Hazard Communication Program' SOP 7.1 'Hazardous Drug Employee Training and Safety Program'*	Yes
LIST OF HAZARDOUS DRUGS & ASSESSMENT OF RISK: Facility maintains a list of HDs that includes any items on the current NIOSH that the entity handles. The list is reviewed every 12 months and whenever a new agent or dosage form is used. All HD drugs follow the requirements of USP 800 unless an assessment of risk (AOR) is performed. If an assessment of risk approach is taken, the entity must documents what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. The AOR minimally contains the type of HD, dosage form, risk of exposure, packaging, and manipulation considerations. The HD drug list & AOR is reviewed at least every 12 months and whenever a new agent or dosage form is used. [USP 800 Section 2] *Not currently available*	No
CONTAINMENT REQUIREMENTS: All antineoplastic HDs requiring manipulation and HD active pharmaceutical ingredients (APIs) on the NIOSH list follow all the requirements of USP 800. [USP 800 Section 2, Box 1] *Not currently compounding HD's*	N/A
HD HANDLING, RECEIPT & STORAGE SOPs: SOPs are created and followed for the safe handling of HDs used by the facility. [USP 800 Section 17] *SOP 7.2 'PPE, Receiving and Transport of Bulk HD API or Medications'*	N/A
HD HANDLING AREAS, SIGNAGE, & ACCESS: Signage designating HD handling areas are prominently displayed and access to HD handling areas is restricted to authorized personnel. Designated areas are available for receipt, unpacking, storage, and sterile compounding of HDs. [USP 800 Section 5] *Signage on HD Suite*	Yes
HD STORAGE: HDs are stored to prevent spillage or breakage, off floors, and in areas appropriate for natural disasters. Antineoplastic HDs and HD API are stored separately from non-HDs to prevent contamination and personnel exposure. HD storage areas are externally ventilated and negative-pressure rooms with at least 12 ACPH. Refrigerated antineoplastic HDs are stored in a dedicated refrigerator, in a negative pressure area with at least 12 ACPH. Pass through refrigerators are not used. [USP 800 Section 5.2] *Medrep tested the ACPH of negative HD prep room to be 26.99 ACPH from Jan 8, 2025 report*	Yes
STERILE HDs COMPOUNDED IN A C-SCA: C-SCA maintains a minimum of 12 ACPH of HEPA- filtered air and has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800, sections 5.3.2 Table 3]	N/A
C-SEC DESIGN AND ENGINEERING CONTROLS: The C-SEC has fixed walls physically separated from other preparation areas, is externally ventilated has 30 ACPH, and negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800 Section 5.3.2 Table 3] *per Jan 8, 2025 Medrep report, HD buffer room ACPH of 60.86, pressures are maintained*	Yes
C-SEC ACCESS: The Ante Room used for entry into the negative pressure buffer room has fixed walls and maintains a minimum of 30 ACPH of HEPA-filtered air, positive pressure of +0.02" w.c. to all adjacent unclassified areas, and ISO7 or better classification. Alternatively, a negative-pressure HD buffer entered exclusively through a positive pressure non-HD buffer room contains a line of demarcation (LOD) within the negative-pressure buffer room for donning/doffing HD PPE and a method a transport of HDs, HD CSPs, and HD waste into and out of the HD buffer (e:g., pass-through chamber). Pass through chambers are included in semi-annual facility certification. [USP 800 Section 5.3.2] *Aka HD gown in room documented as ISO 7 and ACPH of 57.55*	Yes
C-SEC SINK & SAFETY EQUIPMENT: A sink is available for hand washing and an eyewash station and/or other emergency safety precautions meeting applicable laws and regulations are readily available and located where operation does not interfere with ISO classifications. Sinks are located at least 1 meter from the entrance into the buffer room (or at least 1 meter from the C-PEC in a C-SCA). [USP 800 Sections 5.3 & 5.3.2] *Green eyewash station next to sink*	Yes
C-PEC LOCATION, VENTING, & OPERATION: All C-PECs used for sterile HD compounding (e.g., CACIs or BSCs), are located within a C-SEC or C-SCA, externally vented, and maintain an ISO 5 or better air quality. C-PECs operate continuously if supplying some or all the negative pressure in the C-SEC or if used for sterile compounding. During power outages, repairs, or relocation, C-PEC use is suspended immediately. Once C-PEC power is restored, all PEC surfaces are decontaminated, cleaned, and disinfected, and compounding is not resumed until the manufacturer's specified recovery time has elapsed. [USP 800 Section 5.3.2] *ESCO BSC is ventilated to the outside*	Yes
REQUIRED HD PPE: When compounding HDs, gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are donned per facility SOPs. Chemotherapy gloves are tested to ASTM standard D6978 (or its successor) and are powder free and two pair of chemotherapy gloves are donned per SOP. Gloves are inspected for physical defects. Gloves are changed when torn, punctured, or contaminated. Personnel wash hands with soap and water after removing gloves. HD gowns are disposable, resistant to permeability by HDs, close in back, are long sleeved, closed cuff, and seamless. Gowns are changed per manufacturer's permeation information; If no data is available, HD gowns are change every 2-3 hours or immediately after a spill or splash. Gowns are limited to HD handling areas and are donned over the sterile compounding garment. When compounding, a second pair of shoe covers is donned before entering the C-SEC and doffed when exiting the C-SEC. HD PPE is disposed of appropriately prior to exiting the C-SEC. Chemotherapy gloves and sleeve covers (if used during compounding) are carefully removed and discarded immediately into an appropriate waste container inside of the C-PEC or contained in a sealable bag for discarding outside of the C-PEC. Reusable PPE is decontaminated and cleaned after each use. [USP 800 Section 7] *Per Observation, cannot demonstrate proper donning of coverall as incorrect sizes acquired.* *Contec Critigear Nitrile sterile ASTM 6978 gloves*	No
EYE AND FACE PROTECTION: Appropriate eye (goggles) and face protection (face shield) are worn when there is a risk for spills or splashes or when working outside of a C-PEC. Surgical masks are not used when respiratory protection is required per SOP and/or AOR as protection from HD exposure. [USP 800 Section 7.4]	Yes
HD TRAINING & COMPETENCY ASSESSMENT: Personnel who handle HDs are trained and demonstrate competency initially before independently handling HDs, annually, and when a new HD medication, process, SOP, or equipment is introduced. Training minimally includes an overview of the entity's HD list and their risks; review of HD SOPs; proper use of PPE, equipment, and devices; prevention of HD exposures and spills; HD exposure and spill response; use of a spill kit, PPE, and NIOSH-certified respirators; and HD disposal. Based on job duties, personnel receive additional HD training in HD acquisition and receipt, preparation, compounding, dispensing, labeling, storage, and transport. Training and competency assessments are documented. [USP 800 Sections 8, 9, 11.1, 16, & 17] *Dates for SM 12/10/24 and AM 12/10/24 Competnecy assesment for HD storage handling, receiving, transporting, disposal and Assessment for HD general* *RPt must be retrained on proper use of PPE prior to initiating compounding.*	Yes
HD ATTESTATION: Personnel of reproductive capability have a written acknowledgement attesting to their understanding of HD handling risks. [USP 800 Section 8] *Signed Sept 2024*	Yes
DEDICATED HD EQUIPMENT: Disposable or cleanable equipment for compounding (e.g., mortar and pestle, graduated cylinder, spatulas) is dedicated for use with HDs. [USP 800 Section 13] *Dedicated equipment in prep-room*	Yes
NON-HD COMPOUNDING IN A C-PEC: Non-HDs compounded in a HD C-PEC are placed in protective outer wrapping, labeled for PPE handling precautions, and treated as an HD. The C-PEC worksurface is decontaminated between compounding of different HDs. [USP 800 Section 5.3.2 and Table 3]	N/A

DEACTIVATION, DECONTAMINATION, CLEANING & DISINFECTION (D/D/C/D): Areas where HDs are handled and all reusable equipment and devices are deactivated/decontaminated, and cleaned. Sterile compounding areas and devices are subsequently disinfected. Written procedures for decontamination, deactivation, cleaning, and disinfection are available and followed. Procedures include agents used, dilutions (if used), frequency, and documentation requirements. Agents selected are appropriate for the type of HD contamination(s), location, and surface materials. Sterile 70% IPA is used to remove residue left on sterile surfaces and compounding areas by decontaminating agents. [USP 800 Section 15] *SOP 7.4 'HD Spill, Deactivation and Waste Management'*	Yes
D/D/C/D TRAINING & PPE REQUIREMENTS: Personnel are trained in deactivation/decontamination, cleaning, and disinfection to protect themselves and the environment from contamination. Personnel wear appropriate PPE resistant to cleaning agents used, including 2 pairs of ASTM-tested chemotherapy gloves and impermeable disposable gowns. Eye protection and face shields are worn if splashing may occur. [USP 800 Section 15] *See 'Competency Assessment Hazardous Drug'*	Yes
C-PEC D/D/C/D: C-PEC is decontaminated at least daily (when used), after as spill, before and after certification, voluntary interruption, or if ventilation tool is removed. The C-PEC worksurface is decontaminated between compounding of different HDs. The area under the work tray of a C-PEC is deactivated, decontaminated, and cleaned at least monthly. [USP 800 Section 15.2] *Documented in 797 tool using Peridox*	Yes
HD LABELING, PACKAGING, TRANSPORT & SPILLS HANDLING: Facility follows SOP for the labeling, handling, packaging, and transport of HDs which addresses the prevention of spills/exposures, training for exposure, and spill handling. HD CSPs are identified as hazardous and labeled with special handling precautions. Labeling process for compounded HD products does not introduce contaminated materials into non-HD areas. [USP 800 Section 11 & 11.2] *No HD's compounded at this time*	N/A
SPILL KITS, & SINGAGE: Spill kits are readily available with appropriate supplies, PPE, and signs to restrict access to affected areas. restriction posted, and documentation of spills occur when needed. [USP 800 Section 16]	Yes

X. LYOPHILIZATION

Sterile preparations prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling, end transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	
A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times. [64B16-27.797(5) F.A.C.]	
The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.]	
The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.]	
Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]	
The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.]	
SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.]	
The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.]	
Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.]	
Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin. [64B16- 27.797(5) F.A.C.]	
Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product. [64B16- 27.797(5) F.A.C.]	
A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.]	
Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.]	
Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record. [64B16-27.797(5) F.A.C.]	
Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.]	
Potency, radiochemical purity, or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight-based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.]	

Y. SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

Technicians properly identified. [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16- 27.420 F.A.C.].	
Medication is properly labeled for dispensing to patient. [64B16-28.108(2) F.A.C.]	
Outdated medications removed from active stock. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	

INV797 USP Sterile Compounding

Insp # 203292 | **St. Luke Lab LLC** | **File # 30333**

Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality Related Events are available for inspection. [64B 16 27.300 F.A.C.]; [766.101 (1) (a)(l) F.S.]	
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	
Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] [21CFR1304.04]	
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) F.A.C]	
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]	
A special sterile products and parenteral/enteral compounding pharmacy provides telephone accessibility to its pharmacist(s) for its patients at all hours. [64B16-28.820(3)(b)]	
A special sterile products and parenteral/enteral compounding pharmacy provides special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. [64B16-28.820(3)(b)]	

Z. Miscellaneous

BLOOD-DERIVED OR BIOLOGICAL MATERIAL MANIPULATIONS: Compounding activities that require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum), are clearly separated from other compounding activities and equipment used in CSP preparation activities and controlled by specific SOPs to avoid cross-contamination. [USP 797 Section 1.1.2]	
ALLERGENIC EXTRACTS: Licensed allergenic extracts are mixed and diluted to prepare prescription sets for administration to patients. A prescriptions set is a vial or set or vials of premixed licensed allergenic extracts for subcutaneous immunotherapy that have been diluted with an appropriate diluent for an individual patient. Compounding allergenic extracts 1) minimally complies with all aspects of USP <797> Section 21; 2) involves transfer via sterile needles and syringes of conventionally manufactured sterile allergen products and appropriate conventionally manufactured sterile added substances; and 3) manipulations are limited to penetrating stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile vials. If these conditions are not met, compounding of allergenic extracts follows all aspects of USP <797>. [USP 797 Sections 1.1.2 and 21]	

Remarks:

Pharmacy will do mostly non-hazardous and hazardous sterile compounding-classifies as Category 2 compounder initially. No plans on terminal sterilization at this time. Please initiate all required testing prior to release of CSP's

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

CULLIPHER, MALA

Date:3/5/2025

Representative:

Andrew Mesiha

Date:3/5/2025

Your license number is PH 32747.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

Florida HEALTH

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
08/08/2025	PH 32747	155929

THE PHARMACY NAMED BELOW HAS MET ALL REQUIREMENTS OF THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Schedule II & III
Community Pharmacy

EXPIRATION DATE: FEBRUARY 28, 2027

ST. LUKE LAB, LLC
St Luke Compounding Pharmacy
9338 LITTLE RD
NEW PORT RICHEY, FL 34654

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for License Authentication

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
08/08/2025	PH 32747	155929

THE PHARMACY NAMED BELOW HAS MET ALL REQUIREMENTS OF THE LAWS AND RULES OF THE STATE OF FLORIDA.

ST. LUKE LAB, LLC
St Luke Compounding Pharmacy

Expiration Date: FEBRUARY 28, 2027

REGISTRANT SIGNATURE

Your license number is PH 35628.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

Florida HEALTH

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
08/08/2025	PH 35628	155930

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA

QUALIFICATION(S)
Special Sterile Compounding

EXPIRATION DATE: FEBRUARY 28, 2027

ST. LUKE LAB, LLC
St. Luke Compounding Pharmacy
9338 LITTLE ROAD
NEW PORT RICHEY, FL 34654

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

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STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
08/08/2025	PH 35628	155930

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA

ST. LUKE LAB, LLC
St. Luke Compounding
Pharmacy

Expiration Date: FEBRUARY 28, 2027

REGISTRANT SIGNATURE

September 3, 2025

St Luke Lab, Llc
9338 Little Rd
New Port Richey, FL 34654

RE: License Certification for Andrew Emil Makram Hanna Mesiha

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health:

PROFESSION:	Pharmacist
LICENSE NUMBER:	PS59672
ORIGINAL CERTIFICATION:	08/07/2019
EXPIRATION DATE:	09/30/2027
CURRENT STATUS OF LICENSE:	Clear, Active
AGENCY ACTION:	No
LICENSE GRANTED BY:	N/A
OTHER CERTIFICATIONS:	Certified To Administer Immunizations

To expedite the verification process, the above format is the standard format for all license certifications. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Michelle Burns
Michelle Burns
Operations and Management Consultant Manager

September 3, 2025

St Luke Lab, Llc
9338 Little Rd
New Port Richey, FL 34654

RE: License Certification for Andrew Emil Makram Hanna Mesiha

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Sincerely,

Michelle Burns
Michelle Burns
Operations and Management Consultant Manager

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	1880521		Inspection Information
Legal Business Name:	St. Luke Lab, LLC	Conference Call Date:	6/16/2025
Doing Business As (DBA):	St. Luke Pharmacy	Start Time: 24-hour format (13:00)	15:00
Address:	9338 Little Rd	End Time: 24-hour format (13:00)	16:20
City:	New Port Richey	Onsite Inspection Date(s):	06/18/2025; 06/19/2025; 06/20/2025
State:	Florida	Start Time(s): 24-hour format (13:00)	13:40; 09:30; 08:00
Zip Code:	34654	End Time(s): 24-hour format (13:00)	16:40; 16:45; 11:34
Telephone number:	727/416-2006	Inspector Name(s):	Glenn Bolyard, RPh
Toll free number:	877/310-5668	Inspection performed by (NABP, State, etc):	NABP
Fax number:	727/416-2007	Observer Name/Affiliation (if applicable):	N/A
Website:	www.stlukecompounding.com	Observer Name/Affiliation (if applicable):	N/A

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open Start Time: (24-hour format)	End Time: (24-hour format)	Closed (X)
Sunday			X
Monday	9:00	17:00	
Tuesday	9:00	17:00	
Wednesday	9:00	17:00	
Thursday	9:00	17:00	
Friday	9:00	17:00	
Saturday			X

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Andrew Mesiha	admin@stlukecompounding .com	1327432
Nonsterile Designated person(s)	Andrew Mesiha	admin@stlukecompounding .com	1327432
Sterile Designated person(s)	Andrew Mesiha	admin@stlukecompounding .com	1327432
Hazardous Designated person(s)	Andrew Mesiha	admin@stlukecompounding .com	1327432

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Silvana Awadalla	Pharmacy Intern	Y
2	Sahar Mikhail	Pharmacy Technician	Y
3	Andrew Mesiha	PIC	Y
4			
5			
6			
7			
8			
9			
10			

There were no other personnel present at time of inspection.

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Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Drug Enforcement Administration	St. Luke Lab LLC	Pharmacy	[redacted] & 02/28/2027
Florida Board of Pharmacy	St. Luke Lab St. Luke Pharmacy	Pharmacy	PH32747 & 02/28/2027
Florida Board of Pharmacy	St. Luke Lab LLC	Sterile Compounding	PH35628 & 02/28/2027

Inspector Notes: This pharmacy opened 3/6/2025 and is owned by the PIC and 3 other pharmacists. There is a co-owned retail pharmacy next door. Pharmacy is not applying for a license in Massachusetts at this time. Pharmacy does not have a license in any other state or Puerto Rico. Pharmacy does not stock ReliOn insulin. Pharmacy does not compound biologicals. The pharmacy does not use any platforms that are a marketplace for pharmacies to buy, sell, and bid on overstock and short date prescription drugs. The pharmacy does compound tirzepatide using the base. COA, MFR, CR for tirzepatide are Doc03_PI and Photo01_PI - Photo03 are of API.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01_HD1.01	Hazardous drug active pharmaceutical ingredients.
Doc02_PI	The documents include COA examples for manufacturers.
Doc03_PI	The documents include COA, MFR and CR for tirzepatide base used for CSP.
Photo01_PI; Photo02_PI; Photo03_PI	Photographs of tirzepatide base API.
N/A	N/A

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Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply.	
Traditional retail		Central Fill/Processing/Shared Services	
Open to the Public	X	Nuclear Pharmacy	
Closed Door		Specialty Pharmacy	
Drive-through window		White bagging/ clear bagging	
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*		FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)	X	Wholesale Distributor	
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)	X	Provide prescription drugs for "Office Use" (eg distributes)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	X
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	X
Telepharmacy		Sterile Compounding	X
Internet Pharmacy		Sterile Hazardous Drug Compounding	X

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)	X	CSPs with controlled substance(s)	X
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	
CNSPs sold to other pharmacies - If so, list to whom - instate, out of state, under common ownership/shared services – central fill agreement, and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement, and state if patient specific or distributed	
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals	X	CSPs for animals	
CNSPs for human patients	X	CSPs for human patients	X
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous	X	Category 1 CSPs	
Nonaqueous	X	Category 2 CSPs	X
Specific types:		Category 3 CSPs	
Solid oral preparations	X	Types of CSPs:	
Liquid oral preparations	X	Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	
Topical preparations:	X	Blood-derived or other biological material (eg autologous serum)	
Nasal and sinus preparations:		Sterile injections/ sterile infusions	X
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/ Pellets	
		Other (please list):	

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	Facility Size in Square Feet *(can be approximated)* and Number of PECs		Personnel
Total Pharmacy size:	1,800	Total Pharmacists:	1
Nonsterile Compounding Room size:	110	Number of Compounding Pharmacists:	1
Nonsterile Compounding powder hoods number:	3	Total Student Interns:	1
Nonsterile Hazardous Drugs (HD) Compounding Room size:	140	Total Technicians:	1
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	2	Number of Compounding Technicians:	1
Sterile Compounding Ante Room size:	60	Of technicians, how many are nationally certified?	1
Sterile Compounding Clean/Buffer Room size:	210	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number LAFW hoods/areas:	1	Total Other Unlicensed Personnel:	1
Sterile Compounding Number BSC hoods:	1	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	1:1
Sterile Compounding Number CAI/CACI hoods:	0	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs:	N/A
Negative Pressure Sterile HD Room size:	85		
Sterile HD Compounding Number of BSC hoods:	1		
Sterile HD Compounding Number of CACI hoods:	0		

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	Inspector fully garbed and entered buffer rooms and nonsterile HD.

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	25	Total Orders Distributed/day:	0
% Veterinary Prescriptions	1%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	2%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	60%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	40%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	30%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)			
Alaska (AK)			
Arizona (AZ)			
Arkansas (AR)			
California (CA)			
Colorado (CO)			
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)	476	0	May 2025
Georgia (GA)			
Hawaii (HI)			
Idaho (ID)			
Illinois (IL)			
Indiana (IN)			
Iowa (IA)			
Kansas (KS)			
Kentucky (KY)			
Louisiana (LA)			
Maine (ME)			
Maryland (MD)			
Massachusetts (MA)			
Michigan (MI)			
Minnesota (MN)			
Mississippi (MS)			
Missouri (MO)			
Montana (MT)			

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States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)			
Nevada (NV)			
New Hampshire (NH)			
New Jersey (NJ)			
New Mexico (NM)			
New York (NY)			
North Carolina (NC)			
North Dakota (ND)			
Ohio (OH)			
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)			
Rhode Island (RI)			
South Carolina (SC)			
South Dakota (SD)			
Tennessee (TN)			
Texas (TX)			
Utah (UT)			
Vermont (VT)			
Virginia (VA)			
Washington (WA)			
West Virginia (WV)			
Wisconsin (WI)			
Wyoming (WY)			
Other			

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General Pharmacy Inspection

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Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Notes
General Pharmacy			
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	40
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	N/A	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	N/A	
8.00	Are photographs allowed during the inspection (**no PHI**)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**	[redacted]	Sahar Mikhail, Compounding Technician and Silvana Awadalla, Pharmacy Intern

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Facility Name: SL Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Notes
Types of Practice Additional Questions If any part of a question is no, enter "No" and explain the observation.			
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	No	
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, end volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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		Observation	Notes
General Operations and Licensure — If any part of a question is no, enter "No" and explain the observation.			
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	Florida Board of Pharmacy inspected on 3/5/2025 and inspect yearly.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	Yes	Deficiencies noted included: 1. Incomplete label requirements 2. Coverall size was 3XL and was too big for compounder 3. Number of personnel present was not noted for certifications. 4. No documentations that DP reviewed 3 certification reports. 5. Use of sterilization filter beyond capacity and no bubble point testing documented. 6. End time not listed on autoclave log per SOP. 7. List of HD and assessment of risk was not present. Deficiencies were corrected.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	

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Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Notes
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	No	
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	This is a new pharmacy but SOP states 2 years on site.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronic
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronic
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronic
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	Andrew Mesiha PIC is responsible for ensuring the most stringent laws/regulations are followed. He stated his computer system will automatically update with any changes.

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		Observation	Notes
	Personnel If any part of a question is no, enter "No" and explain the observation.		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Licenses renewals are printed yearly and kept in license binder.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	Andrew Mesiha verifies licenses yearly.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	1:1 Maximum number of staff who work at the same time is 2.
	Facility and Security If any part of a question is no, enter "No" and explain the observation.		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	ADT monitors with motion detectors, contact magnets on doors, cameras and glass break alarm.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	N/A	There are no Schedule II drugs.
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	Emergency plan in their P&P. Contractor would secure building and a pharmacist would be on site until it was done. Drugs could be moved to one of the other common ownership retail pharmacies in greater Tampa area.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	

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		Observation	Notes
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Trilogy MedWaste
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Trilogy MedWaste empties the bins when the pharmacy requests.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	There is a room that can be used for counseling to the right inside the front door.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	71°F
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	Elitech Technology Inc. monitors temperatures 24/7 and alerts Andrew Mesiha if there are any excursions beyond set ranges via cell phone and email.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	The pharmacy does not carry any refrigerated medications.

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		Observation	Notes
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	N/A	
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	The range is between −25° to −10°C or −13° to 14 °F. Excursions are sent to Andrew Mesiha cell phone and emailed to the pharmacy. Records are maintained indefinitely.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	Yes	5.2°F
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	There are 5 other pharmacies in the Tampa area that have shared ownership where the drugs can be moved until a new freezer is obtained or the power is fixed.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	Andrew Mesiha would work with local contractor to fix the issue. If necessary, the drugs can be moved to another pharmacy with common ownership.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	No	
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	

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		Observation	Notes
Product Receipt and Inventory	**If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	FDA registered and inspected vendors are the only sources utilized by the pharmacy. Andrew Meshia is responsible for vetting all vendors.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	Yes	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	No	
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	N/A	
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	N/A	
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	Yes	Andrew Mesiha validates all manufacturers through Florida Board of Pharmacy website.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	Yes	Andrew Mesiha checks the FDA Wholesaler Distributor database on line to verify.
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	If a suspect product is detected, it is segregated and an investigation is opened with the manufacturer.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	None to date.

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		Observation	Notes
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	Yes	
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	N/A	There are no Schedule II drugs.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	N/A	
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	Perpetual inventory to monitor inventory levels on high risk medication.

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		Observation	Notes
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	Florida Board of Pharmacy and DEA.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	N/A	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	N/A	
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	2/27/2025 and taken yearly.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	Monthly and includes OTC.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	Examined

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: St. Luke Lab, t.L.C dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Notes
60.02	How often is active-stock examined for drugs past the expiration date?	[redacted]	Monthly
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	Yes	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	Yes	

Prescription Processing

If any part of a question is no, enter "No" and explain the observation.

64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Technician checks and updates on each fill date.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	Yes	Computer signifies its an animal and logs owners names in patient profile.
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and raporting process.*	Yes	Contact the prescriber and verify the prescription. Watch for red flags.

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Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Notes
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	The pharmacist would contact the physician and ask for clinical data to support the prescription. The pharmacist would also compare the addresses of patient and physician.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Both
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	The pharmacist verifies all information that the technician enters at data entry.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	The technician performs data entry and the pharmacist verifies this information/performs DUR. The technician compounds the prescription and the pharmacist does final verification of the product.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	Yes	Pharmetika
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	

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Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Notes
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	Computer software reports PMP information daily to Florida.
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	Only the pharmacist can override a DUR and it is documented in patient profile.
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	Pharmetika
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	Yes	Pharmetika
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	The technician performs data entry and the pharmacist verifies this information/performs DUR. The technician compounds the prescription and the pharmacist does final verification of the product.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	All labels meet federal requirements.
70.00	**Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	Pharmetika

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Facility Name: SL Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Notes
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	

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		Observation	Notes
Patient Counseling and Communication	**If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all new prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
75.01	Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	Technician and pharmacist
76.00	Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	Technician and pharmacist
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	No	
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	Yes	Technician and pharmacist
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Patient is called before delivery and counseling is offered over the phone. There is also a handout that is in the packaging with phone number to contact the pharmacist.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Patient is called before delivery and counseling is offered over the phone. There is also a handout that is in the packaging with phone number to contact the pharmacist.

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		Observation	Notes
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	Computer system automatically prints.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	Yes	Their computer system has the capability to automatically print when the drug is dispensed.
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	N/A	The pharmacy does not dispense these medications.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	This is documented in notes section of the patient profile.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	Yes	Pharmacist cell phone is listed. Toll free number goes directly to pharmacist cell phone.
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	

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Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Notes
Quality Assurance/Quality Improvement Program	**If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	Andrew Mesiha
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	Both
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	N/A	Pharmacy has only been opened since 3/6/2025 but it is in SOP.
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Both
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	

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		Observation	Notes
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	Andrew Mesiha analyzes data with each event.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	Yes	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	

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		Observation	Notes
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	Florida Board of Pharmacy
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	Yes	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	Yes	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

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Nonsterile Compounding Inspection for USP <795>

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)		Please note NABP did not review each SOP for alignment on USP<795>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.	
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes		11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. ***Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.***		SOP 8.7 Nonsterile Area Requirements	4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. ***Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."***		SOP 8.8 Nonsterile Compounding Training and Evaluation	2, 11
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. ***Inspector note: Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."***		8.9 Personnel Hygiene and Garbing for Nonsterile Compounding	3.3, 11
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. ***Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."***		5.1 Inventory Storage and Handling	6.2, 11

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Nonsterile Compounding Inspection for USP <795>

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		Observation	Inspector Notes	USP Reference(s)
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. ***Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."***		5.1 Inventory Storage and Handling	4.2, 11
1.6	**Equipment:** The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). ***Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."***		8.7 Nonsterile Area Requirements	6.1, 11
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. ***Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."***		9.2 General Spill Management (nonHD)	6.2.5, 11
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. ***Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."***		SOP 3.10 MFR (Master Formulation Record)	7.1, 11
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. ***Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."***		SOP 9.3 Labeling of CNSP	9, 11

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel, adherence to procedures, and prevention and detection of errors and quality issues. ***Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."***		SOP 9.4 Quality Program for CNSP	11, 12 USP <1163>
1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. ***Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."***		SOP 8.1 CQI (Continuous Quality Improvement	1.1.3, 11, 12.1, 12.2, 12.3
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. ***Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs:"***		SOP 5.3 Packaging and Delivery of Compounded Medications	11, 13.1
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. ***Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."*** ***If the pharmacy does not transport CNSPs, inspector should answer statement as N/A.***		SOP 5.3 Packaging and Delivery of Compounded Medications	11, 13.2

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		Observation	Inspector Notes	USP Reference(s)
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. ***Inspector note: Per USP, "The facility must have procedures in place to:*** ***- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)*** ***- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy*** ***- Investigate if other lots are affected and recall if necessary*** ***An SOP for recall of dispensed CNSPs must contain:*** ***- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall*** ***- Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution*** ***- Procedures to identify patients who have received the CNSP*** ***- Procedures for disposal and documentation of the recalled CNSP (and)*** ***- Procedures to investigate and document the reason for recall."***		SOP 8.3 Recalls	12.1
	Designated Person(s) and Personnel Training Program Inspector must complete the <795> Records Review module to complete this section.			
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If no, go to compliance statements.***	Yes		1.1.4
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		1.1.4, 12

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		Observation	Inspector Notes	USP Reference(s)
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***	Yes		1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes		1.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes		1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	Yes		1.1.4
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Yes		1.1.4, 11
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.	Yes		1.1.4
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If no, go to compliance statements.***	Yes	There are only 2 compounding employees records to review, since new pharmacy.	2, 14

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		Observation	Inspector Notes	USP Reference(s)
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes		2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes		2, 14
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** ***If questions 2.0-2.12 in the records review tab for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered no. For details, see the Records Review module.***	Yes		2, 14
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*** ***Inspector should complete the <795> Records Review module question 3.0.***	Yes		2, 14

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		Observation	Inspector Notes	USP Reference(s)
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***	Yes		
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.	Yes		3
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***	Yes		3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.	Yes		3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.	Yes		3.2 Box 1

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		Observation	Inspector Notes	USP Reference(s)
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***	Yes		3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.	Yes		3.3
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***	Yes		3.3
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.	Yes		3.3
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).	Yes		3.3
6.7	Gowns that are reused do not leave the compounding area.	Yes		3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).	Yes		3.3
6.9	Soiled garb is disposed of or sent for laundering.	Yes		3.3
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.	Yes		3.3
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.	Yes		4.1
8.2	The compounding area is well lit.	Yes		4.1
8.3	The compounding area is clean and sanitary.	Yes		4.1
8.4	The compounding area is orderly (eg, clutter-free, no tripping hazards).	Yes		4.1
8.5	The compounding area is in a good state of repair.	Yes		4.1
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix-ups among components, containers, labels, in-process materials, and finished CNSPs.	Yes		4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes		4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.	Yes		4.1
9.0	Is the compounding area free of carpet?	Yes		4.1

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		Observation	Inspector Notes	USP Reference(s)
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes	Temperatures are monitored continuously.	4.2
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."***	Yes		4.2
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.*** ***Monitoring devices are typically calibrated or replaced.***	Yes		4.2
10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."***	Yes		4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2

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		Observation	Inspector Notes	USP Reference(s)
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.	Yes		4.2
11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***	[redacted]	71°F	4.2
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.	Yes		4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.	Yes		4.3
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***	Yes	Purified water	4.3 USP <1231>

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		Observation	Inspector Notes	USP Reference(s)
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***		PREempt RTU and Contec IPA 70%	5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If no, go to compliance statements.***	Yes	Compounding cleaning logs reviewed.	5 Table 1
15.1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.	Yes		5 Table 1
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.	Yes		5 Table 1
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components.**	Yes		5 Table 1
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.	Yes		5 Table 1
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***	Yes		5 Table 1
15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.	Yes		5 Table 1
15.7	Storage shelving is cleaned and sanitized at least every three months.	Yes		5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
	Equipment and Components FDA defines manufacturer... as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes the activities of relabelers, repackers, and salvagers. When not modified by "domestic" or "foreign," the term includes both domestic manufacturers and foreign manufacturers.			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***	Yes	BSC and Laminar Flow Powder Hood	6.1
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If no, go to compliance statements.***	Yes	Reviewed	6.1
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***	Yes		6.1
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."*** ***If no, inspector should describe observations.***	Yes		6.1

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		Observation	Inspector Notes	USP Reference(s)
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:*** ***- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;*** ***- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;*** ***- Under the work surface of a BSC is cleaned and sanitized at least monthly; and*** ***- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.*** ***If no, inspector should describe observations.***	Yes		6.1 Table 2
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***	Yes		6.1
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***	Yes		6.1
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***	Yes		6.1

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		Observation	Inspector Notes	USP Reference(s)
19.0	Does the pharmacy compounding CNSPs use APIs?	Yes		6.2
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*** ***If no, go to compliance statements.***	Yes	COAs provided and reviewed.	6.2.1
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***	Yes		6.2.1
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***	Yes		6.2.1
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. Inspector should verify the pharmacy looks up the name of the manufacturer listed on the COA to determine if they are registered as an FDA drug establishment https://dps.fda.gov/decrs.***	Yes		6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	Yes	Sterile water for irrigation	6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***	[redacted]	Sterile water for irrigation	6.2.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
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		Observation	Inspector Notes	USP Reference(s)
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.2
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***	Yes		6.2.2
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	Yes		6.2.2, 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations 797 , 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***	Yes		6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		6.2.2
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.	Yes		6.2.2

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		Observation	Inspector Notes	USP Reference(s)
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.3, 6.2.4
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).	Yes		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	Yes		6.2.3
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.	Yes		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.	Yes		6.2.4
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***	Yes		6.2.4

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		Observation	Inspector Notes	USP Reference(s)
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).	Yes		6.2.5
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	Yes		6.2.5, 14
26.3	The pharmacy has a readily accessible spill kit in the compounding area.	Yes		6.2.5
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.	Yes		6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.5
	Master Formulation Records (MFR) and Compounding Records (CR) Inspector should review a minimum of five (5) MFRs and five (5) CRs.			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If no, go to compliance statements.***	Yes		7.1
27.1	An MFR is created for each unique formulation.	Yes		7.1 Box2
27.2	Any changes or alterations to the MFR are approved and documented.	Yes		7.1

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		Observation	Inspector Notes	USP Reference(s)
27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***	Yes		7.1, 10.2 Table 4
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***	Yes		7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	Yes		7.1
28.3	MFR includes the type of container–closure system(s).	Yes		7.1

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		Observation	Inspector Notes	USP Reference(s)
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***	Yes	Reviewed	7.1
28.5	MFR has a physical description of the final CNSP.	Yes		7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	Yes		7.1
28.7	MFR contains the reference source to support the assigned BUD.	Yes		7.1
28.8	Labeling requirements (eg, shake well) are described on the MFR.	Yes		7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	Yes		7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.	Yes		7.1
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***	Yes		7.2, 14
29.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.2, 14

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		Observation	Inspector Notes	USP Reference(s)
29.3	The CR includes the date (or date and time) the CNSP was prepared.	Yes		7.2, 14
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).	Yes		7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes		7.2, 14
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.	Yes		7.2, 14
29.8	The CR includes the weight or measurement of each component.	Yes		7.2, 14
29.9	The CR identifies the total quantity compounded.	Yes		7.2, 14
29.10	The CR lists the assigned BUD and storage requirements.	Yes		7.2, 14
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.	Yes		7.2, 14
29.12	The CR has a physical description of the final CNSP.	Yes		7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	Yes		7.2, 14
29.14	The CR contains a MFR reference for the CNSP.	Yes		7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.	Yes		7.2, 8
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.	Yes		7.2, 12.1, 14

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		Observation	Inspector Notes	USP Reference(s)
30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation. Inspector should describe their observations in the Inspector Notes.***	Yes	The technician showed the pharmacist through the window the measuring of an API before the compound was finished. An iPad is also used to take pictures for the pharmacist to verify.	2, 7.2, 8
	Labeling			
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		9
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."***	Yes		9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).	Yes		9
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		9
31.6	The label on the immediate container includes the BUD. ***If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***	Yes		9

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		Observation	Inspector Notes	USP Reference(s)
31.7	The label on the immediate container includes the dosage form.	Yes		9
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.	Yes		9
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***	Yes		9
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? ***Inspector note: Per USP, this is a recommendation.***	Yes		9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***	Yes		9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CNSP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.*** ***If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A.***	Yes		9
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date."*** ***If no, go to compliance statements.***	Yes		10 USP <7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.	Yes		10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.	Yes		10.1

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		Observation	Inspector Notes	USP Reference(s)
36.3	BUDs are assigned from the date (and time) of preparation.	Yes		10.1
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***	Yes		10.3
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		10.4
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If no, who establishes the maximum BUD for a MFR?***	Yes		7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?	Yes		10.5

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		Observation	Inspector Notes	USP Reference(s)
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If no, go to compliance statements.***	Yes		10.5
40.1	Pharmacy staff have access to the USP monograph for reference.	Yes		10.5
40.2	CNSPs are prepared in accordance with the USP monographs. ***If no, inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed.***	Yes		10.5
40.3	Components used by the compounder match those listed in the monograph. ***If no, describe the source of the component in monograph and the source that the pharmacy used.***	Yes		10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. ***If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.***	Yes		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	Yes		10.4
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? ***Inspector note: This question is for the CNSPs compounded that are <u>not</u> following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.*** ***If no, go to compliance statements.*** ***If <u>all</u> CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.***	N/A		10.4

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		Observation	Inspector Notes	USP Reference(s)
42.1	**Non-preserved, Aqueous Dosage Forms:** The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.*** ***If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>

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		Observation	Inspector Notes	USP Reference(s)
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?	No		10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If no, go to compliance statements.***	N/A		10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	N/A		10.5
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	N/A		10.5
44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.*** ***If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study.*** ***If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.***	N/A		10.5

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.***	N/A	BUD are not extended.	10.5
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***	Yes		1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***	Yes		12
45.2	The QA/QC programs address adherence to procedures.	Yes		12
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.	Yes		12

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		Observation	Inspector Notes	USP Reference(s)
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***	Yes	There were no complaints so reviewed the process.	12
45.5	The QA/QC programs address appropriate investigations and corrective actions.	Yes		12
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?	No		12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.2
47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."***	Yes		12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes		12.2
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.	Yes		12.2
47.4	Complaints are fully investigated.	Yes		12.2
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***	Yes		12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 12.2
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.*** ***Review most recent recall and describe in the Inspector Notes.*** ***If the pharmacy has not had any recalls within the past two years, inspector should answer the question as No.***	No		12.1, 14
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.1, 12.2, 12.3
49.1	The pharmacy has procedures to determine when recalls must be initiated.	Yes		12.1
49.2	The pharmacy documents the implementation of the recall.	Yes		12.1
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).	Yes		1.1.3, 12.1
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	Yes		12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***	Yes		12.1

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		Observation	Inspector Notes	USP Reference(s)
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If no, go to compliance statements.***	Yes		13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).	Yes		13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).	Yes		13.1
	Compounding Personnel Observations - *Inspector must observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with two creams or other drugs) as long as all observations can be viewed.*			
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).	Yes		3.1
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	Yes		3.1
54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.2, Box 1
54.1	All personnel who enter the compounding area to compound performed hand hygiene.	Yes		3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3 Box 1
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3 Box 1
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***	Yes		3.2, 3.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration.		Testosterone 50mg/gm in Cream	
58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		2 Box 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.	Yes		3.1, 4.1
58.2	The compounding personnel started with a clean compounding area for CNSPs.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.	Yes		7, 7.1 Box 2
58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***	Yes		6.2 (6.2.1 - 6.2.5)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***	Yes		6.1 Table 2

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		Observation	Inspector Notes	USP Reference(s)
58.8	The compounding personnel have knowledge of and access to any SDS.	Yes		6.2
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes		1.1.3
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***	Yes		7.1, 7.2 Box 2
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***	Yes		7.2, 14 Box 3
58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***	Yes		14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If no, describe observations in Inspector Notes.***	Yes		7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.	Yes		8.1 Box 2
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***	Yes		9

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		Observation	Inspector Notes	USP Reference(s)
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***	Yes		7.2, 8, 14 Box 3
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	Yes		5
59.0	**Final CNSP check observation:** Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If no, go to compliance statements.***	Yes	Testosterone 50mg/gm in Cream; Methimazole 5mg/0.1ml cream	8, 8.1, 9
59.1	CNSP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).	Yes		8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
59.3	CNSP label was verified against the prescription or medication order.	Yes		8, 8.1, 9
59.4	CNSP label was verified against the MFR.	Yes		8, 8.1, 9
59.5	CNSP label was verified against the CR.	Yes		8, 8.1, 9
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	Yes		8, 8.1
59.7	All checks and inspection that are performed are properly documented.	Yes		8.1, 14

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		Observation	Inspector Notes	USP Reference(s)
59.8	CNSP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal	Yes		8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12
61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If no, go to compliance statements.***	Yes		5
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	Yes		5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***	Yes		5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).	Yes		6.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	Yes		5 Table 1

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Nonsterile <795> Employee File Records Review

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. Do not record the employee name, list only their title or position.
From the drop-down List:
*Mark as "Yes" if the document is present in the records and the competency evaluation was conducted in compliance with USP <795> requirements.
*Mark as "No" if the document is present in the records but is not in compliance with USP <795> requirements.
*Mark as "Missing" if any part of the record is missing and explain in Notes column.
*Mark as "N/A" if the training does not apply (eg, long-term employee may not have initial training available). Document further in the Notes column.

		Employee Records #1	Employee Records #2	Employee Records #3	Employee Records #4	Employee Records #5	
	Employee Title	PIC	Technician				Notes
1.0	The training program provides initial training, evaluation, and documentation on the core competencies listed below:						
1.1	Compounding personnel are trained on facility SOPs.	Yes	Yes				
1.2	Compounding personnel are trained on USP <795> standards.	Yes	Yes				
1.3	The training record for hand hygiene is complete.	Yes	Yes				
1.4	The training record for garbing is complete.	Yes	Yes				
1.5	The training record for cleaning and sanitizing is complete.	Yes	Yes				
1.6	The training record for handling and transporting components and CNSPs is complete.	Yes	Yes				
1.7	The training record for measuring and mixing is complete.	Yes	Yes				
1.8	The training record for proper use of equipment is complete.	Yes	Yes				
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes				
1.10	The training record for interpreting a Certification of Analysis (COA) is complete.	Yes	Yes				
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete.	Yes	Yes				
1.12	The training record for spill management is complete.	Yes	Yes				

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	Employee Title	PIC	Technician				Notes
2.0	The annual competency assessment was evaluated and documented on the following topics:						New pharmacy--only open since 3/6/2025
2.1	Compounding personnel are re-trained on facility SOPs.	N/A	N/A				
2.2	Compounding personnel are re-trained on USP <795> standards.	N/A	N/A				
2.3	The annual competency assessment for hand hygiene is complete.	N/A	N/A				
2.4	The annual competency assessment for garbing is complete.	N/A	N/A				
2.5	The annual competency assessment for cleaning and sanitizing is complete.	N/A	N/A				
2.6	The annual competency assessment for handling and transporting components and CNSPs is complete.	N/A	N/A				
2.7	The annual competency assessment for measuring and mixing is complete.	N/A	N/A				
2.8	The annual competency assessment for proper use of equipment is complete.	N/A	N/A				
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	N/A	N/A				
2.10	The annual competency assessment for interpreting a COA is complete.	N/A	N/A				
2.11	The annual competency assessment for how to read/interpret a SDS is complete.	N/A	N/A				
2.12	The annual competency assessment for spill management is complete.	N/A	N/A				
3.0	The designated person(s) has documented a (periodic) evaluation of their direct observations for compounding activities and documented any deficiencies in the record. *Inspector note: if there are not observations documented, the inspector should answer this question as N/A.* *Per USP, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*	Yes	Yes				

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Glossary & References	USP <795>
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as a bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added Substance	An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient.
Administration	The preparation of a nonsterile pharmacologic or other therapeutic agent for ingesting, inserting, applying, or otherwise providing a nonsterile medication in its final form to a single patient. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.
Alcohol-based hand rub	An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Assigned trainer	One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CNSPs.
Beyond-use date (BUD)	The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.
Biological Safety Cabinet (BSC)	A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
Bulk drug substance	See the entry for Active Pharmaceutical Ingredient.
Certificate of analysis (COA)	A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
Cleaning	The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleaning agent	An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Closed-system processing device	A device designed to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples include CVEs, BSCs, or single-use containment glove bags.
Component	Any ingredient used in the compounding of a preparation, including any API, added substance, or conventionally manufactured product.
Compounded nonsterile preparation (CNSP)	A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.

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Glossary & References	USP <795>
Compounding	The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.
Compounding area	An area that is specifically designated for nonsterile compounding.
Compounding personnel	Personnel trained to compound or oversee compounding of preparations.
Compounding record (CR)	Documents the compounding of each CNSP.
Container closure system	Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.
Containment glove bag	A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE)	A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high- efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
Conventionally manufactured product	A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Designated person(s)	One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs.
FDA	US Food and Drug Administration
Formulation	The specific qualitative and quantitative composition of the final CNSP.
Hazardous Drug (HD)	Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low dose in humans or animals; genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See <800>.
Label	The part of the labeling on the immediate container.
Labeling	All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container.
Master formulation record (MFR)	A detailed record of procedures that describes how the CNSP is to be prepared.
Monograph	A quality documentary standard within USP–NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Oversight	The review, monitoring, and supervision of actions taken by personnel; bearing responsibility for those actions; and being available if and when needed for consultation, even if not physically present.
Preservative	A substance added to inhibit microbial growth.
Purified water	The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). This source water may be purified using unit operations that include deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See <1231>, 3.1.1 Purified Water.)

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Glossary & References	USP <795>
Quality Assurance (QA)	A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
Quality Control (QC)	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CNSP.
Reconstitution	The process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.
Release inspection and testing	Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Sanitizing agent	An agent for reducing, on inanimate surfaces, the number of microorganisms (eg, 70% isopropyl alcohol).
SDS	Safety data sheet.
SOP	Standard operating procedure.
Specification	The tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.
Stability	The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Verify	To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Water activity (a_w)	A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Note that a_w is not water content.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)		**Please note NABP did not review each SOP for alignment on USP <797>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have a designated person(s) who meets the requirements in compliance with USP <797> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals (ie, the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions." If no, go to compliance statements.***	Yes		1.1.3, 2
1.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		18
1.2	The designated person(s) is responsible and accountable for the performance and operation of the facility. ***Per USP, "The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality."***	Yes		2, 4.2, 4.5

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		Observation	Inspector Notes	USP Reference(s)
1.3	The designated person(s) is responsible for personnel performing sterile compounding or other related functions (eg, quality checks and prescription dispensing of compounded preparations).	Yes		2, 17
1.4	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented.	Yes		2, 17
1.5	The designated person(s) ensures that SOP revisions are implemented.	Yes		2, 17
1.6	The designated person(s) communicates all SOP revisions to all impacted personnel. ***Inspector note: USP <797> recommends that personnel should also document acknowledgment and communication of SOP changes and revisions.***	Yes		2, 17
1.7	The designated person(s) ensures that personnel demonstrate competency in performing every procedure that relates to their job function.	Yes		2, 17
1.8	The designated person(s) ensures that corrective actions are taken if problems, deviations, out-of-range results, failures, or errors are identified. ***Inspector note: Per USP, "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective."***	Yes		2, 5, 12

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		Observation	Inspector Notes	USP Reference(s)
2.0	Has the pharmacy developed and implemented SOPs that describe sterile compounding processes and other support activities in compliance with USP <797> standards? ***Inspector note: In order for this to be answered yes, all topics must be addressed if applicable to their business practices.*** ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes		17
2.1	**Scope of Practice:** Types of CSPs that are prepared (eg, immediate use, allergenic extracts, Category 1, Category 2, Category 3). Roles and responsibilities of the designated person(s).		SOP 1.40 Facility and Personnel Specifications	1.5
2.2	**Personnel Training and Evaluation:** Description of initial and ongoing training and competency for the designated person(s), compounding personnel, personnel with direct oversight of compounding personnel, and personnel who only perform restocking or cleaning, and disinfecting duties outside of the primary engineering control (PEC). Description of media-fill testing procedures, hand hygiene and garbing competency, and aseptic manipulation competency. Training and competency assessment of personnel on all sterilization methods and equipment used by the facility. Frequency of training is defined.		SOP 4.2 Orientation, Training, and Evaluation	2, 2.2, 10 Box 1, Box 2, Table 2, Table 3
2.3	**Personal Hygiene and Garbing:** Description of the required garb, manner of storage, and order of garbing, including disinfection procedures for reusing goggles, respirators, and other reusable equipment. ***Inspector note: Per USP, the RABS (or pharmaceutical isolator) sleeve and glove changes should (not required) be changed per the manufacturer's recommendations and defined in the facility's SOPs.***		SOP 4.1	3, 3.3

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		Observation	Inspector Notes	USP Reference(s)
2.4	**Facility Design and Engineering Controls:** Description of design requirements to maintain air quality standards and procedures for evaluating, maintaining, and certifying the areas used for compounding.		SOP 3.2	4, 4.2
2.5	**Certification and Recertification:** Description of sampling sites and procedures.		SOP 3.3	5, 5.1
2.6	**Microbiological Air and Surface Monitoring:** Description of the pharmacy's microbiological air and surface monitoring program which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (eg, surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective actions and documentation requirements.		SOP 2.3 Viable Air; SOP 2.6 Surface Sampling	6, 6.1, 6.2, 6.3
2.7	**Cleaning, Disinfection, and Application of Sporicidal Disinfectants and Sterile 70% IPA:** Description of procedures for cleaning, disinfecting, and applying sporicidal disinfectants and include the frequency, methods, locations of cleaning, and documentation requirements.		SOP 3.5	7, 7.2 Box 7, Box 8
2.8	**Equipment:** Description of procedures for the calibration, maintenance, cleaning, use of the equipment, and documentation requirements.		SOP 3.3 □	9.1, 10, 20

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		Observation	Inspector Notes	USP Reference(s)
2.9	**Components:** Description of procedures that address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and container closures.		SOP 5.1 Inventory Storage and Handling	9.3
2.10	**Master Formulation and Compounding Records:** Description of procedures for developing and maintaining MFRs and required information, documentation, and record-keeping requirements for MFRs and CRs.		SOP 3.10 MFR (Master Formulation Record)	11.1, 11.2, 20
2.11	**Release Inspections and Testing:** Description of release testing procedures (eg, visual inspections and/or sterility and endotoxin testing), out-of-specification procedures, corrective action procedures, and documentation requirements.		SOP 6.5 Visual Inspection and Release Checks; SOP 6.11 Sterility	12, 18, 20
2.12	**Labeling:** Procedures for labeling and label verification (confirming against the prescription or medication order, the MFR, and the CR) in order to prevent errors, CSP mix-ups, and required displayed information.		SOP 6.12 Labeling of CSP	13
2.13	**CSP handling, storage, packaging, shipping, and transport:** Processes and techniques for handling, storing, packaging, and transporting CSPs that include temperature monitoring, excursions, shipping containers, packaging requirements, and selected transportation modes.		SOP 5.3 Packaging and Delivery of Compounded Medications	19
2.14	**Documentation:** Record keeping requirements and procedures for documentation maintenance and storage. ***Inspector note: USP requires readily retrievable records for two years; however, it is acknowledged that state or accreditation organizations may require records for a longer period of time.***		SOP 1.60 Good Documentation Practices	20

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		Observation	Inspector Notes	USP Reference(s)
2.15	**Sterilization and Depyrogenation:** Description of methods used for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment. ***If not applicable to their business practices, inspector should answer statement as N/A.***		SOP 6.11 Sterility	10
2.16	**Immediate Use CSPs:** Description of processes followed to meet all conditions of exemption from the requirements for Category 1, Category 2, and Category 3 CSPs. ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	1.3
2.17	**Blood/Biological Handling:** Description of processes used to avoid cross-contamination and meet applicable regulatory requirements. ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	1.1.2
2.18	**Allergenic Extracts:** Description of procedures for training, competency assessments, personnel hygiene and garbing, facility requirements, cleaning and disinfecting, beyond use dates (BUDs), labeling, storage, shipping and transporting, and documentation. ***If applicable to their business practices, please complete the Allergenic Extracts module.*** ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	21

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		Observation	Inspector Notes	USP Reference(s)
	CSPs - Immediate Use, Proprietary Vial/Bag Systems, and Blood-Derived			1
3.0	Does the pharmacy prepare and dispense compounded sterile preparations for direct and immediate use? ***If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.***	N/A		1.3
4.0	Does the pharmacy meet all conditions specified in USP <797> for CSPs compounded for direct and immediate use? ***Inspector note: Per USP <797>, all conditions must be met to qualify for exemptions of the requirements for Category 1, Category 2, and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.***	N/A		1.3
4.1	Aseptic techniques, processes, and procedures are followed. ***Inspector note: Per USP <797>, facility SOPs must describe procedures followed "to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs."***	N/A		1.3
4.2	Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. ***Review personnel records to verify.***	N/A		1.3

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		Observation	Inspector Notes	USP Reference(s)
4.3	Preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs. ***Inspector note: Examples of this include approved labeling and/or published or unpublished stability and compatibility studies.***	N/A		1.3
4.4	Preparation involves not more than three (3) different sterile products (eg, ingredients and/or components in a single container).	N/A		1.3
4.5	Unused components from a single-use container are discarded after the preparation for one individual patient is complete (ie, single-dose containers are not used for more than one patient).	N/A		1.3
4.6	Administration begins within four hours of the start of the preparation, and if not, the preparation is discarded. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3
4.7	Unless the person preparing the preparation is administering or witnessing administration, the preparation is labeled with names and amounts of all active ingredients, name or initials of preparer, and exact four-hour time period in which administration must begin. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3

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[redacted] Sterile Compounding Inspection for USP <797> [redacted]

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
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Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

	[redacted]	Observation	Inspector Notes	USP Reference(s)
5.0	Does the pharmacy prepare proprietary bag and vial systems (ex. addEASE, ADD-Vantage, Mini Bag Plus, Vial2Bag) in compliance with USP <797> standards? ***Inspector note: Docking and activation of proprietary bag and vial systems for Immediate administration to an individual patient is out of scope of USP <797> and may be performed outside of an ISO Class 5 environment.*** ***If no, go to compliance statements.*** ***If the pharmacy does not stock, prepare, and/or dispense any proprietary vial and bag systems, inspector should answer statement as N/A.***	N/A		1.4
5.1	Docking for *future activation* and administration is performed in an ISO Class 5 environment and in accordance with requirements of USP <797>, with the exception of BUD assignment.	N/A		1.4
5.2	BUD assignment is not longer than specified in the manufacturer's labeling.	N/A		1.4
6.0	Does the pharmacy meet the conditions specified in USP <797> for CSPs to be prepared per approved labeling? ***Inspector note: Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is considered outside the scope of the USP chapter.*** ***If no, go to compliance statements.*** ***If the pharmacy only <u>compounds</u> sterile preparations (eg, does <u>not</u> prepare sterile preparations that strictly adheres to the conventionally manufactured approved labeling for preparation), inspector should answer statement as N/A.***	N/A		1.4

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		Observation	Inspector Notes	USP Reference(s)
6.1	The product is prepared as a single dose for an individual patient.	N/A		1.4
6.2	The approved labeling includes information for the diluent, the resultant strength, the container closure system, and the storage time.	N/A		1.4
7.0	Does the pharmacy perform compounding activities that require the manipulation of a patient's blood-derived or other biological material (eg, autologous serum)?	N/A		1.1.2
8.0	For compounding activities that require the manipulation of a patient's blood-derived or other biological material, does the pharmacy perform manipulations that are clearly separated from other compounding activities and equipment used in CSP preparation activities and are controlled by specific SOPs to avoid any cross-contamination? ***Inspector note: Per USP, a separate cart could be used for blood-derived or other biological materials (a separate area is not required by the chapter). Pharmacy should change garb. Pharmacy to have cleaning processes as part of SOPs to avoid cross-contamination.*** ***If the pharmacy does not compound with blood products or other biological materials, inspector should answer statement as N/A. If the inspector answers the compliance question as "no", please describe your observations.***	N/A		1.1.2

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		Observation	Inspector Notes	USP Reference(s)
	Facility Design and Engineering Controls			4
9.0	**Segregated Compounding Area (SCA):** Does the pharmacy use an SCA as an SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP, only Category 1 CSPs may be compounded in a SCA.*** ***If no, go to compliance statements.*** ***If pharmacy only uses a cleanroom suite for sterile compounding preparations, inspector should answer question as N/A.***	N/A		4.1, 4.1.1, 4.1.2, 4.2.1 Table 5
9.1	The facility is designed to afford a well-lighted and comfortable working environment.	N/A		4.2, 4.2.1
9.2	Only Category 1 CSPS are prepared in a SCA. ***If pharmacy is compounding Category 2 or Category 3 CSPs in a SCA, inspector should answer this statement as no and collect photographs and copies of the MFR, CR, and provide a description of their observations in the Inspector Notes.***	N/A		4.2.1, 4.2.3 Table 5
9.3	The SCA is located away from unsealed windows, doors that connect to outdoors, and traffic flow. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	N/A		4.2.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
9.4	The SCA is located away from environmental control challenges and separate from areas not related to compounding (ie, restrooms, warehouses, food preparation areas).	N/A		4.2.1
9.5	A visible perimeter establishes the boundaries of the SCA. ***Inspector note: Per USP, the SCA is defined as "a designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only." USP further defines a perimeter as "a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA." The perimeter will be defined in the pharmacy's SOPs. Tape or an alternative method may be used to define this visible perimeter, since this is not a classified space.***	N/A		4.2.1 Glossary
9.6	Access to the SCA is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning.***	N/A		4.2.1
9.7	Free-standing humidifiers/dehumidifiers and air conditioners are not located within the perimeter of the SCA.	N/A		4.2
9.8	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the compounding area. ***Inspector note: Per USP, these items should be low-shedding, easily cleaned, and disinfected. This applies to items within the perimeter around the Primary Engineering Control (PEC).***	N/A		4.5

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National Association of Boards of Pharmacy®
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[redacted] Sterile Compounding Inspection for USP <797>

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e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
9.9	Shipping cartons or other corrugated or uncoated cardboard are not allowed in the SCA.	N/A		4.5
9.10	The SCA and all surfaces (walls, floors, counters, equipment) are clean, uncluttered, and dedicated to compounding.	N/A		4.2.1, 4.3.2
9.11	The sink is located inside the SCA or in close proximity and is located at least one meter away from the PEC.	N/A		4.4
9.12	The area within one meter of the PEC is dedicated only for sterile compounding (eg, not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities, such as patient care).	N/A		4, 4.2.1
9.13	If overhangs or ledges are present in the SCA, are they easily cleanable? ***If no, describe observations in Inspector Notes.***	N/A		4.2.1, 4.3.2
10.0	Are surfaces smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments Inspector Notes (eg, peeling of Formica countertops).***	Yes		4.3.2

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		Observation	Inspector Notes	USP Reference(s)
11.0	Are surfaces resistant to damage from cleaning, sanitizing, and sporicidal agents used? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments inspector observations (ie observed rust on preparation cart or flaking of particle board on shelving).***	Yes		4.2.1, 4.3.2
12.0	**Cleanroom Suite:** Does the pharmacy use a Cleanroom Suite (ISO-classified anteroom and buffer room) as a SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP <797>, a cleanroom suite is required if compounding any Category 2 and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If pharmacy only uses an SCA for Category 1 CSPs, inspector should answer question as N/A.***	Yes		4.1, 4.1.1, 4.1.2, 4.2.1, 4.3.1 Table 5
12.1	Access to the cleanroom suite is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning. Some examples pharmacies may use to demonstrate compliance with this statement (but are not specifically required by the chapter) include posting a sign or creating a badge access point for authorized personnel to enter the cleanroom suite.***	Yes		4.2.1
12.2	The facility is designed to afford a well-lit environment.	Yes		4.2, 4.2.1
12.3	The facility provides a comfortable working environment (eg, temperature and humidity settings so appropriate garb can be donned).	Yes		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
12.4	The anteroom and buffer room are separated from surrounding unclassified areas by fixed walls and doors.	Yes		4, 4.2.1
12.5	Controls are in place to minimize the flow of lower-quality air into the more-controlled areas. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	Yes		4.2.1
12.6	Anterooms providing access to only positive pressure buffer rooms meet at least ISO Class 8 specifications. ***If the pharmacy has a negative pressure room, inspector should answer statement as N/A.***	N/A		4.1.2, 4.2.1
12.7	The anteroom provides access to a negative pressure room and meets at least ISO Class 7 specifications. ***If the pharmacy does not compound hazardous drugs, inspector should answer statement as N/A.***	Yes		4.1.2, 4.2.1
12.8	The buffer room, where the PEC is placed, meets ISO Class 7 or better air quality specifications. ***Inspector note: If the PEC is a pharmaceutical isolator, the buffer room must be at least ISO Class 8 air quality or better and an anteroom is not required.*** ***Per USP <797>, a pharmaceutical isolator is defined as an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. A CAI or CACI is not a pharmaceutical isolator.***	Yes		4.1.2, 4.2.1, 4.2.3

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		Observation	Inspector Notes	USP Reference(s)
12.9	Air supply to the anteroom and buffer room is introduced through HEPA filters in the ceiling.	Yes		4.2.1
12.10	Air returns are located low on the wall. ***If the pharmacy has a visual smoke study (as described in the USP chapter and compliance statement below), inspector should answer statement as N/A.***	Yes		4.2.1
12.11	A visual smoke study demonstrates an absence of stagnant air where particles can accumulate and is repeated if any equipment/placement changes when air returns are not located low on the wall. ***Inspector note: Per USP, "the smoke study, along with environmental monitoring, must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (eg, HVAC alterations, chapter of HEPA filter units)."*** ***If air returns are low on the wall, inspector should answer statement as N/A.***	N/A		4.2.1
12.12	The anteroom has a line of demarcation to separate the dirty side from the clean side or has two separate anterooms, a dirty anteroom and a clean anteroom. ***Describe observations for the type of line of demarcation in the Inspector Notes.***	Yes	The line of demarcation is black tape on the floor.	4.2.1
12.13	Personnel enter the dirty side/room first from the unclassified area and the clean side/room is located closest to the buffer room.	Yes		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
12.14	All surfaces (ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets) are smooth, impervious, free from cracks and crevices, and non-shedding.	Yes		4.2.1, 4.3.1
12.15	Junctures between ceilings and walls and between the walls and floors are sealed.	Yes		4.2.1, 4.3.1
12.16	If the ceiling consists of inlaid panels, the panels are caulked to seal them to the support frame. ***If the ceiling does not consist of inlaid panels, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.17	Walls are constructed of, or covered with, a durable material (eg, epoxy paint, heavy gauge polymer) and integrity of surface maintained.	Yes		4.2.1, 4.3.1
12.18	Walls, if paneled, are joined together and sealed to the support structure. ***If walls are not paneled, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.19	Floors include coving to the sidewall or the juncture between floor and wall is caulked.	Yes		4.2.1, 4.3.1
12.20	If overhangs or ledges are present, they are easily cleanable. ***If there are no overhangs, ledges, utility pipes, windowsills, etc, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1

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		Observation	Inspector Notes	USP Reference(s)
12.21	Exterior lens surfaces of the ceiling light fixtures are smooth, mounted flush, and sealed.	Yes		4.2.1, 4.3.1
12.22	All other penetrations through the ceiling or walls (eg, camera domes) are sealed.	Yes		4.2.1, 4.3.1
12.23	The buffer room does not contain plumbed water sources (eg, sinks, eyewashes, showers, or floor drains).	Yes		4.4
12.24	The anteroom does not contain floor drains.	Yes		4.4
13.0	Are **PECs** used to prepare CSPs located in the appropriate space (eg, buffer room or SCA) for category types prepared in compliance with USP <797> standards? ***Inspector to review certification reports and observe compounding area(s) to evaluate.*** ***If no, go to compliance statements.***	Yes		4.2.1, 4.2.2, 4.2.3 Table 4, Table 5
13.1	All compounded sterile preparations (that are not for immediate use) are compounded in a PEC.	Yes		1.3, 4, 4.1.2
13.2	PEC is certified to maintain ISO 5 classification or better conditions during dynamic operating conditions. ***The inspector should only answer yes if the PEC has been certified within the past six months.***	Yes		4.2.2, 4.2.3, 5

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		Observation	Inspector Notes	USP Reference(s)
13.3	The PEC is located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC. ***Review certification report.***	Yes	Reviewed reports.	4, 4.2.2, 4.2.3
13.4	Placement of the PEC allows for cleaning around the PEC.	Yes		4.2.3
13.5	**Category 2 and Category 3:** PEC(s) are located in a cleanroom suite. ***If pharmacy only compounds Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.2.3 Table 5
14.0	Does the pharmacy have any CAIs/CACIs used for sterile compounded preparations? ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3 Table 5
15.0	Are **CAIs/CACIs** (RABS) used for compounding sterile preparations operated in compliance with manufacturer specifications **and** USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3

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		Observation	Inspector Notes	USP Reference(s)
15.1	The documented recovery time is followed after opening the CAI/CACI transfer chamber to maintain ISO Class 5 air quality. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.2	Staff ensures that adequate recovery time is allowed after closing the CAI/CACI during compounding operations. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.3	Sterile gloves are worn over the gloves attached to the CAI/CACI sleeve. ***Inspector note: Per USP, if using a RABS (ie, a CAI or CACI), disposable gloves should be (not required) worn inside the gloves attached to the RABS sleeves.***	N/A		3.3
16.0	Are there controls in place to minimize the influx of contaminants from materials (supplies and equipment) and personnel as they move from areas of lower quality to those of higher quality in compliance with USP <797> standards? ***Inspector note: An example of material movement from lower quality air to higher quality air includes movement from a non-classified area to an ISO Class 8 anteroom, ISO Class 8 anteroom to an ISO Class 7 buffer room, or from an ISO Class 7 buffer room to an ISO Class 5 PEC.*** ***If no, go to compliance statements.***	Yes		4.5

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		Observation	Inspector Notes	USP Reference(s)
16.1	Before any item is introduced into the SEC, placed into the pass-through chamber, or brought into the SCA (providing that packaging integrity will not be compromised), it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (IPA) using low-lint wipers by personnel wearing gloves.	Yes		4.5
16.2	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.	Yes		4.5
17.0	Does the pharmacy have the appropriate facility design and controls (including the fixtures, types of equipment, materials, and supplies that are stored) in the classified areas in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		4, 9.1, 19.1
17.1	The sink used for hand hygiene, located outside of the anteroom, is placed in an appropriate area and clean space to minimize the risk of bringing contaminants into the anteroom. ***Inspector note: Inspector should evaluate the sink location in relation to the activities that occur where the sink is located as well as the distance between the sink and the entrance to the compounding suite/SCA. Examples that may not be considered appropriate include but are not limited to: sink is located in the bathroom, an adjacent suite or property, or in an employee breakroom where food is prepared.*** ***If the sink is located in the anteroom, inspector should answer statement as N/A.***	Yes		4.4

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		Observation	Inspector Notes	USP Reference(s)
17.2	The sink used for hand hygiene, located inside of the anteroom, is placed in an appropriate area to minimize the risk of bringing contaminants into the buffer room. ***Inspector note: Inspector should evaluate the sink location in relation to the doors and compounding activities. For example, the sink is where compounders perform hand hygiene close to where garb is stored (where it can easily get wet/splashed).*** ***If the sink is located outside the anteroom, inspector should answer statement as N/A.***	N/A		4.4
17.3	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes		4.2.1
17.4	The inside and outside doors of a pass-through are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes		4.2.1
17.5	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. ***Inspector note: Per USP, items necessary for performing compounding activities are low-shedding and can be easily cleaned and disinfected.*** ***If no, describe the types of items that are observed. If appropriate, submit a photograph with inspection report.***	Yes		4.5, 9.1
17.6	Tacky mats are not used in the classified areas. ***Inspector note: Per USP <797>, "Tacky mats must not be placed within ISO-classified areas."***	Yes		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
17.7	Shipping cartons or other corrugated or uncoated cardboard are not permitted in the classified areas.	Yes		4.5
17.8	Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels.	Yes		4.5
17.9	Carts (including casters) are cleaned and disinfected prior to moving from the dirty side to the clean side of the anteroom.	Yes		4.5
18.0	Does the pharmacy's facility design for maintaining (eg, recording, monitoring, and controlling) temperature and humidity (eg, HVAC) comply with USP <797> standards? ***Inspector note: Compounded preparations that are finished and stored will be addressed in the general pharmacy module. Inspector should be aware that USP cleanroom temperature recommendations may not be harmonized with USP, FDA, or manufacturer/supplier temperature requirements for drug storage.*** ***If no, go to compliance statements.***	Yes		4.2, 19.1 USP <659>
18.1	The compounding area temperature and humidity is maintained by a heating, ventilation, and air conditioning (HVAC) system. ***If inspector finds a free-standing air conditioner, humidifier, or dehumidifier within the classified area or the SCA, the inspector should answer statement as "No." Additionally, inspector should describe what they observed, where the equipment was located, and collect/submit photographs.***	Yes		4.2, 9.3.4, 19.1

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		Observation	Inspector Notes	USP Reference(s)
18.2	The pharmacy records the temperature of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes		4.2, 9.3.4, 19.1
18.3	The pharmacy records the humidity of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of humidity recording in the notes.***	Yes		4.2, 9.3.4, 19.1
18.4	The pharmacy maintains records of temperature and humidity that are specific to the cleanroom suite. ***Temperature and humidity for drug storage areas will be documented in the general pharmacy module.*** ***If the pharmacy only uses an SCA, inspector should answer statement as N/A.***	Yes		4.2, 9.3.4, 19.1
18.5	The pharmacy can readily retrieve temperature and humidity records. ***If the electronic monitoring system is only capable of providing text message alerts for excursions alone (eg, a report cannot be generated for ongoing temperature conditions), inspector should answer statement as "No."***	Yes		4.2, 9.3.4, 19.1

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18.6	The pharmacy controls temperature and humidity to maintain appropriate working conditions if no overnight drug storage occurs and/or is following the most restrictive drug label. ***Inspector note: Per USP <797>, the cleanroom suite should be maintained at a temperature of 20°C or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb. CRT is defined as 20°C-25°C per USP <659>.***	Yes		4.2, 9.3.4, 19.1
18.7	The placement of the HVAC unit does not cause cross contamination or interfere with the functioning of the classified area. ***Inspector note: Air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open faced PEC such as a laminar airflow workbench (LAFW).***	Yes		4, 4.2
18.8	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes		4.2, 9.3.4
18.9	Humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes		4.2, 9.3.4

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
19.0	Does the pharmacy store drugs in the cleanroom suite overnight and/or for long periods of time? ***Inspector note: Long periods of time is not defined as pre-compounding preparation right before compounding activities are commenced.***	No		4.2, 9.3.4, 19.1
20.0	If the pharmacy is storing drugs inside the cleanroom suite overnight and/or long periods of time, are any of the drugs stored unable to tolerate temperature excursions?	N/A		4.2, 9.3.4, 19.1
21.0	What is the current temperature of the cleanroom suite/SCA? ***Record in the Inspector Notes.***		62.4°F	4.2, 9.3.4, 19.1
22.0	What is the current relative humidity percentage of the cleanroom suite/SCA? ***Record in the Inspector Notes.***		59.5%	4.2, 9.3.4, 19.1
23.0	Is the humidity maintained at less than 60% relative humidity (RH) in the compounding area to minimize risk of microbial proliferation?	Yes		4.2, 9.3.4, 19.1

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[redacted] Sterile Compounding Inspection for USP <797>: [redacted]

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
24.0	Is differential positive pressure maintained in compliance with USP <797> standards? ***Inspector note: Per USP <797>, no pressure differential is required between the SCA and the surrounding area.*** ***If no, go to compliance statements.*** ***Inspector should view logs and current status (while observing compounding) to verify.*** ***If the pharmacy uses an SCA for sterile compounding environment, inspector should answer statement as N/A.***	Yes	Logs reviewed	4.2.1, 4.2.5, 5
24.1	The facility design creates room separation to allow positive pressure differentials between spaces (rooms) for movement of air from higher quality air to lower quality air. ***Inspector should review a graphic of the airflow contained in the certification report.***	Yes	Graph reviewed	4.2.1, 4.2.5, 5
24.2	The facility has a system in place to continuously monitor pressure differentials (eg, magnehelic gauge). ***Per USP, pressure differentials need to be monitored continuously, but personnel are not specifically required to visually monitor pressure during compounding activities.***	Yes		4.2.1, 4.2.5, 5
24.3	The facility has a record system to record pressure differentials on days when compounding occurs. ***Inspector note: Per USP, the quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurs.***	Yes		4.2.1, 4.2.5, 5

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		Observation	Inspector Notes	USP Reference(s)
24.4	The differential positive pressure between unclassified and the first space in the compounding suite is at least 0.020 inch water column. ***Inspector note: Per USP, certifiers should confirm (this is a USP recommendation) positive pressure around doorways, pass-throughs and any opening in the cleanroom suite with smoke testing (to confirm positive pressure is maintained) with initial certification of the cleanroom suite.*** ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the general pharmacy area).***	Yes		4.2.1, 4.2.5, 5
24.5	The differential positive pressure between adjacent classified areas is at least 0.020 inch water column. ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the ISO Class 7 buffer room).***	Yes		4.2.1, 4.2.5, 5
24.6	Pressure differential monitoring and quantitative results are reviewed and documented at least daily on days when compounding occurs.	Yes		4.2.1, 4.2.5, 5
25.0	Does the pharmacy have a policy in place to cease compounding when the pharmacy is unable to maintain positive pressure differentials (outside of anticipated variations due to opening and closing of doors)?	Yes		4.2.1, 4.2.5, 5
26.0	Are pressure differential monitoring procedures in place that include an alarm or alert when there is an excursion? ***Inspector note: USP <797> does not require there to be an alarm or an alert.***	Yes		4.2.5

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		Observation	Inspector Notes	USP Reference(s)
27.0	Does the facility perform both sterile and nonsterile compounding?	Yes		4.2.1
28.0	If the pharmacy performs nonsterile compounding and sterile compounding, are the designated areas separate and distinct from each other?	Yes		4.2.1
29.0	If PECs are placed into the same room that are used for both sterile and nonsterile compounding, is the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP <797>, PECs used for both sterile and nonsterile compounding may be placed in the same room only if the PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification.*** ***If no, go to compliance statements.*** ***If the pharmacy does not perform nonsterile compounding in the same room as sterile compounding, inspector should answer this question as N/A.***	N/A		4.2.1, 4.2.6
29.1	PECs used for nonsterile compounding are placed at least one meter away from PECs used for sterile compounding.	Yes		4.2.1
29.2	Particle-generating activity must not be performed while sterile compounding is in process.	Yes		4.2.1
29.3	PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification air quality during nonsterile compounding.	Yes		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
30.0	Does the pharmacy prepare Category 2 and Category 3 CSPs from nonsterile components? ***Inspector note: Category 1 CSPs can be made from nonsterile components.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	Yes	Pharmacy does not perform Category 3 compounding.	4.2.1, 4.2.6
31.0	Does the pharmacy's presterilization procedures comply with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	Yes		4.2.6
31.1	Presterilization procedures, such as weighing and mixing, are completed in an ISO Class 8 or better environment (eg, anteroom or buffer room). ***Inspector note: This statement only applies for Category 2 and Category 3.***	Yes		4.2.6
31.2	Presterilization procedures, such as weighing and mixing, are performed in a single-use containment glove bag, CVE, BSC, or CACI to minimize the risk of airborne contamination. ***Inspector note: This statement only applies for Category 2 and Category 3. CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every six months.***	Yes		4.2.6

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		Observation	Inspector Notes	USP Reference(s)
	Certification and Environmental Monitoring Inspector to review past two (2) Certification reports for the SEC and all PECs.			5
32.0	Does the pharmacy ensure that each area related to CSP preparation is certified to meet the classified air quality standard appropriate for the activities conducted in that area in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***Inspector is to review current certification reports.***	Yes	Only 1 report has been done since new pharmacy.	5
32.1	The most recent PEC and SEC certification reports are available for review.	Yes		4.2, 5, 20
32.2	Certification of all classified areas, including PECs, is performed at least every six months.	Yes		4.2.3, 5
32.3	Certification of all classified areas, including PECs, is performed whenever a device is relocated or a major service to the facility is performed. ***Inspector note: Classified areas must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.***	Yes		5
32.4	Certification reports are reviewed by the designated person(s). ***Inspector note: If the designated person(s) review is not documented, describe how it is ensured that the review occurred.***	Yes		4.2, 5

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		Observation	Inspector Notes	USP Reference(s)
32.5	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, pharmaceutical isolators, IVLFZ, and robotic enclosures) have been certified within the last six months. ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.2.3, 5
32.6	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. ***Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.*** ***If no, describe what occurred and the pharmacy's response to total airborne particle sampling results, data evaluation, and action level (eg, pharmacy took PEC out of service, pharmacy ordered new HEPA filter, PEC was repaired and re-certified).***	Yes		4.1.1, 5.1 Table 4
32.7	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last six months. ***Inspector note: Per ISO definition, ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air under dynamic operating conditions and ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air under dynamic operating conditions.*** ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.1.1, 4.1.2, 5.1 Table 4

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		Observation	Inspector Notes	USP Reference(s)
32.8	All SECs meet ISO Class 7 air quality requirements and ISO Class 8 air quality requirements where permitted, with particle counts documented within the report. ***If no, describe what occurred and the pharmacy's response (eg, pharmacy reduced BUD, pharmacy used an alternative facility, pharmacy followed mitigation strategies, and/or disaster planning processes).***	Yes		4.1.1, 5.1 Table 4
33.0	Does the certification report received by the pharmacy have all required elements documented for the pharmacy's designated person(s) to make an informed decision related to functionality of PEC and SEC environments in compliance with USP <797> standards? ***Inspector note: It is recommended that the designated person review the certification report in its entirety.*** ***If no, go to compliance statements.***	No		5, 20
33.1	The certification report includes information about the equipment used for performing each test including last calibration date (or date when next calibration is due). ***Inspector note: Per USP, "total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment" and "all impaction air samplers must be serviced and calibrated as recommended by the manufacturer."***	Yes	Next calibration due June 30, 2025. This report was As-Built and did not include personnel for dynamic operating conditions.	5.1, 6.1, 20
33.2	The certification report includes the name of the certifier. ***Inspector note: Per USP <797>, a qualified certifier may have received training and education from professional organizations such as the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) and Controlled Environment Testing Association (CETA). Both organizations provide certification (Registered Certification Professional – Sterile Compounding Facilities), education, and resources.***	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
33.3	The certification report describes the "dynamic conditions" including the number of personnel in the cleanroom suite. ***Inspector note: Compounders can perform mock compounding activities and/or performing media-fill while the certifier is conducting testing. Number of personnel present in the SEC must be documented.***	No	New pharmacy has only had initial certification preopening. The report notes no personnel present.	5, 20
33.4	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **air volume and room air exchange rate (ACPH)**: ***Inspector note: Per USP <797>, unclassified SCAs have no ACPH requirement.*** ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5 Table 6
33.5	**SEC:** All of the following ACPH required elements were documented on the certification report: the ACPH from HVAC, the ACPH contributed from the PEC, and the total ACPH. ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5
33.6	**The ISO Class 8 anteroom** is certified and documented as having a minimum of 20 ACPH with at least 15 ACPH of the total air change rate coming from HVAC through HEPA filters located in the ceiling. ***If the pharmacy has an ISO Class 7 anteroom, inspector should mark as N/A.***	Yes		4.2.4, 5 Table 6

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		Observation	Inspector Notes	USP Reference(s)
33.7	**The ISO Class 7 buffer room and ISO Class 7 anteroom (if required)** is certified and documented as having a minimum of 30 ACPH with at least 15 ACPH of the total air change rate in a room coming from the HVAC through HEPA filters located in the ceiling. ***Inspector note: If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off, except for maintenance.***	Yes		4.2.4, 5 Table 6
33.8	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **room pressure differential** in doorways between adjacent rooms.	Yes		4.2.5, 5
33.9	**SEC:** The differential pressure measured was at least 0.020 inch water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed. ***Inspector note: No pressure differential is required between the SCA and the surrounding area.***	Yes		4.2.1, 4.2.5, 5
33.10	**SEC:** All SEC HEPA filters were leak tested (to confirm **HEPA filter integrity**).	Yes		5
33.11	**SEC:** All SEC HEPA filters with leaks were repaired. ***If leaks were not repaired, describe what actions pharmacy took (eg, pharmacy implemented mitigation strategies such as reduced BUD or used alternative pharmacy location).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A		5

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		Observation	Inspector Notes	USP Reference(s)
33.12	**PEC: (Dynamic airflow) Smoke pattern tests** are performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the CSPs. ***Inspector note: Per USP, "HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design, control, and use minimizes turbulence and creation of eddies or stagnant air in the PEC."*** ***Describe if smoke pattern testing of PEC was documented thoroughly in the report or through video.***	No	Smoke testing documented in report but not under dynamic operating conditions as noted.	4.2.2, 4.2.3, 5
33.13	**PEC: Dynamic airflow smoke pattern** confirms equipment and supplies necessary for performing compounding activities in the PEC do not disrupt unidirectional airflow. ***Inspector note: Per USP, "Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location."***	Yes		4.2.2, 4.2.3, 4.5, 5, 9.1
33.14	**PEC: Total (nonviable) particle count** testing was performed under dynamic operating conditions using calibrated electronic equipment. ***Inspector note: Per USP, "Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures...Measurements of total airborne particles in other classified areas, including the buffer room(s) and anteroom(s), should be taken at representative locations that reflect the quality of air in the room(s)."***	No	Testing done without personnel present due to As-Built inspection.	5, 5.1

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		Observation	Inspector Notes	USP Reference(s)
33.15	**PEC:** All PEC HEPA filters were leak tested (to confirm HEPA filter integrity). ***Inspector note: The certification report for each PEC should show air velocities within the PEC.***	Yes		5
33.16	**PEC:** All PEC HEPA filters with leaks identified were repaired. ***If leaks were not repaired, describe what actions pharmacy took (example: PEC taken out of service until HEPA filter could be replaced).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A		5
33.17	**PEC-IVLFZ:** Pharmacy's integrated vertical laminar flow zone (IVLFZ) meets design, functional requirements, and certification requirements under USP <797>. ***Inspector note: Per USP <797>, "Strategic location of air returns in addition to full coverage of HEPA-filters above the work surface is required. Both static and dynamic smoke studies of air returns in addition to full coverage of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (eg, with video)."*** ***If pharmacy does not use an IVLFZ, inspector should answer statement as N/A.***	Yes		4.2.3

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		Observation	Inspector Notes	USP Reference(s)
33.18	If a **robotic enclosure is used as the PEC**, or placed within the PEC, a dynamic airflow smoke pattern test must be performed initially and at least every 6 months thereafter to ensure that: 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the direct compounding area(s). ***If pharmacy does not use a robotic enclosure, inspector should answer statement as N/A.***	N/A		4.2.3
34.0	Was smoke testing performed in SEC to confirm all particle generating equipment (eg, computers, printers, refrigerators, PECs) do not disrupt airflow? ***Inspector note: This question will be N/A unless the pharmacy is new, has recently completed construction, or equipment has been moved within SEC since last certification.***	Yes		5
35.0	Does the pharmacy have an established environmental monitoring (eg, microbiological air and surface monitoring) program in compliance with USP <797> standards? ***Inspector note: Per USP, "The goals of a microbiological air and surface monitoring program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained."*** ***If no, go to compliance statements.***	Yes		6, 6.1, 6.2

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		Observation	Inspector Notes	USP Reference(s)
35.1	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed initially in the selected sampling sites to establish a baseline level of environmental quality for each classified area, ie, each ISO Class 5 PEC, each ISO Class 7, and ISO Class 8 room.	Yes		6, 6.1, 6.2
35.2	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in conjunction with the certification of new facilities and equipment.	Yes		6, 6.1, 6.2
35.3	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed after any servicing of facilities or equipment.	Yes		6, 6.1, 6.2
35.4	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified problems (eg, positive growth in sterility tests of sterile compounded preparation).	Yes		6, 6.1, 6.2
35.5	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified trends (eg, repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination).	Yes		6, 6.1, 6.2

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		Observation	Inspector Notes	USP Reference(s)
35.6	Results from the environmental monitoring program (eg, viable air and/or surface monitoring) are reviewed in response to changes that could impact the sterile compounding environment (eg, change in cleaning agents) and in conjunction with personnel data (ie, training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination. ***Inspector note: Per USP, the program is reviewed to "assess risks for contamination, potential routes of contamination, and the adequacy of cleaning and disinfecting agents and procedures. Regular review of the sampling data must be performed to detect trends and the results of the review must be documented."***	Yes		6, 6.1, 6.2, 20 Table 4, Table 7, Table 8
35.7	The pharmacy ensures that viable air and surface sampling is performed by a trained and competent individual who is familiar with the methods and procedures for air sampling and surface testing. ***If sampling is conducted by internal personnel, inspector should verify that documented training and competencies are located in the employee file.***	Yes	Employee file reviewed.	6, 6.1, 6.2
35.8	Environmental monitoring program (eg, viable air and/or surface monitoring) describes/identifies corrective actions to minimize the risk of CSP contamination and that these corrective actions are documented.	Yes		6, 20
36.0	Is surface sampling performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected (to obtain a sample that is representative of the typical compounding conditions at the pharmacy)? ***Inspector note: this is a USP recommendation.***	Yes		6.1, 6.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
37.0	Does the pharmacy send out all air quality for viable airborne samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	N/A		6.2.2
38.0	Does the pharmacy send out all surfaces for viable particle samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	N/A		6.3
39.0	For any samples that are sent to an external lab (third party), does the pharmacy receive a report from the third party confirming incubation parameters meet USP <797> requirements (eg, the correct temperature and the correct length of incubation time are documented in the report)? ***Inspector note: Incubation parameters are the same as seen in statements 40.6-40.7 and 41.4-41.5.*** ***This question applies for any air or surface sample sent to an external lab. If no, describe observations.***	N/A		6.2.2
40.0	Are processes for sampling and monitoring air quality for viable airborne particles in compliance with USP <797> standards? ***Inspector note: Per USP <797>, facilities performing any Category 3 compounding must adhere to the increased environmental monitoring requirements for all classified areas where Category 3 CSPs are compounded and increased environmental monitoring requirements apply at all times regardless of whether Category 3 CSPs are being compounded on a given day.*** ***Review six months of air sampling data to verify. If no, go to compliance statements.***	Yes		6.2, 6.2.1, 6.2.2, 6.2.3, 14.4.2 Box 5, Table 7

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		Observation	Inspector Notes	USP Reference(s)
40.1	All classified areas are sampled using a volumetric active air sampling device (impaction air sampler). ***Inspector note: This sampling must be performed during dynamic operating conditions (to obtain a sample that is representative of the typical compounding conditions at the pharmacy).***	Yes		6.1, 6.2.1
40.2	All classified areas are sampled at the **frequencies** specified by USP for volumetric active air sampling. ***Inspector note: Per USP <797>, Category 1 and Category 2 compounding frequency is every six months and Category 3 compounding frequency is monthly.*** ***For facilities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.***	Yes		6.2.1, 14.4.2
40.3	At least one cubic meter (1000 L) of air is tested using the volumetric active air sampling device from each sample location.	Yes		6.2.2 Box 5
40.4	All impaction air samplers are serviced and calibrated as recommended by the manufacturer.	Yes		6.1
40.5	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a media that supports the growth of bacteria and fungi (eg, TSA), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements.***	Yes		6.2.2 Box 5

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Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
40.6	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797> (Box 5), when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C–35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C–25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.2.2 Box 5
40.7	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797> (Box 5), two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, malt extract agar [MEA] or sabouraud dextrose agar [SDA]). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.2.2 Box 6
40.8	Results for all plates are recorded for each sample and did not exceed USP <797> Table 7 action levels (or internal action levels if more restrictive). **ISO Class 5: >1 cfu/m^3/device** **ISO Class 7: >10 cfu/m^3/device** **ISO Class 8: > 100 cfu/m^3/device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media separately.***	Yes		6.2.3 Table 7

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		Observation	Inspector Notes	USP Reference(s)
40.9	For any air sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes		6.2.3
40.10	For any areas that exceed action levels, an investigation is conducted to attempt to determine cause and a corrective action plan is implemented.	Yes		6.2.3
41.0	Are processes for sampling and monitoring **surfaces for viable particles** in compliance with USP <797> standards? ***Review six months of surface sampling data to verify. If no, go to compliance statements.***	Yes		6.3
41.1	**Surfaces** and pass-through chambers in the cleanroom suite and SCA are sampled for microbial contamination for each classified area. ***Inspector note: Sampling locations must include work surfaces in each classified room, the interior of each ISO Class 5 PEC, and all pass-through chambers connecting to classified areas. USP recommends samples be taken from: equipment contained within the PEC, staging or working area near the PEC, and frequently touched surfaces.***	Yes		6.3, 6.3.1

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		Observation	Inspector Notes	USP Reference(s)
41.2	**Surfaces** within the cleanroom suite and SCA are sampled at the **frequencies** specified by USP for viable particle surface sampling. ***Inspector note: Category 1 and Category 2 CSP surface sampling frequency is monthly and Category 3 compounding is weekly, regardless of the frequency of compounding Category 3 CSPs.*** ***Additionally, surface sampling is to be performed within the PEC used to prepare Category 3 CSPs, at the end of each batch, before cleaning and disinfection occurs unless a self-enclosed robot is used. If a self-enclosed robot is used, frequency is at least once daily at the end of compounding operations.*** ***For facilities compounding any Category 3 CSPs, a surface sampling must be completed prior to assigning BUDs longer than the limits established in Table 13.***	Yes		6.3, 6.3.1, 14.4.2
41.3	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a surface sampling device with a raised convex surface for sampling flat surfaces is used that contain general microbial growth media that supports the growth of bacteria and fungi (eg, TSA supplemented with additives that neutralize effects of any disinfecting agent, eg, lecithin and polysorbate 80), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements. Per USP, "sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations such as crevices, corners, and spaces between surfaces."***	Yes		6.3.2 Box 6

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		Observation	Inspector Notes	USP Reference(s)
41.4	The pharmacy incubates all surface samples in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797>, when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C-35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C-25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.3.2 Box 6
41.5	The pharmacy incubates all surface samples in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797>, two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, MEA or SDA). Media must be supplemented with neutralizing additives (eg, lecithin and polysorbate 80). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.3.2 Box 7

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		Observation	Inspector Notes	USP Reference(s)
41.6	Results for all plates are recorded for each sample and did not exceed USP <797> Table 8 action levels (or internal action levels if more restrictive). **ISO Class 5: >3 cfu/media device** **ISO Class 7: >5 cfu/media device** **ISO Class 8: > 50 cfu/media device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately.***	Yes		6.3.3 Table 8
41.7	For any surface sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes		6.3.3
41.8	For any areas that exceed action levels, an investigation is conducted to determine cause, and a corrective action plan is implemented.	Yes		6.3.3

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		Observation	Inspector Notes	USP Reference(s)
	Compounding Personal Hygiene and Garbing			
42.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1
42.1	Compounding personnel are required to report conditions that may contaminate the sterile preparation and environment to the designated person(s). ***Inspector note: Per USP <797>, examples of conditions that have a higher risk of contaminating the CSP and sterile environment includes: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.***	Yes		3, 3.1
42.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in compounding areas before their conditions have been resolved. ***Inspector note: Per USP <797>, the designated person(s) may permit accommodations as long as the quality of the CSP and environment will not be affected.***	Yes		3, 3.1
42.3	Any accommodations permitted by the designated person(s) are documented.	Yes		3.1
42.4	Food (including mints, gum, etc) and drinks are not permitted in anterooms, buffer rooms, or segregated compounding areas.	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
43.0	Does the pharmacy stock the necessary garb to ensure minimum garbing requirements are continuously met in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3
43.1	The pharmacy stocks gowns and/or coveralls that are low-lint with sleeves that fit snugly around the wrists and an enclosed neck.	Yes		3.3
43.2	The pharmacy stocks shoe covers that are low lint.	Yes		3.3
43.3	The pharmacy stocks head covers that are low lint and cover the hair and ears.	Yes		3.3
43.4	The pharmacy stocks facial hair covers (not masks) that are low-lint. ***If the pharmacy does not have personnel with beards, inspector should answer this statement as N/A.***	N/A		3.3
43.5	The pharmacy stocks masks that are low lint.	Yes		3.3
43.6	The pharmacy stocks sterile, powder-free gloves.	Yes		3.3
43.7	**Category 1 and Category 2:** All non-disposable garb used to prepare Category 1 and Category 2 CSPs is laundered before reuse. ***If only disposable items are used, inspector should mark as N/A.***	N/A		3.3

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		Observation	Inspector Notes	USP Reference(s)
43.8	**Category 3 only:** The pharmacy stocks low lint face and neck coverings that ensure no skin is exposed. ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2
43.9	**Category 3 only:** The pharmacy stocks sterile, low lint outer garb (including sterile sleeves over gauntlet sleeves when a RABS is used). ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3
43.10	**Category 3 only:** All non-disposable garb used to prepare Category 3 CSPs is **laundered and resterilized** with a validated cycle before each use. ***Document whether laundering and sterilization is performed in-house or by an outside vendor.*** ***If only disposable items are used, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2

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		Observation	Inspector Notes	USP Reference(s)
	Media-Fill			
44.0	Is the media-fill testing simulation performed by the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP, "When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean-casein digest media. The simulation must capture elements that could potentially affect the sterility of the CSP."*** ***If no, go to compliance statements.***	Yes		2.3
44.1	The simulation captures factors associated with the length of the process that can pose contamination risk (eg, operator fatigue, quality of equipment).	Yes		2.3
44.2	The simulation captures number of aseptic additions or transfers.	Yes		2.3
44.3	The simulation captures number, type, and complexity of manipulations.	Yes		2.3
44.4	The simulation captures number of personnel in the buffer room or SCA.	Yes		2.3
44.5	Does the facility define "the most difficult and challenging procedures" and the rationale for how they are the most challenging? ***Inspector note: Best practice is for this to be documented in an SOP. Inspectors may also find this information documented on a training/competency assessment checklist. For complex/variety of compounding practices, inspectors may find additional media fills are completed (more than what is required by the USP chapters).***	Yes		2.3, 20

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		Observation	Inspector Notes	USP Reference(s)
45.0	Are the pharmacy's media-fill storage, review, and preparation processes in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		2.3
45.1	If pharmacy uses commercial sterile microbial growth media, a COA was obtained. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.2	The COA for the commercial sterile microbial growth media includes statements from the supplier that the lot of the growth media will support the growth of microorganisms. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.3	Storage of commercial sterile microbial growth media is in accordance with manufacturer instructions. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3

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		Observation	Inspector Notes	USP Reference(s)
45.4	Commercial sterile microbial growth media is stored and used before its expiration date. ***Inspector note: Media is to be inoculated by the expiration date, meaning that the test needs to be started (not that incubation needs to be completed before the expiration date).*** ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.5	Sterile-to-sterile media-fill testing microbial growth media (non-commercial) was prepared and growth promotion capability was demonstrated prior to use, following USP <71>. ***If pharmacy only uses commercial sterile microbial growth media, inspector should answer statement as N/A.***	N/A		2.3
45.6	Nonsterile starting components (commercially available nonsterile soybean-casein digest powder) are dissolved to make a 3% nonsterile solution, manipulated in a manner that simulates nonsterile-to-sterile compounding activities, with a minimum of one positive control container. ***If pharmacy does not perform sterile compounding using nonsterile ingredients, inspector should answer statement as N/A.***	Yes		Box 2

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		Observation	Inspector Notes	USP Reference(s)
	Cleaning and Disinfection			7
46.0	Is the pharmacy equipped with the necessary cleaning and disinfecting equipment and supplies that comply with USP <797> standards? ***If no, go to compliance statements.***	Yes		7, 7.1.1, 7.1.2 <1072>
46.1	All cleaning and disinfecting supplies (eg, wipers, sponges, pads, and mop heads), with the exception of tool handles and holders, are low lint (and sterile if used within PEC).	Yes		7.1.2
46.2	Reusable cleaning tools are made of cleanable materials (no wood handles or any other porous material).	Yes		7.1.2
46.3	Reusable cleaning tools are dedicated for use in the classified areas or SCA and are not removed from these areas except for disposal.	Yes		7.1.2
46.4	The pharmacy has the appropriate cleaners **EPA-registered disinfecting agent(s)** to adequately perform cleaning and disinfection. ***Inspector note: Examples of EPA-registered disinfectants include, but are not limited to: phenolics; oxidizers, such as peroxyacetic acid and sodium hypochlorite; quaternary ammonium; and hydrogen peroxide. If the agent is EPA-registered, a registration number will be on the label. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 7, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.***	Yes		7.1.1 Box 7 <1072>

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[redacted] Sterile Compounding Inspection for USP <797> [redacted]

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
46.5	The pharmacy has the appropriate **EPA-registered sporicidal agent(s)** to adequately perform sporicidal disinfection. ***Inspector notes: Examples of EPA-registered agents include but are not limited to: oxidizers such as peroxyacetic acid, sodium hypochlorite, and hydrogen peroxide.*** ***Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 8, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.*** ***Per USP, Inspector should check to see if agent is effective against Clostridium difficile.***	Yes	Peridox RTU	7.1.1 Box 7 <1072>
46.6	All cleaning and disinfectant agents are appropriately labeled including expiration dates. ***Inspector should verify that no expired agents are present.***	Yes	There are no expired agents present.	7.1.1
46.7	When used in the PEC, any cleaning and disinfecting agents that are not "ready-to-use" sterile formulations are diluted using sterile water. ***If only ready-to-use sterile formulations are used, inspector should answer statement as N/A.***	N/A		7.1.1
47.0	Does the pharmacy's documented **cleaning and disinfection** activities for surfaces in the classified areas and/or SCA comply with the **frequencies** specified in USP <797> Table 10? ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes	Logs reviewed.	7.2 Table 10
47.1	All interior surfaces of the PEC are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
47.2	All interior surfaces of the PEC are cleaned and disinfected when surface contamination is known or suspected.	Yes		7.2 Table 10
47.3	The removable work tray inside the PEC is cleaned and disinfected on days when compounding occurs. ***If the PEC is not equipped with a removeable work tray, inspector should answer statement as N/A.***	Yes	There is only a removable work tray in BSC.	7.2 Table 10
47.4	All equipment inside the PEC is cleaned and disinfected on days when compounding occurs.	Yes		7.2, 9.1 Table 10
47.5	All work surfaces outside of the PEC (eg, counters, work tables) are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.6	All pass-through chambers are cleaned and disinfected on days when compounding occurs. ***If the pharmacy is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.7	Floors in the buffer room, anteroom, and/or SCA are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.8	Sinks used for hand hygiene are cleaned and disinfected on each day of use.	Yes		4.4, 7.2, Table 10
47.9	Walls, doors, and door frames are cleaned and disinfected monthly.	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.10	Storage and shelving bins are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.11	All equipment outside the PEC are cleaned and disinfected monthly. ***Inspector note: Equipment in the SEC/SCA may include, but is not limited to: carts, refrigerators, computers, barcode readers, and label printers.***	Yes		7.2 Table 10
47.12	Ceilings in the buffer room and anteroom are cleaned and disinfected monthly. ***If the pharmacy performs compounding only in a SCA, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.13	Ceilings in the SCA are required to be cleaned and disinfected only when visibly soiled and when surface contamination is suspected. ***If the pharmacy performs compounding only in a cleanroom suite, inspector should answer statement as N/A.***	N/A		7.2 Table 10
47.14	The surface of the removable work tray and the area underneath the removable work tray of the PEC is cleaned and disinfected monthly. ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	Yes		7.2 Table 10
48.0	Does the pharmacy's documented application of **sporicidal disinfectant** on surfaces comply with the **frequencies** specified for each CSP category in USP <797> Table 10? ***Inspector note: Per USP <797>, if the pharmacy prepares any Category 3 CSPs, the cleaning requirements for Category 3 must be followed at all times regardless of whether a Category 3 CSPs is prepared on any given day.*** ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2, 14.4.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.1	**Sporicidal disinfectant** is applied to all interior surfaces of the **PEC** at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2, Table 10
48.2	Sporicidal disinfectant is applied to equipment inside the PEC at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10
48.3	Sporicidal disinfectant is applied to work surfaces outside the PEC (eg, counters, work tables) at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, application frequency is monthly. For any Category 3 compounding, application frequency is weekly.***	Yes		7.2 Table 10
48.4	Sporicidal disinfectant is applied to surfaces in the pass-through chambers at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.*** ***If the facility is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10

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[redacted] Sterile Compounding Inspection for USP<797> [redacted]

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
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		Observation	Inspector Notes	USP Reference(s)
48.5	Sporicidal disinfectant is applied to the floors in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10
48.6	Sporicidal disinfectant is applied to walls, doors, and door frames at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.7	Sporicidal disinfectant is applied to storage shelving and bins at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.8	Sporicidal disinfectant is applied to equipment stored outside the PEC at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.9	Sporicidal disinfectant is applied to ceilings in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: Per USP <797>, Table 10, the application frequency is monthly for all category types. Per USP, ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is suspected. The SCA may not have an accessible ceiling.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.10	Sporicidal disinfectant is applied to sinks used for hand hygiene at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		4.4, 7.2 Table 10
48.11	Sporicidal disinfectant is applied to the work surface of the removable tray in the PEC and area underneath the removable work tray at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*** ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	Yes	BSC has a removable work tray.	7.2 Table 10
	Components FDA defines manufacturer, as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes the activities of relabelers, repackers, and salvagers. When not modified by "domestic" or "foreign," the term includes both domestic manufacturers and foreign manufacturers.			9
49.0	Does the pharmacy compound CSPs using active pharmaceutical ingredients (APIs) and non-API components? ***Inspector note: Per USP <797>, non-API components may include pharmaceutical excipients, sterile containers, and container closure systems.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	Yes		9.3
50.0	Is the pharmacy's selection of active API and non-API components in compliance with USP <797> standards? ***Verify by selecting products from the shelf of different suppliers and ask to see the COAs for those products. If no, go to compliance statements.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	Yes	COAs reviewed	9.3

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		Observation	Inspector Notes	USP Reference(s)
50.1	**APIs:** APIs used are compliant with the criteria in the USP–NF monograph, if one exists. ***If pharmacy does not compound CSPs that have a USP monograph, inspector should answer this statement as N/A.***	Yes		9.3.1
50.2	**APIs:** All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that test results for the component show that the API meets expected quality.	Yes		9.3.1
50.3	**APIs:** All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. Inspector should verify the pharmacy looks up the name of the manufacturer listed on the COA to determine if they are registered as an FDA drug establishment https://dps.fda.gov/decrs.***	Yes		9.3.1
50.4	All **non-API components** comply with the criteria in the USP–NF monograph, if one exists.	Yes		9.3.1
50.5	All **non-API components** are accompanied by documentation (eg, COA, labeling) that include the specifications and test results and shows that the component meets the specifications.	Yes		9.3.1

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		Observation	Inspector Notes	USP Reference(s)
50.6	All **non-API components** used are manufactured by an FDA-registered facility. ***Inspector note: Per USP <797>, "If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see USP <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications."***	Yes		9.3.1
51.0	Does the pharmacy have processes in place to evaluate API and non-API components upon receipt and before use in compliance with USP <797> standards? ***Inspector note: Non-API components may be defined as excipients, containers, and container closure systems.*** ***If no, go to compliance statements.*** ***If the pharmacy does not compound with API or other non-API components, inspector should answer question as N/A.***	Yes		9.3.2, 9.3.3
51.1	APIs or other components have been evaluated for use in sterile drug preparation. ***Inspector note: Per USP <797>, "Components labeled with 'not for pharmaceutical use,' 'not for injectable use,' 'not for human use' or an equivalent statement must not be used to compound for these purposes."*** ***If no, photograph and describe in the notes column. Request copies of the invoices for products with these types of labels.***	Yes		9.3.2, 9.3.3

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		Observation	Inspector Notes	USP Reference(s)
51.2	Upon receipt of each lot of a component, personnel verify the labeling and condition of each component and examine the external packaging for evidence of deterioration and other aspects of unacceptable quality (eg, outer packaging is damaged, temperature-sensing indicators show that the component has been exposed to excessive temperatures).	Yes		9.3.2, 9.3.3
51.3	Each lot of commercially available sterile, depyrogenated containers and container-closure systems are accompanied by a COA or other documentation showing conformance with established specifications for sterility and depyrogenation requirements.	Yes		9.3.1, 9.3.2, 9.3.3
51.4	The date of receipt by the pharmacy is clearly marked on each API or component package that lacks a vendor expiration date and are assigned and labeled with an expiration date not to exceed one year after receipt by the pharmacy.	Yes		9.3.2, 9.3.3
51.5	All components are reinspected before use. ***Inspector note: Per USP <797>, all packages must be inspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures are visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use.***	Yes		9.3.2, 9.3.3
51.6	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		9.3.2, 9.3.3
51.7	Any other lots of that component from that vendor are examined to determine whether other lots have the same defect.	Yes		9.3.2, 9.3.3

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Sterile Compounding Inspection for USP <797>

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Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
	Equipment and Supplies			9
52.0	Is the pharmacy equipped with the appropriate supplies and equipment used for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		9, 9.1, 9.2
52.1	Supplies (eg, beakers, utensils, needles, syringes, filters, and tubing sets) that contact components are not reactive, additive, sorptive, and do not alter the quality of sterile compounded preparation. ***Inspector note: The appropriate supplies are available as applicable to the type of CSPs prepared (eg, non-PVC, silicone-free, able to withstand high heat, able to be sterilized).***	Yes		9.2
52.2	Any supplies that are in direct contact with CSPs are sterile and/or depyrogenated.	Yes		9.2
52.3	The equipment must be able to be cleaned using the required agents and tools without damaging the equipment and/or contaminating the compounded preparation. ***Inspector note: Equipment used in compounding are of suitable composition and the surfaces that contact components are not reactive or sorptive.***	Yes		9.1

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[redacted] Sterile Compounding Inspection for USP <797> [redacted]

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[redacted]		Observation	Inspector Notes	USP Reference(s)
52.4	When nonsterile ingredients, products, components, or devices (eg, non-sterile APIs and nonsterile vials and closures) are used for compounding, the pharmacy has the appropriate equipment to sterilize the finished product. Per USP, "Injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure must be sterilized within 6 hours after completing the preparation to minimize the generation of bacterial endotoxins in CSPs." ***If the pharmacy does not perform compounding that requires sterilization, inspector should answer statement as N/A.***	Yes	Filter sterilization	9.1, 9.3.1, 10
53.0	Does the pharmacy operate and maintain records for all equipment used for compounding in accordance with manufacturer specifications and USP <797> standards? ***If no, go to compliance statements.***	Yes		9.1, 20
53.1	Automated, mechanical, or electronic equipment (monitoring equipment, autoclaves, ovens, etc) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines.	Yes		9.1, 9.3.4
53.2	Automated compounding devices (ACDs) and other similar equipment (single channel or multi-channel) are assessed for accuracy and calibrated daily, prior to initial use, and a daily record is maintained. ***Inspector note: Per USP, "The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification."***	Yes		9.1

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		Observation	Inspector Notes	USP Reference(s)
53.3	Incubators used for environmental and personnel monitoring are placed in a location outside of the sterile compounding area and calibrated in accordance with manufacturer's instructions. ***If the pharmacy does not incubate samples and or/media-fills in-house, inspector should answer statement as N/A.***	Yes		6.1, 6.2.2, 6.3.2
53.4	Incubators used for environmental and personnel monitoring are monitored for temperature during incubation periods either manually or by use of a continuous recording device. ***Inspector note: Incubators store media at 20˚C-25˚C and 30˚C-35˚C. If the pharmacy has more than one incubator, review records for both incubators.*** ***View incubator temperature records to verify. Evaluate the size of the incubator and volume of media it can store. If the pharmacy does not incubate samples and/or media-fills in-house, inspector should answer statement as N/A.***	Yes	Reviewed incubator temperature records.	6.2.2, 6.3.2 Box 5
	Compounding Personnel Observation - Inspector ***must*** observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. If the inspector is unable to view activities from a window or other observation area, it is expected they will gown/garb into compounding area. It is acceptable for pharmacy staff to perform mock compounding activities (with sterile saline or other drug) as long as all observations can be viewed.			
54.0	**Personnel Preparation Observation:** Before entering the compounding area, do compounding personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1
54.1	All outer garments such as hats, scarves, sweaters, bandanas, vests, coats, and jackets are removed.	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
54.2	Makeup and/or cosmetics are removed.	Yes		3.1
54.3	All hand, wrist, and other exposed jewelry, including piercings such as earrings, lip or eyebrow piercings, etc. are removed and any jewelry that cannot be removed is covered.	Yes		3.1
54.4	Earbuds or headphones are removed.	Yes		3.1
54.5	Electronic devices that are not necessary for compounding or other required tasks are prohibited from entering the compounding areas.	Yes		3.1
54.6	Nails are kept clean and neatly trimmed.	Yes		3.1
54.7	Any nail polish, artificial nails, or extenders are removed.	Yes		3.1
54.8	If worn, eyeglasses are wiped. ***If none of the pharmacy staff wear glasses, inspector should answer statement as N/A.***	Yes		3.1
54.9	Any accommodations permitted by the designated person(s) have been documented. ***Inspector note: Per USP <797>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
55.0	**Hand Hygiene Observation:** Were compounding personnel entering the compounding area observed performing the appropriate hand washing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.2 Box 3
55.1	All personnel entering the compounding area performed hand hygiene.	Yes		3.2 Box 3
55.2	The order of hand washing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2 Box 3
55.3	Fingernails are cleaned under warm running water using a disposable nail cleaner (eg, nail pick). ***Inspector note: During observations, inspect whether nail picks are available for use when performing hand hygiene.***	Yes		3.2 Box 3
55.4	Brushes are not used for hand hygiene.	Yes	Brushes are no longer used after Florida BOP inspection.	3.2 Box 3
55.5	Hands and forearms are washed up to the elbows with soap and warm water for at least 30 seconds. ***Inspector note: Compounding personnel describe method for ensuring they have washed for 30 seconds (example: clock or timer is available near the sink).***	Yes		3.2 Box 3

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		Observation	Inspector Notes	USP Reference(s)
55.6	Soap containers are not refilled or topped off.	Yes		3.2
55.7	Hands and forearms are completely dried up to the elbows with low-lint disposable towels or wipers.	Yes		3.2 Box 3
55.8	Hand dryers are not used for hand hygiene.	Yes		3.2 Box 3
56.0	**Garbing Observation:** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3
56.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3
56.2	Compounding personnel entering the cleanroom suite and/or SCA adhere to the minimum garbing requirements in USP <797>. ***Inspector note: Per USP <797>, additional garbing requirements must be continuously met in the buffer room where Category 3 CSPs are prepared, regardless of whether Category 3 CSPs are compounded on a given day.***	Yes		3.3
56.3	Donning procedures are performed in an order that reduces the risk of contamination. ***Inspector note: USP recommends (not requires) the donning procedure to be performed in the anteroom.*** ***If no, inspector must describe in the notes column why a risk of contamination is a concern.***	Yes		3.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
56.4	Doffing procedures are performed in an order that reduces the risk of contamination.	Yes		3.3
56.5	The order of garbing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2, 3.3
56.6	Sterile gloves are donned in a classified room or SCA. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb and again before sterile gloves are donned, see USP <797> FAQ #97.***	Yes		3.2
56.7	Skin is not exposed inside the ISO Class 5 PEC.	Yes		3.3
56.8	Garb is replaced immediately if it becomes visibly soiled or if its integrity is compromised.	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
56.9	**Category 1 and Category 2 only:** Upon exit of the compounding area, all garb (except for gowns) is discarded or laundered prior to reuse. ***Inspector note: Gowns (disposable and non-disposable) may be reused within the same shift by the same person only if stored appropriately.*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused; inspector should answer statement as N/A.***	Yes		3.3
56.10	**Category 1 and Category 2 only:** Gowns reused within the same shift and by the same person are maintained in a manner that prevents contamination. ***Inspector note: Per USP <797>, gowns stored for reuse must be maintained in a classified area or adjacent to or within the SCA in a manner that prevents contamination (eg, away from sinks to avoid splashing).*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused; inspector should answer statement as N/A.***	Yes		3.3
57.0	List the name(s) of the CSPs observed by the inspector as part of live compounding demonstration.	[redacted]	Mock compounding with normal saline was performed.	
58.0	**Compounding Observation:** Are compounding personnel observed using the appropriate aseptic technique that ensures the quality of the CSP and the environment is maintained in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		1, 2.1, 2.3

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		Observation	Inspector Notes	USP Reference(s)
58.1	All sterile compounding is performed in a PEC with ISO Class 5 conditions or better. ***If the pharmacy only performs immediate use compounding, inspector should answer this statement as N/A.***	Yes		4.1.2
58.2	**Category 2 and Category 3 only:** All PECs are placed in a cleanroom suite. ***Inspector note: Per USP, "If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA."*** ***If the pharmacy only prepares Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.1.2
58.3	Compounding personnel ascertain before use that components are of the correct identity, appropriate quality, within the expiration date, and have been stored under the proper conditions.	Yes		9.3.3
58.4	All items are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA prior to being introduced into the clean side of the anteroom, placed into a pass-through chamber, and/or brought into the SCA. ***Inspector note: The wiping procedure or agents used should not compromise the packaging integrity or render the product label unreadable. Disinfectant dwell time minimums, as specified by the manufacturer, are to be followed.***	Yes		8.1

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		Observation	Inspector Notes	USP Reference(s)
58.5	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. ***Inspector note: Per USP, "When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable."***	Yes		8.2
58.6	Aseptic processes and manipulations are performed in a manner intended to minimize the risk of contamination. ***Inspector note: Observe the compounder's technique to ensure proper aseptic technique is utilized such as: preparation occurs in the direct compounding area (DCA); the compounder does not interrupt first air during the compounding process; proper set up of equipment, supplies, and components that ensure first air is not interrupted; the compounder handles the syringe in a manner that does not introduce contaminates (touch contamination on the plunger rod); proper entry and exit of materials in ISO Class 5 PEC; and frequent sanitization of gloves.***	Yes		2.3
58.7	All critical sites (eg, vial stoppers, ampule necks, and IV bag septums) are wiped with sterile 70% IPA in the PEC and allowed to dry before puncturing.	Yes		7, 8.3
58.8	Gloves are disinfected with sterile 70% IPA immediately before compounding and regularly throughout the compounding process. ***Inspector note: Per USP, best practice is to re-sanitize each time hands re-enter the PEC. This may not occur when compounder is staging the next batch.***	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
58.9	Gloves are regularly inspected for holes, punctures, or tears, and are replaced immediately if such defects are detected.	Yes		3.3
59.0	Do compounding personnel adhere to the USP established time limits for components after initial puncture or entry in compliance with USP <797> standards? ***Look at punctured, stored containers and confirm if puncture time or BUD is noted on the container and stored within time limits. If no, go to the compliance statements.***	Yes		15
59.1	Single dose containers (entered or punctured only in an ISO Class 5 air or cleaner air) are not used beyond 12 hours after initial puncture or entry or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured single-dose vials, compounded single-dose CSPs used as components, and CSP stock solutions. The labeled storage requirements during that 12-hour period must be maintained. Additionally, per USP, "This time limit for entering or puncturing (a single-dose CSP or CSP stock solution) is not intended to restrict the BUD of the final CSP."***	Yes		15.1, 16.2
59.2	Multiple-use containers are not used for more than 28 days after initial puncture or entry, manufacturer specifications, or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured multiple-dose vials and compounded multiple-dose CSPs used as components. Multiple-dose CSPs are required to meet the criteria for antimicrobial effectiveness testing (USP <51>) and must be stored under the conditions upon which its BUD is based (eg, refrigerator or controlled room temperature).***	Yes		14.5, 15.2, 16.1

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		Observation*	Inspector Notes	USP Reference(s)
59.3	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. ***Inspector note: Ampules or vials where the container closure system has been removed must not be stored for any time period.***	Yes		15.1
59.4	Pharmacy bulk package containers of sterile drugs for parenteral use are only entered or punctured in an ISO Class 5 PEC. ***Inspector note: Per USP, the pharmacy bulk package system must be used according to the manufacturer's labeling.***	Yes		15.3
60.0	**Inspect several different finished compounded sterile preparations.** Are all the finished compounded sterile preparations free from any evidence of particulates, filaments, floaters, or signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately. Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, filament or floater); number of preparations affected (eg, two of the five vials on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12

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		Observation	Inspector Notes	USP Reference(s)
61.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes or high risk drugs or high risk populations (eg, neonates).*** ***These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage. Some checks may be done retrospectively and with the assistance of technology.***	Yes		2 Table 2, Table 3
62.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and disinfection activities in compliance with USP <797> standards? ***If inspector is unable to observe cleaning activities (due to timing of compounding activities observed), inspector should interview compounder(s) to have them walk through their normal process. If this occurs, inspector should record in notes column "process only."*** ***If no, go to compliance statements.***	Yes		7
62.1	All cleaning and disinfection activities are performed by appropriately garbed personnel.	Yes		7
62.2	Cleaning and disinfection are performed on all surfaces in the classified area and SCA.	Yes		7

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		Observation	Inspector Notes	USP Reference(s)
624	Cleaning is performed in the direction of clean to dirty areas.	Yes		7
625	Reusable cleaning tools are disinfected prior to and after each use.	Yes		7.1.2
626	Only sterile cleaning, disinfecting, and sporicidal agents are permitted for use in the PEC. ***Inspector note: If pharmacy utilizes non-ready to use (RTU) agents, they must be diluted with sterile water. Per USP, "Once opened, sterile cleaning and disinfecting agents and supplies (eg, closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs."***	Yes		7.1.1, 7.1.2
627	Only sterile supplies and equipment are permitted for use in the PEC. ***Inspector notes: Non-disposable cleaning tools or handles must be properly disinfected prior to entering the PEC and prior to use.***	Yes		7.1.1, 7.1.2
628	Compounding personnel are using the appropriate sterile cleaning, disinfecting, and sporicidal agents within the PEC.	Yes		7.1.1

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		Observation	Inspector Notes	USP Reference(s)
62.8	Compounding personnel are using the appropriate cleaning and disinfecting procedures and techniques within the PEC. ***Inspector note: Per USP, "All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs"; "Cleaning must be performed in the direction of clean to dirty areas"; and when 70% sterile IPA is used, it is used last and allowed to dry. There are differing opinions on the best order of cleaning. Procedure includes using a sterile low-lint wiper to all surfaces. Allow surfaces to dry completely before beginning compounding.***	Yes		7.1.2 Box 7, Box 8
62.9	The manufacturer's directions or published data for the minimum contact time is followed for each of the cleaning, disinfecting, and sporicidal disinfectant used. ***Per USP, contact times should be included in the SOP based on the agent used.***	Yes		7.1.1 Box 7, Box 8
62.10	Sterile 70% IPA is applied to all surfaces in the ISO Class 5 PEC at the frequencies specified by USP during active compounding. ***Inspector note: Per USP <797>, sterile 70% IPA must be applied: immediately before initiating compounding procedures, to the work surface of the PEC at least every 30 minutes (if the compounding process takes 30 minutes or less), to the work surface of the PEC immediately after compounding (when the compounding process takes more than 30 minutes), after each batch or lot is completed, and after cleaning and disinfecting.***	Yes		7

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		Observation	Inspector Notes	USP Reference(s)
	Sterilization and Depyrogenation			10
63.0	Does the pharmacy compound preparations with any nonsterile starting components? ***If the pharmacy does not compound preparations with any nonsterile starting components, inspector should answer question as N/A.***	Yes		10
64.0	Are injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure, sterilized within six hours after completing the preparation? ***If no, describe observations and collect a copy of the master formulation record, a copy of the compounding record, and a copy of the process for sterilization.*** ***If the pharmacy does not compound with nonsterile components or devices, or they only compound sterile ophthalmic and/or sterile drugs administered by inhalation, inspector should answer question as N/A.***	Yes		10
65.0	**Filter Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***View compounding records for CSPs sterilized by filtration to verify.*** ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	Yes		10.2 USP <1229.4>

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		Observation	Inspector Notes	USP Reference(s)
65.1	Sterilization by filtration is performed in an ISO 5 environment.	Yes		4.1.2, 10.2
65.2	Filters used have enough capacity to filter the required volumes. ***Inspector note: Per USP, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process."***	Yes		10.2
65.3	The 0.2 micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP. Inspector note: Per USP <797>, sterilizing filters must be appropriate for pharmaceutical use. Sterilizing filters labeled "for laboratory use" or equivalent must not be used. "Sterilizing filters must be certified by the manufacturer to retain at least 107 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (ie, pressure, flow rate, and volume filtered)."	Yes		10.2
65.4	Confirmation of filter integrity (bubble testing) is performed and documented for each filter used with each batch sterilized by filtration. ***Inspector note: If multiple filters are required for the compounding process, each of the filters must be tested.*** ***If no, collect a copy of the master formulation record and compounding record.***	Yes		10.2

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		Observation	Inspector Notes	USP Reference(s)
65.5	A prefiltration step is performed for any CSPs that are known to contain excessive particulate matter. ***Inspector note: The prefiltration step consists of using a filter with a larger nominal pore size (eg, 1.2 micron) or a separate filter of larger nominal pore size should be placed upstream of (ie, prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter.***	Yes		10.2
65.6	CSPs that are prepared using a filter that failed integrity tests are either discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time. ***If no, collect a copy of the master formulation record and compounding record.***	Yes		10.2
65.7	Single-use filters are only used once.	Yes		4.1.2, 10.2
66.0	**Steam Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment (autoclave), documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***View documentation on compounding records for CSPs sterilized by steam to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.3 USP <1229.1>

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		Observation	Inspector Notes	USP Reference(s)
66.1	The pharmacy has evaluated if steam sterilization would cause degradation of the drug. ***Inspector note: Per USP, compounded preparations that are degraded by moisture, pressure, or temperatures used may not be sterilized by steam heat.***	N/A		10.3
66.2	Steam supplied is free of contaminants and generated using water per manufacturer's specifications.	N/A		10.3
66.3	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.3
66.4	Items are placed in the autoclave in a manner that allows steam to reach them without entrapment of air. ***Inspector note: The pharmacy should have the autoclave cycle validated for the size of the batch, sterilization temperature, and sterilization time to ensure the load will be sterile.***	N/A		10.3 USP <1229.1>
66.5	Sealed containers used are able to generate steam internally (eg, small amount of water in empty crimped vials).	N/A		10.3

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[redacted] Sterile Compounding Inspection for USP <797> [redacted]

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		Observation	Inspector Notes	USP Reference(s)
66.6	The appropriate biological indicators (USP <1229>) are used to verify the effectiveness of each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent; see Biological Indicators for Sterilization USP <1229.5>), and other confirmation methods such as physicochemical indicators (see Physicochemical Integrators and Indicators for Sterilization USP <1229.9>). The date, run, and load numbers of the steam sterilizer used to sterilize a CSP is documented in the compounding record."***	N/A		10.3 USP <1229.5> USP <1229.9>
66.7	All items are directly exposed to steam under adequate pressure for the length of time necessary as determined by use of appropriate biological indicators to render the items sterile. ***Inspector note: Per USP <797>, the duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period (an example provided in the chapter is 20-60 minutes at 121°C saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized).*** ***Any parameters for the autoclave must be set through validation.***	N/A		10.3 USP <1229.1>
66.8	A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (eg, deviations in temperature or pressure) and results documented on the CR.	N/A		10.3, 20

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		Observation	Inspector Notes	USP Reference(s)
67.0	**Dry Heat Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity. USP <1229.8> also applies.*** ***View documentation on compounding records for CSPs sterilized by dry heat to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.4 USP <1229.8>
67.1	The pharmacy has the appropriate dry heat sterilization equipment. ***Inspector note: Dry heat sterilization is usually performed in an oven designed for sterilization at 160°C or higher. The dry heat oven should be able to get to the appropriate temperature and pressure, for example, not be a toaster oven.***	N/A		10.4
67.2	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.4
67.3	During sterilization, sufficient space is left between materials to allow for circulation of hot air.	N/A		10.4
67.4	CSPs and other items are exposed to dry heat for the length of time necessary for all items to reach sterilizing temperature of 160°C or higher. ***Inspector note: Per USP <797>, if lower temperatures are used, they are validated by biological indicators (see USP <1229.8>, Validation of Dry Heat Sterilization, Biological Indicators). The calibrated oven must be equipped with temperature controls and a timer.***	N/A		10.4

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

[redacted] Sterile Compounding Inspection for USP <797>

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
67.5	The appropriate biological indicators are used to verify the effectiveness each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of dry heat sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus atrophaeus (ATCC 9372; see Biological Indicators for Sterilization USP <1229.5>) and other confirmation methods (e.g., temperature-sensing devices). The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR."***	N/A		10.4 USP <1229.5>
67.6	A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (eg, deviations in temperature or exposure time) and results documented on the CR.	N/A		10.4, 20
68.0	**Dry Heat Depyrogenation:** Is the appropriate depyrogenation method used and documented in compliance with USP <797> standards? ***View documentation records of items depyrogenated to confirm.*** ***If the pharmacy does not use this method, inspector should answer question as N/A.***	N/A		10.1 USP <1228.1>
68.1	Glassware, metal, and other thermostable containers are exposed to dry heat for the length of time necessary for all items to be rendered pyrogen free.	N/A		10.1

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		Observation	Inspector Notes	USP Reference(s)
68.2	The effectiveness of the dry heat depyrogenation cycle is established and documented. ***Inspector note: Per USP <797>, this must be done initially, re-established any time there are changes made to the cycle (eg, load conditions, duration, temperature), and verified at least annually by using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥ 3-log reduction in endotoxins (see Bacterial Endotoxins Test USP <85>). The verification must be documented.***	N/A		10.1 USP <1228.1> USP <85>
68.3	Items that are not thermostable are depyrogenated by multiple rinses with sterile, nonpyrogenic water (eg, sterile water for injection or sterile water for irrigation) and then thoroughly drained or dried immediately before use in compounding. ***Inspector note: USP <1228.4> Depyrogenation by Rinsing also applies.***	N/A		10.1 USP <1228.4>
	Master Formulation and Compounding Records Inspector should review a minimum of five (5) master formulation records and five (5) compounding records.			11
69.0	Are **Master Formulation Records (MFRs)** created and maintained in compliance with USP <797> standards? ***If no, go to the compliance statements.***	Yes		11.1
69.1	The pharmacy creates and maintains MFRs for CSPs that are prepared for more than one patient.	Yes		11.1, 20
69.2	MFR changes and alterations are approved and documented according to the pharmacy's SOPs.	Yes		11.1
69.3	The pharmacy creates and maintains MFRs for CSPs that are prepared from nonsterile ingredients.	Yes		11.1, 20

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		Observation	Inspector Notes	USP Reference(s)
69.4	The MFR includes the name, strength or activity, and dosage form of the sterile compounded preparation.	Yes		11.1, 20
69.5	The MFR includes the identities and amounts of all ingredients.	Yes		11.1, 20
69.6	The MFR includes the type and size of container closure.	Yes		11.1, 20
69.7	The MFR includes complete instructions for preparing the sterile compounded preparation, including equipment, supplies, a description of the compounding steps, and any special precautions.	Yes		11.1, 20
69.8	The MFR includes a physical description of the final CSP.	Yes		11.1, 20
69.9	The MFR includes the BUD and storage requirements.	Yes		11.1, 14.2, 20
69.10	The MFR includes the reference source to support the stability of the CSP.	Yes		11.1, 20
69.11	The MFR includes quality control procedures (eg, pH testing, filter integrity testing).	Yes		11.1, 20

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		Observation	Inspector Notes	USP Reference(s)
69.12	The MFR includes other information as needed to describe the compounding process and ensure repeatability (eg, adjusting pH and tonicity, sterilization method).	Yes		11.1, 20
69.13	The MFR includes all required release tests, and if applicable, sterility test methods, process, number and endotoxin test and limits.	Yes		11.1, 12, 20
70.0	Are **Compounding Records (CR)** created and maintained in compliance with USP <797> standards? ***Inspector note: Per USP, a prescription or medication order or label may serve as the CR. Also, a copy of the MFR can be made that contains spaces for recording the information needed to complete the CR (eg, both the MFR and CR are on the same document/form). A CR may be kept electronically, if readily retrievable, as long as it contains all required information.*** ***If no, go to compliance statements.***	Yes		11.2 Box 10
70.1	The pharmacy creates and maintains CRs for all for immediate-use CSPs prepared for more than one patient. ***Inspector note: if pharmacy does not prepare any CSPs for immediate-use, inspector should answer compliance statement as N/A.***	Yes		11.2 Box 10
70.2	The pharmacy creates and maintains CRs for all Category 1, Category 2, and Category 3 CSPs.	Yes		11.2 Box 10
70.3	The CR includes the name, strength or activity, dosage form of the CSP, and (if applicable) the MFR reference.	Yes		11.2 Box 10

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		Observation	Inspector Notes	USP Reference(s)
70.4	The CR includes the date and time of preparation.	Yes		11.2 Box 10
70.5	The CR includes an assigned internal identification number (eg, prescription, order, or lot number).	Yes		11.2 Box 10
70.6	The CR includes the identity of the individual(s) involved in the compounding process.	Yes		11.2 Box 10
70.7	The CR includes identity of the individual(s) verifying the final CSP.	Yes		11.2 Box 10
70.8	The CR includes the name of each component.	Yes		11.2 Box 10
70.9	The CR includes the vendor/manufacturer, lot number, and expiration date for each component. ***Inspector note: this is required for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).***	Yes		11.2 Box 10
70.10	The CR includes the weight or volume of each component.	Yes		11.2 Box 10
70.11	The CR includes the strength or activity of each component.	Yes		11.2 Box 10
70.12	The CR includes the total quantity compounded.	Yes		11.2 Box 10

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		Observation	Inspector Notes	USP Reference(s)
70.13	The CR includes the final yield (eg, quantity, containers, number of units).	Yes		11.2 Box 10
70.14	The CR includes the assigned BUD and storage requirements.	Yes		11.2 Box 10
70.15	The CR includes results of quality-control procedures (eg, visual inspection, filter integrity testing, pH testing).	Yes		11.2, 12 Box 10
70.16	The CR includes calculations made to determine and verify quantities and/or concentrations of components. ***Inspector note: Per USP, "If applicable, the CR must also include...Calculations."***	Yes		11.2 Box 10
70.17	The CR is verified by the pharmacist for appropriateness and accuracy with in-process and final checks. ***Inspector note: "Documentation must comply with all laws and regulations of the applicable regulatory jurisdiction."***	Yes		2, 11.2, 12.1, 13, 20 Box 10
71.0	Are the pharmacy's labels for CSPs in compliance with USP <797> standards and display all required information? ***If no, go to compliance statements.***	Yes		13 USP <7>

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		Observation	Inspector Notes	USP Reference(s)
71.1	Information on the label is prominently and legibly displayed. ***Inspector note: Definition of labeling includes other accompanying materials with the CSP, which includes, "written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed." The shipping container is not included in the definition of the "label."***	Yes		13
71.2	Labeling meets any state or federal regulatory requirements.	Yes		13
71.3	Labeling on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		13
71.4	Labeling on the immediate container includes the active ingredients and their amounts, activity, or concentration.	Yes		13
71.5	Labeling on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		13
71.6	Labeling on the immediate container includes the BUD. Per USP, "Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded (ie, the BUD)."	Yes		13, 14.1
71.7	The compounded CSP label does not use the term "expiration date" or equivalent.	Yes		13, 14.1 USP <7>
71.8	Labeling on the immediate container includes the dosage form.	Yes		13

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		Observation	Inspector Notes	USP Reference(s)
71.9	Labeling on the immediate container includes the total amount or volume when not obvious from the container.	Yes		13
71.10	Labeling on the immediate container states that the CSP is a single-dose container (when space permits).	Yes		13
71.11	Labeling on the immediate container states that the CSP is a multiple-dose container.	Yes		13
71.12	Labeling includes the route of administration, as applicable.	Yes		13
71.13	Labeling includes any special handling instructions and/or warning statements, as applicable.	Yes		13
71.14	Labeling includes the compounding facility name and contact information if the CSP is to be sent outside of the facility or health care system in which it was compounded.	Yes		13
72.0	Does the label contain information identifying the CSP is a compounded preparation? ***Inspector note: Per USP, this is a recommendation/should.***	Yes		13 USP <7>

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		Observation	Inspector Notes	USP Reference(s)
	Establishing BUDs			14
73.0	**Category 1 and Category 2 CSPs:** Does the pharmacy assign BUDs for Category 1 and Category 2 CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		14, 14.1, 14.2
73.1	The assigned BUD does not exceed the shortest expiration date of any of the individual commercially available starting components.	Yes		14.3
73.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and that its packaging maintains its integrity for the duration of the assigned BUD.	Yes		14.3
73.3	**Category 1 CSPs:** BUDs for **Category 1 CSPs** prepared in an SCA do not exceed the limits established in Table 12. ***Inspector note: Per USP <797> Table 12, BUD maximum limits for Category 1 CSPs are defined as 12 hours at controlled room temperature (CRT 20°C-25°C) or 24 hours refrigerated (2°C-8°C). If no Category 1 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, Table 12

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		Observation	Inspector Notes	USP Reference(s)
73.4	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs using one or more nonsterile starting components are defined as: one day CRT; four days refrigerator; and 45 days freezer. Aseptically processed Category 2 CSPs using only sterile starting components are defined as: four days CRT; 10 days refrigerator; and 45 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, Table 13
73.5	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs, that were sterility tested and passed, regardless of starting components being sterile or nonsterile, are defined as: 30 days CRT; 45 days refrigerator; and 60 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, 14.2.1, 14.2.3, Table 13

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		Observation	Inspector Notes	USP Reference(s)
736	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** that do **not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to probability of nonsterile unit (PNSU) of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 14 days CRT; 28 days refrigerator; and 45 days freezer.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, 14.2.1, Table 13
737	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to PNSU of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 45 days CRT; 60 days refrigerator; and 90 days freezer. Endotoxin testing is required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing.*** ***USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components are also endotoxin tested.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, 14.2.1, 14.2.3, Table 13

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		Observation	Inspector Notes	USP Reference(s)
74.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest beyond use date of any individual compounded components? ***Inspector note: Per USP, "the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (eg, pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted." Other examples where this may occur: formula within a formula, preservative-free compounded component used in a preserved final CSP, "in-use" times for pharmacy bulk packages, and cyclosporine ophthalmic stock solution.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		14.3
75.0	Are BUDs for **Category 3 CSPs** assigned in compliance with all conditions outlined in USP <797> standards and do not exceed the maximum limits established in Table 14? ***Inspector note: If all of the conditions described for Category 3 CSPs are not met, the applicable BUD must not exceed the established maximum limits in Table 13 for Category 2 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare Category 3 CSPs, Inspector should answer question as N/A.***	N/A		14.3, 14.4., 14.4.1, 14.4.2, 14.4.3, 14.4.4, Table 14
75.1	The assigned BUD does not exceed the shortest expiration date of any of the individual starting components.	N/A		14.3 Table 14

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[redacted] Sterile Compounding Inspection for USP <797> [redacted]

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		Observation	Inspector Notes	USP Reference(s)
75.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and its packaging maintains its integrity for the duration of the assigned BUD.	N/A		14.3 Table 15
75.3	BUDs for **Category 3 CSPs** do not exceed the maximum limits for aseptically processed (eg, filtered) established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits for aseptically processed Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 60 days CRT; 90 days refrigerator; and 120 days frozen.***	N/A		14.4.1 Table 14
75.4	BUDs for **Category 3 CSPs** do not exceed the maximum limits for terminally sterilized established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits terminally sterilized Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 90 days CRT; 120 days refrigerator; and 180 days frozen.***	N/A		14.4.1 Table 14

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		Observation	Inspector Notes	USP Reference(s)
75.5	**Category 3 CSPs** are supported by stability data obtained using methods described in USP <1225> or a validated noninferior stability-indicating analytical method. ***Inspector note: Per USP <797>, Category 3 CSPs must prepared according to the EXACT formulation (API and other ingredients of identical grade and procedures) from which the stability data is derived. Category 3 CSPs must be packaged and stored in container closure of the same materials of composition as used in study and the facility must have documentation of the stability study.*** ***View records to verify the preparation exactly matches the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.***	N/A		14.4.3 Table 14 USP <1225>
75.6	**Category 3 CSPs** undergo sterility testing. ***Inspector note: Sterility testing is performed on all Category 3 CSPs.***	N/A		14.4.4 Table 14 USP <71>
75.7	**Category 3 CSPs** undergo bacterial endotoxin testing. ***If all compounds prepared are ophthalmics and/or drug administered by inhalation, bacterial endotoxin is not required, inspector should answer statement as N/A.***	N/A		12.3, 14.4.4 Table 14 USP <85>
75.8	**Category 3 CSPs** undergo particulate matter testing. ***Inspector note: If the Category 3 CSP is an injection or an ophthalmic solution, particulate matter testing is also conducted once per formulation with acceptable results (See USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions).***	N/A		14.4.3 Table 14 USP <788>, <789>

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e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Inspector Notes	USP Reference(s)
75.9	**Category 3 CSPs** undergo an evaluation for the container closure system. ***Inspector note: The container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD (see USP <1207> Package Integrity Evaluation—Sterile Products). Evaluation must be done once for each formulation and for each container closure system in which it will be packaged.***	N/A		14.4.3 Table 14 USP <1207>
76.0	Are **multiple-dose CSPs prepared** in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not prepare multiple-dose CSPs, inspector should answer question as N/A.***	Yes		14.5
76.1	Multiple-dose CSPs are prepared as a Category 2 or Category 3 CSP only.	Yes		14.5
76.2	When preservatives are used, they are appropriate for the CSP formulation and the route of administration. Inspector note: Per USP <797>, "The preservative must not be inactivated by any ingredients in the CSP, and some preservatives are not always appropriate for the patient (eg, neonates) or route of administration (eg, intrathecal or ophthalmic injection)."	Yes		14.5

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		Observation	Inspector Notes	USP Reference(s)
76.3	Aqueous multiple-dose CSPs pass antimicrobial effectiveness testing in accordance with USP <51>. ***Inspector note: Per USP <797>, a test can be one test done for each formulation in the particular container-closure system in which it will be packaged, or test results provided by an FDA-registered facility or in appropriate peer-reviewed literature,, provided the sterile compounded preparation formulation and container-closure system used are exactly the same as those tested, unless a bracketing study is performed. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study. Additionally, multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs prepared as a Category 2 or Category 3 CSP are not required to pass antimicrobial effectiveness testing if the preparation is: For use by a single patient, labeled (in the label or labeling) to indicate that, once opened, it must be discarded after 24 hours when stored at controlled room temperature and/or that, once opened, it must be discarded after 72 hours when stored under refrigeration.***	Yes		14.5 USP <51>
76.4	Multiple-dose CSPs are labeled to indicate the beyond use date of the CSP once it is opened or punctured. ***Inspector note: Labeling on the CSP should indicate that once the CSP container is entered or punctured, it must not be used for longer than the assigned BUD or 28 days (if supported by antimicrobial effectiveness testing results), whichever is shorter.*** ***Inspector should review the CR or final compounded preparation to verify the label contains this information.***	Yes		14.5
76.5	Container-closure systems used are evaluated for maintaining integrity (USP <1207>) for each formulation and fill volume. ***Inspector note: Per USP <797>, the container closure integrity test needs to be conducted only once on each formulation and on fill volume in the particular container closure system in which the multiple-dose CSP will be packaged.***	Yes		14.5 USP <1207>

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		Observation	Inspector Notes	USP Reference(s)
	Finished Preparation Release Checks and Tests			12
77.0	Are all CSPs visually inspected for quality prior to release or dispensing in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		12.1
77.1	The CSP label is visually inspected to confirm that the CSP and its labeling match the prescription or medication order.	Yes		12.1
77.2	CSPs are visually inspected for quality characteristics such as discoloration, visible particulates, or cloudiness.	Yes		12.1
77.3	CSPs are visually inspected to verify container closure integrity (eg, checking for leakage, cracks in the container, or improper seals).	Yes		12.1
77.4	A visual inspection is also repeated prior to release or dispense for CSPs that have been stored in the pharmacy and not released or dispensed on the day of preparation.	Yes		12.1

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		Observation	Inspector Notes	USP Reference(s)
77.5	Any CSPs found to be of unacceptable quality (eg, observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		12.1
78.0	For any CSPs assigned beyond use dates that require sterility testing, does the pharmacy ensure that all testing is performed, evaluated, and documented in accordance with USP <71> or a validated alternative method that is noninferior to USP <71> testing and USP <797> standards? ***Inspector note: Alternative testing methods may not be accepted in all regulatory jurisdictions that the pharmacy conducts business.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare any CSPs that require sterility testing, inspector should mark as N/A.***	Yes		12.2

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[redacted] Sterile Compounding Inspection for USP <797> [redacted]

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		Observation	Inspector Notes	USP Reference(s)
78.1	The required number of sterile compounded preparation units, as described in USP <71> and USP <797>, are tested. ***Inspector note: Per USP <71> Table 3, the minimum number of items to be tested for each medium is:*** ***Parenterals*** ***Not more than 100 containers = 10% or four containers, whichever is greater*** ***More than 100, but not more than 250 containers = 10 containers*** ***Large volume parenterals*** ***2% or 10 containers, whichever is less*** ***Non-parenterals (eye drops, inhalation, pellets, etc.)*** ***Not more than 200 containers = 5% or two containers, whichever is greater*** ***More than 200, but not more than 250 containers = 10 containers*** ***Per USP <797>, if the number of CSPs compounded in a single batch is less than what is needed for testing as specified in USP <71> Table 3, additional units must be compounded to be able to perform testing as follows:*** ****If 1-39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number.*** ****If more than 40 CSPs are prepared in a single batch, the sample sizes specified in USP <71> Table 3 must be used.***	Yes		12.2, 14.2.3 USP <71>
78.2	Batch sizes of sterile CSPs do not exceed 250. ***Inspector Note: Per USP <797>, the maximum batch size for all sterile compounded preparation requiring sterility testing is limited to 250 final yield units.***	Yes		12.2, 14.2.3

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		Observation	Inspector Notes	USP Reference(s)
78.3	Pharmacy is utilizing an alternative method for sterility assurance testing (other than USP <71>). ***Inspector note: Per USP, "If an alternative method is used for sterility testing, the method must be validated (see USP <1223>) and demonstrated to be suitable for that CSP formulation."*** ***If an alternative method is used, describe the method used and how the pharmacy ensures they are compliant with state-specific regulations.***	N/A		12.2 USP <71>, <1223>
78.4	When sterility testing identifies a failure, the pharmacy has processes to investigate and identify any contributing factors. ***Inspector note: Per USP, "Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented." Additionally, some rapid sterility test methods do not allow for the identification of the recovered microorganisms. If one of these methods is used, the pharmacy is not in compliance with the chapter, as the investigation must include identification of the recovered microorganism.***	Yes		12.2

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[redacted]		Observation	Inspector Notes	USP Reference(s)
79.0	For any CSPs assigned BUDs that require **bacterial endotoxin testing**, does the pharmacy ensure that all testing is performed and documented in compliance with USP <85> and USP <797> standards? ***Inspector note: Endotoxin limits reflect limits in an official monograph, or calculated as described in USP Chapter <85> for the route of administration for humans, and for animals based on weight.*** ***Although USP <797> refers to USP <85> Bacterial Endotoxins Test for calculating endotoxin limits for the appropriate route of administration, it does not address products administered epidurally or administered directly into the central nervous system. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare CSPs that require bacterial endotoxin testing, inspector should answer question as N/A.***	N/A		12.3 USP <85>
79.1	The pharmacy has an appropriate procedure for calculating/determining endotoxin limits. ***Per USP, there are endotoxin limits listed in USP product and compounded preparation monographs. The laboratory may be performing the calculation rather than the pharmacy; however, if done in house, this should be included in the pharmacy SOPs.*** ***If the dosage form does not require, inspector should answer statement as N/A.***	N/A		12.3
79.2	The pharmacy collects patient weight to make bacterial endotoxin calculation for an animal patient. ***If the dosage form does not require or the pharmacy does not compound sterile preparations for animals, inspector should answer statement as N/A.***	N/A		12.3

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		Observation	Inspector Notes	USP Reference(s)
79.3	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 2 CSPs** compounded from one or more nonsterile components that are assigned a BUD requiring sterility testing per Table 13. ***Inspector note: USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components is also endotoxin tested.***	N/A		12.3 Table 13 USP <85>
79.4	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 3 CSPs** compounded from one or more nonsterile components.	N/A		12.3 Table 13 USP <85>
79.5	Any CSPs with failed endotoxin testing are quarantined, not further released, and action is taken for any product released prior to receipt of failed test results. ***View testing records and note any products with failed results and actions taken.***	N/A		12.2, 12.3
	CSP Packaging, Shipping and Transport			19
80.0	Are processes and techniques for packaging and transporting CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		19.1, 19.2, 19.3
80.1	The pharmacy uses the appropriate shipping containers and packaging materials (eg, coolers and light-resistant packaging) based on the product specifications.	Yes		19.2

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		Observation	Inspector Notes	USP Reference(s)
80.2	CSPs are appropriately packaged to protect against damage, leakage, contamination, degradation, and adsorption during storage and transport. ***Inspector should look at packaging materials used to ensure cushioning to prevent breakage of glass vials and ensure that container is generally clean without non-microbial growth that would come in direct contact with CSPs.***	Yes	Inspected packaging materials.	19.2
80.3	Specific handling instructions when applicable, are included on the exterior of the container.	Yes		19.3
80.4	The pharmacy selects transport modes that ensure CSPs are delivered properly in undamaged, sterile, and stable conditions (eg, no undue exposure to heat, cold, or light). ***Inspector note: Transport modes include pneumatic tube transport systems and should not be used if the CSP is sensitive to shaking.***	Yes		19.3
	Quality Assurance and Quality Control			18
81.0	**Quality Assurance and Quality Control (QA/QC):** Does the pharmacy's SOP on quality assurance and quality control meet the requirements in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		18 USP <1163>
81.1	Description of procedures for complaint handling, adverse events, and recalls that include corrective action, investigation, reporting, and documentation requirements.	Yes		18.1, 18.2

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		Observation	Inspector Notes	USP Reference(s)
81.2	**QA/QC Out-Of-Specification (OOS) SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the severity of the problem and the urgency for implementation and completion of the recall.	Yes		18.1
81.3	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the distribution of any affected CSP, including the date and quantity of distribution.	Yes		18.1
81.4	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to identify patients who have received the CSP.	Yes		18.1
81.5	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process for the disposal and documentation of the recalled CSP.	Yes		18.1
81.6	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to investigate and document the reason for failure.	Yes		18.1
82.0	Does the pharmacy ensure that QA and QC programs are conducted in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		18, 20

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		Observation	Inspector Notes	USP Reference(s)
82.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of: adherence to procedures; prevention and detection of errors and other quality problems; evaluation of complaints and adverse events; and appropriate investigations and corrective actions."***	Yes		18
82.2	The pharmacy's QA/QC program is reviewed at least once every 12 months by the designated person(s) and the results of the review are documented.	Yes		18
82.3	The designated person(s) reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.	Yes		18.2, 20
82.4	All complaints and adverse events are thoroughly investigated. ***Inspector note: Per USP <797>, the timeframe is specified in the facility SOP. Additionally, USP states, "The investigation must consider whether the quality problem extends to other CSPs."*** ***If facility SOP permits a long investigation period, include in the inspector notes the SOP's expected time frame to complete an investigation. State may have a more aggressive time frame to complete an investigation and report quality events to the state.***	Yes		18.2, 18.3, 20

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		Observation	Inspector Notes	USP Reference(s)
82.5	The record of each complaint is maintained by the pharmacy regardless of the source of the complaint (eg, email, telephone, or mail) and includes the minimum required information. ***Inspector note: Per USP <797>, the complaint record must contain the following information:*** ***-Name of the complainant or other unique identifier;*** ***-Date the complaint was received;*** ***-Nature of the complaint;*** ***-The response to the complaint; and*** ***-Results of any investigation and any follow-up.*** ***In addition, to the extent that the information is known, the following should be recorded:*** ***-The name and strength of the CSP and the assigned internal identification number (eg, prescription, order, or lot number).*** ***If no, inspector should document what is missing in the notes column.***	Yes		18.2, 20
82.6	The pharmacy's QA/QC program includes documentation of steps necessary for completing a recall, including reporting the recall to appropriate regulatory agencies. ***Inspector note: Per USP, "The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction."***	Yes		18.1, 18.2

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		Observation	Inspector Notes	USP Reference(s)
83.0	If a CSP is dispensed or administered **before the results of release testing are known**, does the pharmacy ensure procedures for recalls and out-of-specification notifications are conducted and documented in compliance with USP <797> standards? ***Inspector note: Per USP <797>, if a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to notify, recall, and investigate.*** ***If no, go to the compliance statements.***	Yes		18.1, 20
83.1	The pharmacy has a process in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, sterility, strength, purity, bacterial endotoxin, or other quality attributes).	Yes		18.1
83.2	The pharmacy has a process in place to recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy.	Yes		18.1
83.3	The pharmacy has a process in place to investigate if other lots are affected and recall if necessary.	Yes		18.1

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		Observation	Inspector Notes	USP Reference(s)
	Personnel Training and Evaluation - Verify records of all compounding personnel (up to 10). Use the records tab to document records reviewed.			2
84.0	Is the pharmacy's documented hand hygiene and garbing competency evaluations compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	Yes		2.2, 20 Box 1, Table 1
85.0	Is the pharmacy's documented aseptic manipulation competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	Yes		2.3, 20 Box 2, Table 1
86.0	Is the pharmacy's documented training program and ongoing competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	Yes		2, 2.1, 17 Table 2, Table 3

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Sterile Compounding Personnel Records Review

Select personnel with compounding responsibilities for your records review; preferably select staff performing compounding duties at time of inspection or staff identified during CR review.
- Recommend also pulling supervising personnel file.
- Inspector can consider pulling non-compounder employee file ("Other") who cleans and stocks compounding area but who does not compound (Note: frequency of competency assessment will be defined by pharmacy SOPs).

Review five (5) personnel files and document your observations. (For applicants seeking a Class E-S Non-Resident Sterile Compounding Inspection (Texas Sampling), review a total of 10 personnel records.)
- *Note: long-term employees may not have initial training available. If this is the case, you may select an alternative file. If an alternate file is not available, document length of service of long-term employee.

Inspector Note: soybean casein digest medium and trypticase soy broth are the same media.

Inspector Instructions

1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position.
2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.
3. Select the appropriate response for each item reviewed.
-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.
-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.
-Select "Missing" if the document is not present in the file.
-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.
4. Use the notes column to document any pertinent information.

Demonstrating Knowledge and Competency of Core Skills (Section 2.1)

USP requirements:
1. Personnel who perform or oversee compounding *or support activities* must be trained in the SOPs and trained on maintaining the quality of the environment (See Table 2).
2. Compounding personnel and supervising personnel must complete training needed to demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions (See Table 2 and Table 3). This must be completed initially and every 12 months in at least the following areas:
-Hand hygiene
-Garbing
-Cleaning and disinfection
-Calculations, measuring, and mixing
-Aseptic technique
-Achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components)
-Use of equipment
-Documentation of the compounding process (eg, master formulation and compounding records)
-Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area
-Proper use of PECs
-Principles of movement of materials and personnel within the compounding area
3. Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control (PEC) must complete ongoing training as required by the facility's SOPs (See Table 3).
4. Personnel compounding only immediate-use CSPs must complete training as required by the facility's SOPs (See Table 3).
5. All training and evaluations must be documented.

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Compounding SOPs	*Initial Training and Competency in Maintaining the Quality of the Environment	*Initial Training and Competency in Sterile Compounding Principles and Practices	Ongoing Training and Competency in Sterile Compounding Principles and Practices	Notes
				Compounders and Supervising Personnel: Initially and at least every 12 months Other Personnel (examples: persons who do not compound but clean/disinfect and restock or who perform in-process checks; persons who only compound immediate use): Initially and as defined by pharmacy SOPs				
#1	Pharmacist	Designated Person	Category 2 only	Yes	Yes	Yes	Yes	

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#2	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	
#3								
#4								
#5								
#6								
#7								
#8								
#9								
#10								

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Inspector Instructions	Hand Hygiene and Garbing Competency Evaluation (Section 2.2)
1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position. 2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency. 3. Select the appropriate response for each item reviewed. -Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards. -Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column. -Select "Missing" if the document is not present in the file. -Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column. 4. Use the notes column to document any pertinent information.	USP requirements: 1.The garbing and hand hygiene competency evaluation consists of a visual observation and gloved fingertip and thumb sampling (GFT) of both hands. 2.The initial competency evaluation consists of three (3) separate and complete hand hygiene observation, followed by a full garbing procedure and a GFT after garbing. The initial three (3) successful completions must be in succession—failure of any of the three (3) initial garbing competency evaluations requires repeat testing until personnel successfully complete three (3) evaluations in a row. 3.The pharmacy uses a microbiological growth media device (eg, plates, paddles, or slides) containing general microbial growth agar (eg, trypticase soy agar [TSA]) supplemented with neutralizing additives (eg, lecithin and polysorbate 80) that supports both bacterial and fungal growth. 4.The media device is incubated at 30°C-35°C for no less than 48h and then at 20°C-25°C for no less than an additional five days. 5.Failure is indicated by visual observation of improper hand hygiene and garbing procedures and/or GFT results that exceed the defined action levels. Action level after garbing: >0 cfu/total from both hands. 6.Documentation includes, at minimum: -Name of the person evaluated -Evaluation date and time -Media and components used including manufacturer, expiration date, and lot number -Starting temperature for each interval of incubation -Dates of incubation -Results (the number of cfu per hand must be recorded; microbial identification of the cfu is not required by the chapter for GFT) -Results of the evaluation and any corrective actions -Name of the observer and personnel reading and documenting the results

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Hand Hygiene and Garbing Visual Observation	Initial GFT x 3 (Post hand washing and garbing)	Subsequent GFT (Post handwashing and garbing)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
				Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially at least every 3 months Supervising Personnel: Initially and at least every 12 months				
#1	Pharmacist	Designated Person	Category 2 only	Yes	Yes	Yes	N/A	
#2	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	N/A	
#3								
#4								
#5								
#6								
#7								
#8								
#9								
#10								

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Inspector Instructions
1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position. 2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency. 3. Select the appropriate response for each item reviewed. -Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards. -Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column. -Select "Missing" if the document is not present in the file. -Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column. 4. Use the notes column to document any pertinent information. 5. Document in notes if initial aseptic manipulation competencies are present in files (*unless long-term employee).

Aseptic Manipulation Competency (Section 2.3)
USP requirements: 1. Media-fill testing procedures simulate the most difficult compounding procedures encountered by personnel. 2. The pharmacy conducts media-fill testing as described in Box 2. 3. The final containers are incubated at 20°C-25°C and 30°C-35°C for a minimum of seven days at each temperature band. 4. Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container closure unit(s) on or before 14 days. 5. Immediately following the media-fill test, GFT is performed on both hands and inside of an ISO Class 5 PEC. Failure is indicated by visual observation of GFT results that exceed defined action levels. Action level after media-fill testing: >3 cfu/total from both hands. 6. Immediately following the GFT, a surface sample of the direct compounding area inside the PEC is performed in accordance with USP standards for surface sample monitoring and action levels. Action level ISO Class 5: >3 cfu/media device. 7. Failure in the media fill, GFT, or surface sampling constitutes an overall failure of the aseptic manipulation competency. 8. Documentation includes, at minimum: -Name of the person evaluated -Evaluation date and time -Media and components used including manufacturer, expiration date, and lot number -Starting temperature for each interval of incubation -Dates of incubation -Results (for GFT, the number of cfu per hand must be recorded and for surface samples, the number of cfu per sample must be recorded. Note: microbial identification of the cfu is not required for media-fill testing) -Results of the evaluation and any corrective actions -Name of the observer and personnel reading and documenting the results

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Aseptic Manipulation Visual Observation	Media-fill	GFT (post media-fill)	Surface Sampling (post media-fill)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
				Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially and at least every 3 months Supervising Personnel: Initially and at least every 12 months					
#1	Pharmacist	Designated Person	Category 2 only	Yes	Yes	Yes	Yes	N/A	
#2	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	N/A	
#3									
#4									
#5									
#6									
#7									
#8									
#9									
#10									

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GLOSSARY/USP<797>
ACD: Automated compounding device.
ACPH: Air changes per hour.
Active pharmaceutical ingredient (API): Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as *Bulk drug substance*. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added substance: An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms *inactive ingredient, excipient, and pharmaceutical ingredient.*
Administration: The direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise providing a sterile product or preparation in its final form.
Airlock: A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas (generally with different air cleanliness standards). The intent of an airlock is to prevent ingress of particulate matter and microbial contamination from a lesser-controlled area.
Alcohol-based hand rub: An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Allergenic extract compounding area (AECA): A designated space, area, or room that is not required to be classified, with a visible perimeter that is suitable for preparation of allergenic extract prescription sets.
Allergenic extract prescription set: Combinations of licensed allergenic extracts that would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved BLAs for the licensed biological products.
Allergenic extract: A biological substance used for the diagnosis and/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy.
Anteroom: An ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The anteroom is the transition room between the unclassified area of the facility and the buffer room.

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GLOSSARY USP <797>
Aseptic processing: A method by which separate, sterile components (eg, drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (eg, by membrane filtration or by autoclave).
Aseptic technique: A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.
Assigned trainer: One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CSPs.
Batch: More than one CSP prepared as described in the MFR in a single, discrete process, and expected to have uniform character and quality, within specified limits.
Beyond-use date (BUD): The date, or the hour and date, after which a CSP must not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
Biological safety cabinet (BSC), Class II: A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare a CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.
Biological safety cabinet (BSC): A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
BLA: Biological license application.
Blood components: Any therapeutic constituent of blood separated by physical or mechanical means (eg, white cells, red cells, platelets, plasma, serum). It is not intended to include plasma-derived products (eg, albumin, coagulation factors, immunoglobulins) manufactured under an approved BLA or equivalent.
BMBL: Biosafety in Microbiological and Biomedical Laboratories.
Buffer room: An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.
Bulk drug substance: See the entry for *Active pharmaceutical ingredient.*

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GLOSSARY USP<797>
Category 1 CSP: A CSP that is assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in this chapter.
Category 2 CSP: A CSP that may be assigned a BUD of greater than 12 hours at controlled room temperature or greater than 24 hours refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in this chapter.
Category 3 CSP: A CSP that may be assigned a BUD exceeding the limits in *Table 13* for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter.
CDC: Centers for Disease Control and Prevention.
Certificate of analysis (COA): A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
CFU: Colony-forming units.
Classified area: An area that maintains an air quality classification based on the ISO standards required in this chapter (see also the definition for *ISO class).*
Cleaning agent: An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Cleaning: The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleanroom suite: A classified area that consists of both an anteroom and buffer room.
Component: Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.
Compounded sterile preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.
Compounded stock solution: A sterile mixture of components that is used to compound additional CSPs.
Compounding area: The area where compounding is occurring (ie, a cleanroom suite, inside the perimeter of the SCA, or AECA).

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GLOSSARY USP<797>
Compounding aseptic containment isolator (CACI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for the compounding of sterile HDs.
Compounding aseptic isolator (CAI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile non-HDs.
Compounding record (CR): Documents the compounding of each CSP.
Compounding: The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation.
Container closure system: Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection.
Containment glove bag: A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE): A non-ISO classified full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.
Conventionally manufactured product: A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Critical site: A location that includes any component or fluid pathway surfaces (eg, vial septa, injection ports, and beakers) or openings (eg, opened ampules and needle hubs) that are exposed and at risk of direct contact with air (eg, ambient room or HEPA filtered), moisture (eg, oral and mucosal secretions), or touch contamination.
Designated person(s): One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CSPs.
Direct compounding area (DCA): A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
Disinfectant: A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that also are effective against bacterial and fungal spores.
Dynamic airflow smoke pattern test: A PEC test in which a visible source of smoke, which is neutrally buoyant, is used to observe air patterns within the unidirectional space (i.e., the DCA) under dynamic operating conditions (see the entry for *Dynamic operating conditions).* This test is not appropriate for ISO Class 7 or ISO Class 8 cleanrooms that do not have unidirectional airflow (see the entry for *Visual smoke study).*

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GLOSSARY USP<797>
Dynamic operating conditions: Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).
ECV: Endotoxin challenge vial.
EPA: US Environmental Protection Agency.
Excipient: See the entry for *Added substance*.
FDA: US Food and Drug Administration.
Filter integrity test: A test (eg, bubble point test) of the integrity of a sterilizing-grade filter performed after the filtration process to detect whether the integrity of the filter has been compromised.
Final yield: The total number of containers prepared at the end of the compounding process prior to release testing.
First air: The air exiting the HEPA filter in a unidirectional air stream.
Formulation: The specific qualitative and quantitative composition of the final CSP.
Garb: Items such as gloves, garments (eg, gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle shedding from personnel and minimize the risk of contamination of CSP(s).
GFT: Gloved fingertip and thumb testing.
Hazardous drug (HD): Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.
High-efficiency particulate air (HEPA) filtration: Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.
HVAC: Heating, ventilation, and air conditioning.
Integrated vertical laminar flow zone (IVLFZ): A designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room. In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the worktables and by effective placement of air returns.
IPA: Isopropyl alcohol.

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GLOSSARY USP <797>
ISO class: An air-quality classification from the International Organization for Standardization.
ISO: International Organization for Standardization.
Label: The part of the labeling on the immediate container.
Labeling: All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except any outer shipping container.
Laminar airflow system (LAFS): A device or zone within a buffer room that provides an ISO Class 5 or better air quality environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow.
Laminar airflow workbench (LAFW): A device that is a type of LAFS that provides an ISO Class 5 or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.
Line of demarcation: A visible line on the floor that separates the clean and dirty sides of the anteroom.
Low-lint wiper: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from or easily removed from the wiper material in a dry condition.
Master formulation record (MFR): A detailed record of procedures that describes how the CSP is to be prepared.
MEA: Malt extract agar.
Media-fill test: A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.
Monograph: A quality documentary standard within *USP–NF* that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Multiple-dose container: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed to contain more than one dose of the sterile product. A multiple-dose container is usually required to meet the antimicrobial effectiveness testing criteria. See <659>Injection Packaging Systems, Multiple-dose container.
One-step disinfectant cleaner: A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.

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GLOSSARY USP<797>
Oversight: The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available for consultation if and when needed, even if not physically present.
Pass-through chamber: An enclosure with sealed doors on both sides that should be interlocked. The pass-through chamber is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.
Perimeter: A visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA.
Pharmaceutical isolator: An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. [Note—A CAI or CACI is not a pharmaceutical isolator.]
Pharmacy bulk package: A conventionally manufactured sterile product for parenteral use that contains many single doses intended for use in a pharmacy admixture program. A pharmacy bulk package may either be used to prepare admixtures for infusion or, through a sterile transfer device, for filling sterile containers. See <659>*Injection Packaging Systems, Pharmacy bulk package*.
Positive-pressure room: A room that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the room.
PPE: Personal protective equipment.
Preservative: A substance added to inhibit microbial growth.
Primary engineering control (PEC): A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
Probability of a nonsterile unit (PNSU): The probability of an item being nonsterile after it has been exposed to a verified sterilization process. A PNSU value can only be applied to terminal sterilization. [Note—This is also called the sterility assurance level (SAL).]
Pyrogen: A substance that induces a febrile reaction in a patient.
Quality assurance (QA): A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
Quality control (QC): The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.
Reconstitution: The process of adding a diluent to a conventionally manufactured product to prepare a sterile solution or suspension.
Release inspection and testing: Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.

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GLOSSARY USP<797>
Repackaging: The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation.
Restricted-access barrier system (RABS): An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.
SDA: Sabouraud dextrose agar.
Secondary engineering control (SEC): The area where the PEC is placed (eg, a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
Segregated compounding area (SCA): A designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only.
Single-dose containers: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed for use with a single patient as a single injection/infusion. A single-dose container usually does not contain a preservative. See <659> Injection Packaging Systems, Single-dose container.
SOP: Standard operating procedure.
Specification: The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.
Sporicidal disinfectant: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.
Stability: The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Sterility assurance level (SAL): See the entry for *Probability of a nonsterile unit* (PNSU).
Sterility: The absence of viable microorganisms.
Sterilization by filtration: Passage of a gas or liquid through a sterilizing-grade membrane to yield filtrates that are sterile.

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GLOSSARY USP <797>
Sterilizing-grade filter: Filter membranes that are documented to retain 100% of a culture of 10^7 microorganisms of a strain of *Brevundimonas diminuta* per square centimeters of membrane surface under a pressure of not less than 30 psi. Such filter membranes are nominally 0.22- or 0.2-µm pore size.
Terminal sterilization: The application of a lethal process (eg, steam, dry heat, irradiation) to sealed containers for the purpose of achieving a predetermined PNSU of greater than 10−6 or a probability of less than one in one million of a nonsterile unit.
TSA: Trypticase soy agar.
Unclassified space: A space not required to meet any air cleanliness classification based on the ISO.
Unidirectional airflow: Air within a PEC moving in a single direction in a uniform manner and at sufficient velocity to sweep particles away from the DCA.
Verify: To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Visual smoke study: A test, used in ISO Class 7 and ISO Class 8 rooms that do not have unidirectional airflow, in which a visible source of smoke, which is neutrally buoyant, is used to verify an absence of stagnant airflow. This test does not need to be performed under dynamic operating conditions and is not appropriate for PECs (see the entry for *Dynamic airflow smoke pattern test*).
Workflow management system: Technology comprised of hardware and/or software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes.

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Hazardous Drugs - Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs - Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

	General Information and Scope:	Observation	Notes
1.00	Does the pharmacy handle any drugs on the National Institute for Occupational Safety and Health (NIOSH) list that **require** all the containment requirements of USP <800>?	Yes	
1.01	Does the pharmacy handle any ***hazardous drug*** active pharmaceutical ingredients (HD API)? *If yes, please list.*	Yes	Doc01_HD1.01
1.02	Does the pharmacy handle any antineoplastic requiring manipulations (which can produce particles, aerosols, or gasses)? *If yes, please list.*	No	
2.00	Does the pharmacy handle any drugs on the NIOSH list that **do not** require all containment requirements of <800>?	No	
2.01	Does the pharmacy handle any final dosage forms of HDs (either compounded or manufactured unless required by the manufacturer) that do not require further manipulation other than counting and repackaging? *If yes, please list.*	No	
2.02	Does the pharmacy handle any dosage forms of other HDs **that are handled in full compliance** with containment requirements of <800>? *If yes, please list.*	No	
2.03	Does the pharmacy handle any dosage forms of other HDs **that are not handled** using all containment requirements of <800>? *If yes, please list.*	No	

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Hazardous Drugs - Handling in Health Care Settings

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e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Notes
	List of Hazardous Drugs		
3.00	The pharmacy maintains a list of any items it handles that are included on the current NIOSH list of antineoplastic and other HDs. ***Review and attach list.*** *Verify that pharmacy has access to a copy of current NIOSH list.*	Yes	
4.00	The pharmacy reviews this list at least every 12 months for additions, deletions, or other changes and documents the review. *Verify documentation and* ***list date*** *of last change/review.*	N/A	Pharmacy has only been open 3/6/2025. This is in SOP.
5.00	The pharmacy reviews this list whenever the pharmacy adds a new agent or dosage form to the items it handles.	Yes	
6.00	The pharmacy has a system in place for the evaluation of new drugs (purchased, stored, handled, and/or dispensed) to determine whether they are considered HD.	Yes	
6.01	Pharmacy evaluates the drugs against the current version of the NIOSH list.	Yes	
6.02	In the absence of information, the pharmacy treats any new drug as an HD.	Yes	
7.00	If the pharmacy handles any HDs not using all containment requirements of <800>, an assessment of risk was performed for each drug and dosage form individually to determine alternative containment strategies, if needed, and work practices for each. *Review documentation of assessment and SOPs related to work practices/alternative containment.*	N/A	

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		Observation	Notes
8.00	The assessment of risk evaluation performed by the pharmacy's organization includes all required information, for each drug and dosage form. *The first five (5) items below must be included in the evaluation in order to be compliant.*	Yes	
8.01	Type of HD (eg, antineoplastic, non-antineoplastic, reproductive risk only);	Yes	
8.02	Dosage form;	Yes	
8.03	Risk of exposure;	Yes	
8.04	Packaging;	Yes	
8.05	Manipulation; and	Yes	
8.06	If applicable, Table II and III drugs have alternative containment strategies and/or work practices to minimize occupational exposure.	Yes	
8.07	The assessment of risk is reviewed at least every 12 months, and the review is documented. *Enter date of last review in the notes.*	Yes	Initial date 3/6/2025.
	Personnel Responsibilities		
9.00	The pharmacy has a designated person(s) to oversee the handling of HDs who is qualified and trained for development of standard operating procedures (SOPs); overseeing compliance with standards, laws, and rules; ensuring competency of personnel; and ensuring environmental control.	Yes	
9.01	The designated person oversees the monitoring of the facility, including testing/sampling programs, maintaining, and documentation, and acting on results.	Yes	

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		Observation	Notes
Documentation and Standard Operating Procedures (SOPs)			
10.00	The assessment of risk and SOPs for handling HDs addresses all potential types of exposure, including all activities occurring within the operation that present an opportunity for exposure:		
10.01	**Receiving:** Contacting HD residues on packaging, work surfaces, floors	Yes	
10.02	**Dispensing:** Counting or packaging tablets and capsules	Yes	
10.03	**Compounding/other manipulations:** Crushing/splitting tablets, opening capsules, pouring liquids, weighing or mixing, constituting/reconstituting powdered/lyophilized HDs, expelling air from HD syringes, HD residue on personal protective equipment (PPE), cleaning activities of HD areas, and HD equipment maintenance.	Yes	
10.04	**Administration and other patient care activities** (if applicable).	Yes	
10.05	**Spills:** Spill generation, management, and disposal.	Yes	
10.06	**Transport**	Yes	
10.07	**Waste:** Collection and disposal of HD waste and trace contaminated waste	Yes	
11.00	SOPs are reviewed at least every 12 months by the designated person, and the review is documented.	Yes	

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		Observation	Notes
12.00	SOPs are readily available to all who may need to handle HD or respond to a spill (pharmacy employees, housekeeping, nursing personnel, delivery personnel, etc). *Describe whether P&Ps are available electronically, by paper, or both.*	Yes	Both
13.00	SOPs address at a minimum: *If no, document "missing" in Inspector Notes for each SOP topic*		**Please note NABP did not review each SOP for alignment on USP <800>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**
13.01	Hazard communication program plan	Yes	
13.02	Competent personnel	Yes	
13.03	Occupational safety program	Yes	
13.04	Designation of HD areas	Yes	
13.05	Receiving HDs, including handling of damaged shipping containers/breakages	Yes	
13.06	A list of HDs	Yes	
13.07	Storage of HDs	Yes	
13.08	Compounding of HDs	Yes	
13.09	Use and maintenance of proper engineering controls (eg, containment primary engineering control [C-PECs], containment secondary engineering control [C-SECs], and closed system drug transfer device [CSTDs]) to include SOPs for repairs, loss of power, moving, etc.	Yes	

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		Observation	Notes
13.10	Hand hygiene and proper use of appropriate PPE based on activity (eg, receipt, transport, compounding, administration, spill, disposal).	Yes	
13.11	Deactivation, decontamination, cleaning, disinfection SOPs include all of the following:		
13.11.01	Agents used	Yes	
13.11.02	Dilutions, if used	Yes	
13.11.03	Frequency	Yes	
13.11.04	PPE to be worn (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted–addressed in SOPs)	Yes	
13.11.05	Documentation requirements	Yes	
13.12	Receiving SOPs to include communications with suppliers about packaging and visual/other inspection of shipping containers for signs of damage and how to handle damaged containers.	Yes	
13.13	If a shipping container appears damaged and **does not need to be opened:**		
13.13.01	It is sealed without opening and wrapped in impervious plastic;	Yes	
13.13.02	Labeled as "hazardous"; and	Yes	
13.13.03	Returned to the supplier after contacting the supplier or disposed of as hazardous waste if supplier declines return.	Yes	

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		Observation	Notes
13.14	If a damaged shipping container **must be opened**:	[redacted]	
13.14.01	Container is sealed in plastic or an impervious container;	Yes	
13.14.02	It is transported to the C-PEC before opening, preferably nonsterile compounding C-PEC, if available;	Yes	
13.14.03	container is placed on a plastic-backed preparation mat;	Yes	
13.14.04	It is opened and undamaged items are removed and wiped down with a disposable wipe;	Yes	
13.14.05	Damaged item is enclosed in an impervious container and labeled "hazardous";	Yes	
13.14.06	Damaged item is returned to the supplier or disposed of as hazardous waste;	Yes	
13.14.07	Deactivate, decontaminate, and clean the C-PEC in accordance with SOPs; and	Yes	
13.14.08	If a sterile compounding C-PEC must be used, it is also disinfected after cleaning prior to resuming any sterile compounding activities.	Yes	
13.15	Safe work Practices SOPs	Yes	
13.16	Dispensing SOPs	Yes	
13.17	Packaging and labeling SOPs	Yes	
13.18	Transport SOPs	Yes	

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		Observation	Notes
13.19	Administering SOPs, if applicable	Yes	
13.20	***Recommendation: Environmental monitoring (eg, wipe sampling) SOPs***	Yes	
13.21	HD waste segregation and disposal (including reference to following local, state, and federal regulations) SOPs	Yes	
13.22	Spill prevention and direction of spill cleanup and control SOPs must address the following:		
13.22.01	Size and scope of spill;	Yes	
13.22.02	Responsible person for handling spills;	Yes	
13.22.03	Location of spill kits and clean-up materials;	Yes	
13.22.04	Capacity of the spill kits;	Yes	
13.22.05	PPE to be worn during spills;	Yes	
13.22.06	Handling of worn PPE and any exposed clothing under PPE;	Yes	
13.22.07	Use of appropriate full-face, chemical cartridge-type respirator or powered air-purifying respirators (PAPR) if capacity of spill kit is exceeded or known or suspected airborne exposure to vapors/gases; and	Yes	
13.22.08	Medical evaluation/incident reporting/documentation/other handling of persons potentially exposed or with direct skin/eye contact to the HD.	Yes	

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		Observation	Notes
13.23	***Recommendation:*** *Does the pharmacy have a medical surveillance program? (a comprehensive control program to monitor and identify potential worker health care issues from HD exposure.)*	No	
14.00	The **hazard communication program** SOP has policies and procedures that ensure worker safety in all aspects of HD handling relevant to the pharmacy and ensure effective personnel training in proper labeling, transport, storage, and disposal of HDs, use of Safety Data Sheets (SDSs), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).	Yes	
15.00	The pharmacy's hazard communication program includes, at a minimum, all of the following:		
15.01	A written plan that describes how the standard will be implemented;	Yes	
15.02	How containers of HDs/hazardous chemicals will be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings;	Yes	
15.03	SDSs are maintained for each hazardous chemical they use (29 CFR 1910.1200);	Yes	
15.04	How SDSs are readily accessible to personnel during each work shift and when they are in their work areas;	Yes	
15.05	Information and training provided to personnel prior to initial assignment to work with a hazardous chemical and whenever the hazard changes; and	Yes	
15.06	Personnel of reproductive capability confirm in writing that they understand the risks of handling HDs.	Yes	

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		Observation	Notes
Personnel Training —*Check four employee files for documentation*			
16.00	All personnel handling HDs are trained based on their job function prior to independently handling HDs.	Yes	
17.00	Personnel file contains the employee's acknowledgement of the risk of handling HD (as part of the hazardous communication program).	Yes	
18.00	For non-sterile HD compounding, personnel competency is observed and assessed at least annually for proper compounding technique, with no concerns identified.	Yes	
19.00	For sterile HD compounding, personnel competency is observed and assessed at least annually for proper sterile compounding aseptic technique, with no concerns identified.	Yes	
20.00	After initial HD training, personnel are trained prior to introduction of any new HD or new equipment, or prior to any significant change in process or SOP.	Yes	
21.00	All HD training and assessments are documented for each employee who transports, compounds, or administers HDs, and meets Occupational Safety and Health Administration Standard 1910.120 and any other requirements of law or regulation.	Yes	
22.00	All personnel who perform custodial HD waste removal and cleaning in HD handling areas are trained in appropriate procedures to protect themselves and the environment.	Yes	
23.00	HD training, based on employee file review, all of the following are present:		
23.01	Overview of pharmacy's HD list and their risks;	Yes	

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		Observation	Notes
23.02	Review of the SOPs related to HDs;	Yes	
23.03	Proper use of PPE;	Yes	
23.04	Proper use of equipment and devices (eg, engineering controls);	Yes	
23.05	Appropriate procedures for deactivation, decontamination, cleaning, and disinfection (if applicable);	Yes	
23.06	Response to known or suspected HD exposure;	Yes	
23.07	Spill management;	Yes	
23.08	Proper disposal of HDs and trace-contaminated materials; and	Yes	
23.09	New HD drug/new equipment or prior to any significant change in process or SOP.	Yes	
24.00	If respiratory protection is needed for any HDs handled, personnel are fit tested and trained in the proper use of the respirator.	Yes	
	Personal Protective Equipment		
25.00	For sterile and nonsterile compounding with HDs, personnel wear gowns; head, hair, and shoe covers; and two pairs of chemotherapy gloves.	Yes	
26.00	Appropriate PPE is readily accessible where HD is handled, include all of the following:		

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		Observation	Notes
26.01	Receipt (PPE appropriate to HD as set forth in SOPs, and at a minimum, chemotherapy gloves worn);	Yes	
26.02	Storage;	Yes	
26.03	Transport;	Yes	
26.04	Nonsterile Compounding (if performed by the pharmacy);	Yes	
26.05	Sterile Compounding (if performed by the pharmacy);	Yes	
26.06	Administration, if applicable;	Yes	
26.07	Deactivation/decontamination, cleaning, and disinfecting (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted/addressed in SOPs);	Yes	
26.08	Spill control;	Yes	
26.09	Waste disposal; and	Yes	
26.10	If administering injectable antineoplastics, two pairs of chemotherapy gloves and permeability resistant gowns are worn.	N/A	
27.00	Disposable PPE is not reused.	Yes	
28.00	Reusable PPE is decontaminated and cleaned after each use.	N/A	

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		Observation	Notes
29.00	**Gloves:** The pharmacy is using appropriate gloves for the activities conducted (chemotherapy gloves meet ASTM standard D6978 – or its successor – and are resistant to cleaning agents used) and are resistant to cleaning agents used.	Yes	
29.01	**Recommendation:** Are *chemotherapy gloves worn for handling all HDs including non-antineoplastics and for reproductive risk only HDs?*	Yes	
29.02	Chemotherapy gloves are powder-free.	Yes	
29.03	Chemotherapy gloves are inspected for physical defects before use and defective gloves (eg, pin holes, tears, weak spots) are discarded.	Yes	
29.04	For sterile compounding, the outer chemotherapy gloves are sterile.	Yes	
29.05	Chemotherapy gloves are changed when torn, punctured, or contaminated.	Yes	
29.06	**Recommendation:** Are *chemotherapy gloves changed every 30 minutes (unless otherwise recommended by the manufacturer)?*	Yes	
29.07	Hands are washed with soap and water after removing chemotherapy gloves.	Yes	
30.00	**Gowns:** The pharmacy is using appropriate gowns for the activities conducted (if required for type of compounding based on standards or assessment of risk).	Yes	
30.01	Gowns are disposable.	Yes	

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		Observation	Notes
30.02	Gowns resist permeability of HDs and are not laboratory coats, surgical scrubs, or isolation gowns (selected based on HDs handled).	Yes	
30.03	Gowns close in the back, are long sleeved, and have closed cuffs that are elastic or knit.	Yes	
30.04	Gowns do not have seams or closures that will allow HDs to pass through.	Yes	
30.05	Gowns are changed in accordance with the manufacturer's instructions, or if no permeation information is available, they are changed every two to three hours or immediately after a spill or splash.	Yes	
30.06	Gowns worn in HD areas are not worn to other areas.	Yes	
31.00	**Head, hair** (beard and moustache, if appropriate), **and shoe and sleeve covers.** The pharmacy is using appropriate head, hair, and shoe and sleeve covers for the type of compounding based on standards or assessment of risk to provide protection from contact with HD residue, if required.	Yes	
31.01	When HD compounding, a second pair of shoe covers are donned before entering the C-SEC and doffed when exiting the C-SEC.	Yes	
31.02	Shoe covers worn in HD areas are not worn into other areas of the facility.	Yes	
32.00	**Eye and Face Protection**: The pharmacy is using appropriate eye and face PPE protection for the activities conducted (based on assessment of risk that HDs are irritating to the eyes and mucous membranes, where there is risk of spills or splashes when working outside of a C-PEC), if required.	Yes	

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Hazardous Drugs-Handling in Health Care Settings

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Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Notes
32.01	If a risk to eyes, goggles (or a full-face respirator) are worn. *Eyeglasses or safety glasses with side shields are not substituted for goggles.*	Yes	
32.02	If a risk to face and eyes, goggles plus a face shield (or a full-face respirator) are worn.	Yes	
33.00	**Respiratory Protection:** The pharmacy is using appropriate respiratory PPE protection for the activities conducted (receiving, transport, compounding, administration, and waste disposal) based on assessment of risk based on type of HD and type of activity, if required. *Indicate what type of PPE which is available to employees (and is fit-tested, when required).*	Yes	Akron Pharma N95 respirator and it is fit tested.
33.01	Fit-tested NIOSH-certified N95 respirator;	Yes	
33.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	N/A	
33.03	Full-face piece, chemical cartridge-type respirator;	Yes	
33.04	PAPR; and/or	N/A	
33.05	Other (describe in notes).	N/A	
34.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	

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		Observation	Notes
35.00	The pharmacy uses an appropriate respiratory PPE for large HD spills; deactivating, decontaminating, and cleaning underneath the work surface of the C-PEC; and when there is known or suspected airborne exposure to powders or vapors. *Indicate what type of PPE which is available to employees (and is fit-tested, when required).*	Yes	3M Full face piece respirator–fit tested
35.01	Fit-tested NIOSH-certified N95 respirator;	Yes	
35.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	N/A	
35.03	Full-facepiece, chemical cartridge-type respirator;	N/A	
35.04	PAPR; and/or	N/A	
35.05	Other (describe in notes).	N/A	
36.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	
37.00	**Disposal of Used PPE:** Is all PPE worn during handling of HDs considered contaminated with at least trace quantities?	Yes	
37.01	Worn PPE is placed in an appropriate HD waste container.	Yes	
37.02	The HD waste container is located in reasonable proximity to HD PPE doffing activities.	Yes	
37.03	Chemotherapy gloves, and sleeve covers if worn, are carefully removed and discarded immediately into an approved HD trace waste container inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.	Yes	

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		Observation	Notes
Facilities and Engineering Controls			
38.00	There are signs prominently displayed before the entrance to all HD handling areas designating the hazard.	Yes	
38.01	Access to these areas are restricted to authorized personnel who have been appropriately trained.	Yes	
38.02	HD areas are located away from breakrooms/refreshment areas for personnel, patients, and/or visitors.	Yes	
39.00	There are designated HD areas for any of the following:		
39.01	Receiving and unpacking of HDs	Yes	
39.02	Storage of HDs	Yes	
39.03	Nonsterile HD compounding (if performed by the pharmacy)	Yes	
39.04	Sterile HD compounding (if performed by the pharmacy)	Yes	
40.00	***Recommendation:*** *If there is a requirement for certain designated areas to have negative pressure from surrounding areas, is there an uninterrupted power source (UPS) to the ventilation systems in order to maintain negative pressure in the case of power loss?*	No	
41.00	**Receipt:** Are HDs received and unpacked (removed from external shipping containers) in an appropriate environment? *Describe.*	Yes	The compounding technician receives and unpacks in the HD nonsterile room.

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		Observation	Notes
41.01	HD	Yes	
41.01.01	Neutral	No	
41.01.02	Negative	Yes	
42.00	HDs are not unpacked in a sterile compounding area (eg, no external containers are brought into C-SEC).	Yes	
43.00	**Storage:** Are HDs stored in a manner to minimize accidental exposure? *Describe.*	Yes	All HDs are stored in the nonsterile HD room. They are neat and organized.
43.01	HDs are not stored on the floor.	Yes	
43.02	HDs are stored in a manner to minimize breakage and spillage.	Yes	
43.03	If facility is in an area prone to specific types of natural disasters, appropriate precautions are taken (eg, raised front lips on shelving in earthquake prone areas).	Yes	
44.00	Antineoplastic HDs that require manipulation (other than counting and repackaging final dosage forms) and HD API are stored separately from non-HDs.	Yes	
44.01	These HDs are stored in an externally ventilated, negative pressure room.	Yes	

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		Observation	Notes
44.02	The HD storage room has at least 12 air changes per hour (ACPH).	Yes	
44.03	Refrigerated antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH (eg, storage room, buffer room, or containment segregated compounding area [C-SCA]).	N/A	There are no refrigerated drugs in the pharmacy.
44.04	**Recommendation:** *If the refrigerator is located in a buffer room, is an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator?*	N/A	There are no refrigerators in the pharmacy.
45.00	If non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastics are stored with other non-HD inventory, there is a written policy/SOP addressing it.	Yes	
46.00	**Compounding:** There are appropriate engineering controls to protect the HD preparation from cross-contamination, and if sterile compounding, from microbial contamination, during all phases of the compounding process.	Yes	
47.00	All HD compounding are performed within a C-PEC located in a C-SEC room.	Yes	
47.01	The C-SEC for both sterile and nonsterile HD compounding has all of the following:		
47.01.01	Has fixed walls;	Yes	
47.01.02	Is externally vented;	Yes	

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		Observation	Notes
47.01.03	Is able to meet (12) or exceed ACPH requirements;	Yes	
47.01.04	Is physically separated (ie, a different room) from other preparation areas; and	Yes	
47.01.05	Has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to all adjacent areas.	Yes	
48.00	The C-PEC operates continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding.	Yes	
49.00	There is a sink readily available for handwashing on the hazardous side.	Yes	
49.01	There is an eyewash station readily available.	Yes	
49.02	Water sources and drains are a minimum of 1 meter away from the C-PEC.	Yes	
50.00	Does the pharmacy engage in **nonsterile HD compounding**? If yes, complete 50.01-54. If no, skip to 55:	Yes	
50.01	Select the location where **nonsterile HD compounding** is performed type(s):		
50.01.01	C-PECs used for sterile HD compounding are located in a different room than C-PECs used for nonsterile HD compounding	Yes	

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		Observation	Notes
50.01.02	C-PECs used for sterile HD compounding are located in the same room as C-PECs used for nonsterile HD compounding.	No	
50.02	Select the type(s) of containment primary engineering control(s) used for **nonsterile HD compounding**:		
50.02.01	Class I biological safety cabinet (BSC)	N/A	
50.02.02	Class II BSC	N/A	
50.02.03	Containment ventilated enclosure (CVE)	Yes	
50.02.04	Compounding aseptic containment isolator (CACI)	N/A	
50.02.05	Other, describe	N/A	
51.00	Indicate if the C-PEC used for **nonsterile HD compounding** (must be one of two below in order to be compliant):		
51.01	Is externally vented *(preferred)* ; **and/or**	No	Ductless Fume Hood
51.02	Has redundant High Efficiency Particulate Air (HEPA) filters in series	Yes	
52.00	Does the pharmacy use the same C-PEC (Class II BSC or CACI) used for sterile HD compounding and nonsterile HD compounding?	No	
52.01	Is **nonsterile HD compounding** only "occasional"? */ If yes, please describe frequency and quantity.*	N/A	

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		Observation	Notes
52.02	Is the **nonsterile HD compounding** activity only occurring when sterile HD compounding is not being performed?	Yes	
52.03	Is the C-PEC decontaminated, cleaned, and disinfected prior to resuming sterile compounding?	N/A	
53.00	The C-SEC has at least 12 ACPH. *Verify documentation and monitoring.*	Yes	Verified
54.00	The ceilings, walls, floors, fixtures, shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, and non-shedding. *If non-compliant describe.*	Yes	
55.00	Does the pharmacy engage in **sterile HD compounding**? If yes, complete 55.01-61.02.03. If no, skip to 62.	Yes	
55.01	Select the type(s) of containment primary engineering control(s) used for **sterile HD compounding:**		
55.01.01	CACI	N/A	
55.01.02	Class II BSC, Type A1 (formerly Type A and not suitable for volatile toxic chemicals and volatile radionuclides)	N/A	
55.01.03	Class II BSC, Type A2 (formerly Type B3)	N/A	
55.01.04	Class II BSC, Type B1	N/A	
55.01.05	Class II BSC, Type B2 (total exhaust for volatile components)	Yes	

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		Observation	Notes
55.01.06	Class III BSC	N/A	
55.01.07	LAFW (not for antineoplastics)	N/A	
55.01.08	CAI (not for antineoplastics)	N/A	
56.00	The C-PEC maintains ISO Class 5 or better air quality and is under continuous operation, unless power loss or repair occurs.	Yes	
57.00	Is the C-PEC used for **sterile HD compounding** externally vented?	Yes	
58.00	If a BSC or CACI that is used for **sterile HD compounding** is also used for non-HD preparations, is the non-HD preparation placed into a protective outer wrapper during removal from the C-PEC?	N/A	
58.01	If used for both, is the non-HD preparation labeled to require PPE handling precautions?	N/A	
59.00	If the C-SEC is an unclassified containment segregated HD compounding area (C-SCA: enclosed separate room with fixed walls, but not ISO classified), beyond-use dates (BUDs) are limited in accordance with <797> as Category 1 compounded sterile preparations.	N/A	
59.01	The C-SEC (C-SCA) has at least 12 ACPH. *Verify documentation and monitoring.*	Yes	Verified
59.02	A handwashing sink is at least one meter or more away from the C-PEC	Yes	

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		Observation	Notes
59.02.01	Describe whether the sink is inside the C-SCA or directly outside the C-SCA		
60.00	If BUDs are longer than the Category 1 BUDs specified in <797>, the PEC is located in a C-SEC, which is an ISO Class 7 buffer room adjacent to an ISO Class 7 anteroom.	Yes	
60.01	The buffer room has fixed walls.	Yes	
60.02	The buffer room is externally vented.	Yes	
60.03	The buffer room has HEPA-filtered supply air.	Yes	
60.04	The buffer room has at least 30 ACPH.	Yes	
60.05	The buffer room has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to the anteroom.	Yes	
60.06	The anteroom has fixed walls.	Yes	
60.07	The ante room has a minimum of 30 ACPH of HEPA-filtered supply air.	Yes	
60.08	The ante room maintains positive pressure of at least 0.02 inches water column relative to any adjacent unclassified areas.	Yes	
60.09	The handwashing sink is located in the anteroom at least 1 meter or more away from the door to the buffer room to prevent contamination into the negative pressure buffer room.	Yes	

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		Observation	Notes
61.00	If the negative-pressure HD buffer room is entered through a positive-pressure non-HD buffer room, there is a line of demarcation within the buffer room for donning and doffing PPE.	Yes	
61.01	There is a design and method to contain and minimize HD contamination when **transporting** HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room:	Yes	
61.02	Indicate how HD contamination is minimized:		
61.02.01	Pass-through chamber between negative pressure buffer room and adjacent space included in the facility's certification not compromising air quality in the buffer room *(verified in the facility's semi-annual certification report that pass through has not compromised air quality in the buffer room).*	Yes	Verified
61.02.02	Use of sealed containers	Yes	
61.02.03	Other, *describe*	N/A	
	Environmental Quality and Control - Surface wipe sampling		
62.00	**Recommendation: Surface wipe sampling** is performed routinely (initially and at least every six months) to monitor HD containment processes and trends, which includes all of the following:	Yes	
62.01	Interior of C-PEC and equipment within the C-PEC	Yes	
62.02	Pass-through chambers	Yes	
62.03	Surfaces in staging or work areas near the C-PEC	Yes	
62.04	Areas adjacent to the C-PEC (eg,. floors directly under, staging, and dispensing areas)	Yes	
62.05	Areas immediately outside the HD buffer room or the C-SCA	Yes	

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		Observation	Notes
Receiving			
63.00	**Recommendation:** HDs are packaged by the supplier in impervious plastic to segregate them from other drugs and decrease possibility of exposure during unpacking and internal transfer.	Yes	
64.00	HDs are delivered to the HD storage area immediately after unpacking.	Yes	
65.00	A spill kit is readily accessible in the receiving area.	Yes	
66.00	Containers are visually examined for signs of damage or breakage prior to opening.	Yes	
67.00	If a shipping container appears damaged and does not need to be opened, it is sealed, enclosed in an impervious container, labeled "hazardous" on the outside, and returned to the supplier after contact or disposed of as hazardous waste.	Yes	
67.01	If a damaged shipping container must be opened, it is done so according to SOPs, to include sealing the container in plastic or an impervious container, transporting it to the C- PEC for unpacking, removing, and wiping the outside of the undamaged items with disposable wipes, resealing the damaged items in an impervious container and marking it "hazardous," returning it to the supplier after contact or disposing as hazardous waste, and deactivating, decontaminating, and cleaning the C-PEC.\	Yes	
68.00	Damaged packages are considered spills and reported to the designated person. ***List last date of damaged package receipt.***	Yes	There have not been any damaged packages received since opened 3/6/2025.

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		Observation	Notes
Labeling, Packaging, Transport, and Disposal			
69.00	HDs requiring special HD handling are always clearly labeled as hazardous during transport and in accordance with any laws related to labeling of HDs.	Yes	
70.00	Labeling processes do not introduce contamination into non-HD handling areas.	Yes	
71.00	Packaging materials are chosen that protect the HD and healthcare worker against damage, leakage, contamination, and degradation during transport, but also maintains the physical integrity, stability, and sterility of the HD.	Yes	
72.00	Pneumatic tubes are not used for transporting any liquid HDs or antineoplastic HDs.	Yes	
73.00	Labeling on HDs shipped outside the pharmacy meets all of the following requirements:		
73.01	Labeling specified in SDS for transport;	Yes	
73.02	Storage and disposal instructions; and	Yes	
73.03	Labeled with HD category.	Yes	

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs - Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs - Handling in Health Care Settings Inspection is based on USP Chapter <800>.
Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Notes
Dispensing, Packaging, and Compounding Processes			
74.00	Counting of antineoplastics is done by hand (eg, not placed into automated counting devices).	Yes	
75.00	Clean, dedicated (not used for non-HD purposes), or disposable equipment is used for counting, packaging, and compounding of HDs.	Yes	
75.01	**Recommendation:** Equipment is decontaminated after every use.	Yes	
75.02	**Recommendation:** When compounding, a plastic-backed preparation mat is placed on the C-PEC work surface and changed and discarded appropriately as HD waste. All of the following should apply in order to make this a Yes.	Yes	
75.02.01	Immediately if a spill occurs	Yes	
75.02.02	Regularly during use	Yes	
75.02.03	At the end of a shift	Yes	
76.00	APIs or other powdered HDs are handled in a C-PEC during particle-generating activities, such as crushing, opening capsules, and weighing powders.	Yes	

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Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Notes
	Deactivating and Decontaminating (Cleaning and Disinfecting are performed in accordance with Chapters <795> and <797>)		
77.00	The pharmacy has chosen appropriate oxidizing agent(s) for deactivation and decontamination and proven effective by testing.	Yes	
78.00	Wipes or other appropriate delivery mechanisms (eg, not a spray bottle) are used for deactivation and decontamination.	Yes	
79.00	The C-PEC must be decontaminated. *All of the following must be done to be compliant:*	Yes	
79.01	Between compounding of different HDs	Yes	
79.02	At least daily when used	Yes	
79.03	Any time a spill occurs	Yes	
79.04	Before and after certification	Yes	
79.05	Any time voluntary interruption occurs	Yes	
79.06	If the ventilation tool is moved	Yes	
80.00	HD containers are wiped down prior to placing them in the C-PEC and the solution used does not alter the product label.	Yes	

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Facility Name: St. Luke Lab, LLC dba St. Luke Pharmacy
e-Profile ID: 1880521
Inspection Date: 6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025

		Observation	Notes
81.00	Areas, other than the work surface of the C-PEC, where contamination can build up (such as areas under the work tray), are deactivated, decontaminated, and cleaned at least monthly.	Yes	
82.00	Additional PPE (eg, respirator) is used in accordance with SOPs, to protect the worker if containment airflows are compromised by opening the cabinets to get to these areas.	Yes	
Spill Control			
83.00	Spills are contained and cleaned immediately.	Yes	
84.00	Trained/qualified personnel are always available during operation with HDs to handle spills.	Yes	
85.00	Only trained/qualified personnel engage in spill containment and cleanup.	Yes	
86.00	There are signs available to restrict access to spill areas.	Yes	
87.00	Spill kits, containing all ingredients necessary to clean HD spills, are readily available in all areas where HDs are routinely handled.	Yes	
88.00	Spill materials are disposed of as hazardous waste.	Yes	
89.00	The circumstances and management of all spills are documented. ***Review documentation for spills for the last year and list the most recent date.***	Yes	There were no spills since opening 3/6/2025.

Pharmacy Name:	St. Luke Lab, LLC dba St. Luke Pharmacy
Pharmacy Address:	9338 Little Rd. New Port Richey, FL 34654
NABP Business e-Profile ID:	1880521
VPP Inspection Date(s):	6/16/2025, 6/18/2025, 6/19/2025 & 6/20/2025
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Is Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Updates/New SOPs or P&Ps	104	33.0	Next certification report was completed on July 3rd and was performed in dynamic conditions. All future certifications will be preformed under dynamic conditions.	07/03/2025	Y	St Luke Lab Compounding Letter 08.14.25.pdf Sterile Room Signage St. Luke Lab, LLC.pdf St. Luke Compounding Pharmacy Certification Reports (NV) July 2025(Electronic).pdf
Updates/New SOPs or P&Ps	105	33.3	Next certification report was completed on July 3rd and was performed in dynamic conditions. All future certifications will be preformed under dynamic conditions.	07/03/2025	Y	St. Luke Compounding Pharmacy Certification Reports (NV) July 2025(Electronic).pdf
Updates/New SOPs or P&Ps	107	33.12	Next certification report was completed on July 3rd and was performed in dynamic conditions. All future certifications will be preformed under dynamic conditions.	07/03/2025	Y	St. Luke Compounding Pharmacy Certification Reports (NV) July 2025(Electronic).pdf
Updates/New SOPs or P&Ps	107	33.14	Next certification report was completed on July 3rd and was performed in dynamic conditions. All future certifications will be preformed under dynamic conditions.	07/03/2025	Y	St Luke Lab Compounding Letter 08.14.25.pdf HD Sterile Room Signage St. Luke Lab, LLC.pdf St. Luke Compounding Pharmacy Certification Reports (NV) July 2025(Electronic).pdf

This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

CLEANROOM INSPECTION REPORT

July 2025

Prepared for:

ST. LUKE
COMPOUNDING PHARMACY

New Port Richey, Florida

All material ©2025, unless otherwise noted.

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Section 1

SUMMARY

St. Luke Compounding Pharmacy
New Port Richey, Florida
ISO Class 7 Facility
ISO Class 5 Horizontal Laminar Airflow Clean Bench
Containment Ventilated Enclosure

SUMMARY

Of Testing Performed July 02 & 03, 2025

The purpose of this inspection was to prove continued compliance within the facility to the requirements of a non-unidirectional ISO Class 7 & 8 clean rooms as defined by ISO 14644-1:2015, referenced in USP<800>, USP<797>, 64B16-27.797, USP<795>, cand other applicable documents listed herein.

This facility is considered a Category 1 and Category 2 compounding facility with hazardous and non-hazardous zones.

Testing was performed during dynamic conditions with up to two personnel present and two Medrep employees performing the testing.

Ante Gown In has changed from an ISO Class 7 environment to an ISO Class 8 environment.

The biological safety cabinet Model #AC2-6S9-NS (S# 2024-204033) was not certified at this time due to pending repair.

This scheduled inspection is part of a semi-annual monitoring and periodic test program designed to document long-term compliance. The most recent inspections were performed on November 06, December 30 & 31, 2024 & January 02 & 08, 2025.

Following the testing and based upon the results of those tests listed, the facility and the clean air device were found to be in full conformance and a certificate of compliance has been issued.

Testing performed by: Gene Formanek
IEST Level 3 Technician

Testing performed by: Frank Vargas
IEST Level 2 Technician

Report prepared by: James Rice
Tier 2 Compliance Officer

Report approved by: Caroline Arnold
Tier 2 Compliance Officer

Respectfully submitted: July 08, 2025

This scheduled facility inspection consisted of the following tests:

1. Determining Air Exchange Rate per Hour	MEDREP-Proc-18
2. Non-Viable Airborne Particle Count in a Facility	MEDREP-Proc-21
3. Air Volume Test in a Facility	MEDREP-Proc-23
4. Facility Differential Pressurization Test	MEDREP-Proc-24
5. Leak Testing Room HEPA Filters	MEDREP-Proc-25
6. Temperature Uniformity Test	MEDREP-Proc-27
7. Humidity Uniformity Test	MEDREP-Proc-28
8. Check/Adjust Gages	MEDREP-Proc-61

The tests performed upon the device were:

1. Airflow Adjustment for Class II BSCs	MEDREP-Proc-1
2. Laminar Flow Clean Bench Airflow Profile	MEDREP-Proc-3
3. Testing Fluorescent Illumination Level	MEDREP-Proc-4
4. Testing Sound Level	MEDREP-Proc-6
5. Smoke Pattern in a Device	MEDREP-Proc-7
6. Check Leveling of a Device	MEDREP-Proc-8
7. Testing HEPA Filters for Laminar Airflow CBs	MEDREP-Proc-12
8. Testing Airflow in Ventilated Enclosure	MEDREP-Proc-13
9. Performing the Site Installation Assessment	MEDREP-Proc-39
10. Testing Device Alarm Functions	MEDREP-Proc-40
11. Non-Viable Particle Counts in a Device	MEDREP-Proc-48
12. Check/Adjust Gage	MEDREP-Proc-60

Section 2

RESULTS OF TESTING

RESULTS OF FACILITY TEST

Buffer Room ISO 14644-1 Class 7 Environment				
TEST	Criteria	Result	Pass/Fail	Comments
Air Volume Test	---	491 cfm	---	
Adjusted Hourly Air Exchange Rate	>30 ACPH	85.63 ACPH	Pass	Includes airflow from device Model #HLF-72-A (UA) (S# HLF000645)
Non-Viable Particle Count	<352,000	125	Pass	
HEPA Filter Leak Test	<0.01%	<0.01%	Pass	
Temperature Average	66°-70°f	70.1°f	--	
Relative Humidity Average	<60%	58.2%	--	
Room Segregation Test	≥ +0.020"wc	+0.023"wc	Pass	Compared to Ante Gown In Room

Occupancy State at time of test: DYNAMIC

Date of test: July 02, 2025

Result of Facility Tests: PASS

RESULTS OF FACILITY TEST

Ante Gown-In Room				
ISO 14644-1 Class 8 Environment				
TEST	Criteria	Result	Pass/Fail	Comments
Air Volume Test	--	119 cfm	--	
Hourly Air Exchange Rate	>20 ACPH	26.98 ACPH	Pass	
Non-Viable Particle Count	<3,520,000	19,270	Pass	
HEPA Filter Leak Test	<0.01%	<0.01%	Pass	
Temperature Average	66°-70°f	70.2°f	--	
Relative Humidity Average	<60%	59.9%	--	
Room Segregation Test	≥ -0.020"wc	-0.023"wc	Pass	Compared to Buffer Room
Room Segregation Test	≥ +0.020"wc	+0.021"wc	Pass	Compared to Sterile Prep Room

Occupancy State at time of test: DYNAMIC

Date of test: July 02, 2025

Result of Facility Tests: PASS

RESULTS OF FACILITY TEST

Buffer H.D. Room				
ISO 14644-1 Class 7 Environment				
TEST	Criteria	Result	Pass/Fail	Comments
Air Volume Test	--	573 cfm	--	
Hourly Air Exchange Rate	>30 ACPH	52.55 ACPH	Pass	
Non-Viable Particle Count	<352,000	4,852	Pass	
HEPA Filter Leak Test	<0.01%	<0.01%	Pass	
Temperature Average	66°-70°f	68.2°f	--	
Relative Humidity Average	<60%	52.7%	--	
Room Segregation Test	-0.010" to -0.030"wc	-0.019"wc	Pass	Compared to H.D. Gown In Room

Occupancy State at time of test: DYNAMIC

Date of test: July 02, 2025

Result of Facility Tests: PASS

RESULTS OF FACILITY TEST

H.D. Gown-In Room ISO 14644-1 Class 7 Environment				
TEST	Criteria	Result	Pass/Fail	Comments
Air Volume Test	--	171 cfm	--	
Hourly Air Exchange Rate	>30 ACPH	33.36 ACPH	Pass	
Non-Viable Particle Count	<352,000	4,404	Pass	
HEPA Filter Leak Test	<0.01%	<0.01%	Pass	
Temperature Average	66°-70°f	68.2°f	--	
Relative Humidity Average	<60%	59.3%	--	
Room Segregation Test	+0.010" to +0.030"wc	+0.019"wc	Pass	Compared to Buffer H.D. Room
Room Segregation Test	+0.010" to +0.030"wc	+0.023"wc	Pass	Compared to H.D. Prep Room
Room Segregation Test	+0.010" to +0.030"wc	+0.020"wc	Pass	Compared to Outside

Occupancy State at time of test: DYNAMIC

Date of test: July 02, 2025

Result of Facility Tests: PASS

RESULTS OF FACILITY TEST

Double Interlock Pass Through #1				
ISO 14644-1 Class 7 Environment				
TEST	Criteria	Result	Pass/Fail	Comments
Non-Viable Particle Count	<352,000	71,757	Pass	
Temperature	66°-70°f	70.0°f	--	
Relative Humidity	<60%	58.0%	--	

Occupancy State at time of test: DYNAMIC

Date of test: July 02, 2025

Result of Facility Tests: PASS

RESULTS OF FACILITY TEST

Double Interlock Pass Through #2 ISO 14644-1 Class 7 Environment				
TEST	Criteria	Result	Pass/Fail	Comments
Non-Viable Particle Count	<352,000	13,952	Pass	
Temperature	66°-70°f	68.4°f	--	
Relative Humidity	<60%	53.1%	--	

Occupancy State at time of test: DYNAMIC

Date of test: July 02, 2025

Result of Facility Tests: PASS

RESULTS OF FACILITY TEST

Sterile Prep Room ISO 14644-1 Class 8 Environment				
TEST	Criteria	Result	Pass/Fail	Comments
Air Volume Test	--	182 cfm	--	
Adjusted Hourly Air Exchange Rate	>20 ACPH	39.22 ACPH	Pass	Includes airflow from device Model #P5-48-HEAD-A (S# PB003500)
Non-Viable Particle Count	<3,520,000	9,335	Pass	
HEPA Filter Leak Test	<0.01%	<0.01%	Pass	
Temperature Average	66°-70°f	70.1°f	--	
Relative Humidity Average	<60%	59.4%	--	
Room Segregation Test	≥ -0.020"wc	-0.021"wc	Pass	Compared to Ante Gown In Room
Room Segregation Test	≥ +0.020"wc	+0.021"wc	Pass	Compared to Outside

Occupancy State at time of test: DYNAMIC

Date of test: July 02, 2025

Result of Facility Tests: PASS

RESULTS OF FACILITY TEST

H.D. Prep Room ISO 14644-1 Class 8 Environment				
TEST	Criteria	Result	Pass/Fail	Comments
Air Volume Test	--	180 cfm	--	
Hourly Air Exchange Rate	>20 ACPH	23.25 ACPH	Pass	
Adjusted Hourly Air Exchange Rate	--	49.98 ACPH	--	Includes airflow from device Model #P5-48-HEAD-A (S# PB003503)
Non-Viable Particle Count	<3,520,000	7,569	Pass	
HEPA Filter Leak Test	<0.01%	<0.01%	Pass	
Temperature Average	66°-70°f	68.4°f	--	
Relative Humidity Average	<60%	57.5%	--	
Room Segregation Test	-0.010" to -0.030"wc	-0.023"wc	Pass	Compared to H.D. Gown In Room

Occupancy State at time of test: DYNAMIC

Date of test: July 02, 2025

Result of Facility Tests: PASS

RESULTS OF FACILITY TEST

Non-Sterile H.D. Room Unclassified Environment				
TEST	Criteria	Result	Pass/Fail	Comments
Exhausted Air Volume Test	--	570 cfm	--	
Hourly Air Exchange Rate	>12 ACPH	29.80 cfm	Pass	
Room Segregation Test	-0.010" to -0.030"wc	-0.024"wc	Pass	Compared to Outside

Occupancy State at time of test: DYNAMIC

Dates of test: July 02 & 03, 2025

Result of Facility Tests: PASS

RESULTS OF CLEAN AIR DEVICE TEST

Buffer H.D. Room				
Class II Type A2 Biological Safety Cabinet				
Esco Model #AC2-6S9-NS Serial #2024-204033				
ISO 14644-1 Class 5 Environment				
Test	Criteria	Result	Pass/Fail	Comment
Supply Airflow	55-65 fpm	41 fpm	[redacted]	

Date of test: July 02, 2025

Result of Facility Tests: FAIL

RESULTS OF CLEAN AIR DEVICE TEST

Buffer Room				
Horizontal Laminar Airflow Clean Bench				
Purair Model #HLF-72-A (UV) Serial #HLF000645				
ISO 14644-1 Class 5 Environment				
Test	Criteria	Result	Pass/Fail	Comment
Non-Viable Particle Count	<3,520	0	Pass	
HEPA Filter Pressure Gage	--	ΔP 0.63"wc	--	
Supply Airflow	80-100 fpm	90 fpm	Pass	
Supply HEPA Leak Test	<0.01%	<0.01%	Pass	
Site Assessment	See Methodology	Acceptable	Pass	
Visual Smoke Pattern Test		Acceptable	Pass	
Illumination Test	--	119 fc	--	
Sound Level Test	--	75 dBA	--	

This device was tested to meet the requirements of an ISO Class 5 environment and the standards of the manufacturer.

Occupancy State at time of test: DYNAMIC

Date of test: July 02, 2025

Result of Facility Tests: PASS

RESULTS OF CONTAINMENT VENTILATED ENCLOSURE TEST

Sterile Prep Room				
Containment Ventilated Enclosure				
Purair Model #P5-48-HEAD-A Serial #PB003500				
Test	Criteria	Result	Pass/Fail	Comment
Airflow Face Operating height	--	86 fpm	--	Tested at 7.25" Sash Height
Air Flow Exhaust Volume	--	193 cfm	--	
Exhaust HEPA Leak Test	<0.01%	<0.01%	Pass	
Site Installation	See Methodology	Acceptable	Pass	
Visual Smoke Pattern Test		Acceptable	Pass	
Illumination Test	--	29 fc	--	
Sound Level Test	--	72 dBA	--	
Exhaust Status	--	Vented into Room	Pass	

This device was tested to meet the standards of the manufacturer.

Date of test: July 02, 2025

Result of Facility Tests: PASS

RESULTS OF CONTAINMENT VENTILATED ENCLOSURE TEST

Hazardous Prep Room				
Containment Ventilated Enclosure				
Purair Model #P5-48-HEAD-A Serial #PB003503				
Test	Criteria	Result	Pass/Fail	Comment
Airflow Face Operating height	--	85 fpm	--	Tested at 7.25" Sash Height
Air Flow Exhaust Volume	--	207 cfm	--	
Dual Exhaust HEPA Leak Test	<0.01%	<0.01%	Pass	Dual HEPA filtered
Site Installation	See Methodology	Acceptable	Pass	
Visual Smoke Pattern Test		Acceptable	Pass	
Illumination Test	--	60 fc	--	
Sound Level Test	--	69 dBA	--	
Exhaust Status	--	Vented into Room	Pass	

This device was tested to meet the standards of the manufacturer.

Date of test: July 02, 2025

Result of Facility Tests: PASS

RESULTS OF CONTAINMENT VENTILATED ENCLOSURE TEST

Non-Sterile H.D. Room				
Containment Ventilated Enclosure				
Purair Model #P5-48-HEAD-A Serial #PB003501				
Test	Criteria	Result	Pass/Fail	Comment
Airflow Face Operating height	--	67 fpm	--	Tested at 7.25" Sash Height
Air Flow Exhaust Volume	--	150 cfm	--	
Dual Exhaust HEPA Leak Test	<0.01%	<0.01%	Pass	Dual HEPA filtered
Site Installation	See Methodology	Acceptable	Pass	
Visual Smoke Pattern Test		Acceptable	Pass	
Illumination Test	--	54 fc	--	
Sound Level Test	--	69 dBA	--	
Exhaust Status	--	Vented into Room	Pass	

This device was tested to meet the standards of the manufacturer.

Date of test: July 03, 2025

Result of Facility Tests: PASS

Section 3

TEST DATA

Section 3A

FACILITY TEST DATA

RESULTS OF NON-VIABLE PARTICLE COUNT TEST

Buffer Room					
ISO 14644-1 Class 7 Environment					
Sample Location	Size Sampled: 0.5 micron	Size Sampled 1.0 micron	Size Sampled 5.0 micron	Day/ Time	Pass/ Fail
Control	0	0	0	07/02/2025 10:10	Pass
1	0	0	0	07/02/2025 10:29	Pass
2	0	0	0	07/02/2025 10:34	Pass
3	78	14	0	07/02/2025 10:40	Pass
4	0	14	0	07/02/2025 10:45	Pass
5	219	283	21	07/02/2025 10:51	Pass
6	99	14	7	07/02/2025 10:56	Pass
Mean of the Average $Ft.^3$	2	2	0		
Maximum Concentration Limit	352,000	83,200	2,930		
Mean of the Average m^3	66	54	5	Total	
				125	Pass

Occupancy State at time of test: DYNAMIC

Result of Particle Count Test: PASS

RESULTS OF NON-VIABLE PARTICLE COUNT TEST

Ante Gown In Room					
ISO 14644-1 Class 8 Environment					
Sample Location	Size Sampled: 0.5 micron	Size Sampled 1.0 micron	Size Sampled 5.0 micron	Day/ Time	Pass/ Fail
Control	0	0	0	07/02/2025 10:10	Pass
7	3,150	1,321	14	07/02/2025 11:02	Pass
8	12,417	19,650	1,985	07/02/2025 11:07	Pass
Mean of the Average Ft.³	221	297	28		
Maximum Concentration Limit	3,520,000	832,000	29,300		
Mean of the Average m³	7,784	10,486	1,000	Total	
				19,270	Pass

Occupancy State at time of test: DYNAMIC

Result of Particle Count Test: PASS

RESULTS OF NON-VIABLE PARTICLE COUNT TEST

Buffer H.D. Room					
ISO 14644-1 Class 7 Environment					
Sample Location	Size Sampled: 0.5 micron	Size Sampled 1.0 micron	Size Sampled 5.0 micron	Day/ Time	Pass/ Fail
Control	0	0	0	07/02/2025 10:02	Pass
9	2,133	982	127	07/02/2025 10:35	Pass
10	5,177	1,956	120	07/02/2025 10:41	Pass
11	2,458	1,264	177	07/02/2025 10:46	Pass
12	3,920	1,038	57	07/02/2025 10:52	Pass
Mean of the Average Ft.³	97	37	3		
Maximum Concentration Limit	352,000	83,200	2,930		
Mean of the Average m³	3,422	1,310	120	Total	
				4,852	Pass

Occupancy State at time of test: DYNAMIC

Result of Particle Count Test: PASS

RESULTS OF NON-VIABLE PARTICLE COUNT TEST

H.D. Gown In Room					
ISO 14644-1 Class 7 Environment					
Sample Location	Size Sampled: 0.5 micron	Size Sampled 1.0 micron	Size Sampled 5.0 micron	Day/ Time	Pass/ Fail
Control	0	0	0	07/02/2025 10:02	Pass
13	2,246	1,370	205	07/02/2025 10:57	Pass
14	3,150	1,575	261	07/02/2025 11:03	Pass
Mean of the Average Ft.³	76	42	7		
Maximum Concentration Limit	352,000	83,200	2,930		
Mean of the Average m³	2,698	1,473	233	Total	
				4,404	Pass

Occupancy State at time of test: DYNAMIC

Result of Particle Count Test: PASS

RESULTS OF NON-VIABLE PARTICLE COUNT TEST

Double Interlock Pass Through #1					
ISO 14644-1 Class 7 Environment					
Sample Location	Size Sampled: 0.5 micron	Size Sampled 1.0 micron	Size Sampled 5.0 micron	Day/ Time	Pass/ Fail
Control	0	0	0	07/02/2025 10:10	Pass
15-1	43,971	54,072	5,898	07/02/2025 11:37	Alert
15-2	28,537	35,954	2,790	07/02/2025 11:38	Pass
15-3	19,498	22,500	2,049	07/02/2025 11:40	Pass
Mean of the Average Ft.³	869	1,063	101		
Maximum Concentration Limit	352,000	83,200	2,930		
Mean of the Average m³	30,669	37,509	3,579	Total	
				71,757	Pass

Occupancy State at time of test: DYNAMIC

Result of Particle Count Test: PASS

RESULTS OF NON-VIABLE PARTICLE COUNT TEST

Double Interlock Pass Through #2					
ISO 14644-1 Class 7 Environment					
Sample Location	Size Sampled: 0.5 micron	Size Sampled 1.0 micron	Size Sampled 5.0 micron	Day/ Time	Pass/ Fail
Control	0	0	0	07/02/2025 10:10	Pass
16-1	17,344	4,239	424	07/02/2025 11:36	Pass
16-2	8,759	2,825	106	07/02/2025 11:38	Pass
16-3	6,145	1,872	141	07/02/2025 11:39	Pass
Mean of the Average Ft.³	305	84	6		
Maximum Concentration Limit	352,000	83,200	2,930		
Mean of the Average m³	10,749	2,979	224	Total	
				13,952	Pass

Occupancy State at time of test: DYNAMIC

Result of Particle Count Test: PASS

RESULTS OF NON-VIABLE PARTICLE COUNT TEST

Sterile Prep Room					
ISO 14644-1 Class 8 Environment					
Sample Location	Size Sampled: 0.5 micron	Size Sampled 1.0 micron	Size Sampled 5.0 micron	Day/ Time	Pass/ Fail
Control	0	0	0	07/02/2025 10:02	Pass
17	6,384	5,367	325	07/02/2025 11:13	Pass
18	1,398	1,010	120	07/02/2025 11:18	Pass
19	7,119	3,580	113	07/02/2025 11:24	Pass
20	8,249	3,503	170	07/02/2025 11:29	Pass
Mean of the Average Ft.³	164	95	5		
Maximum Concentration Limit	3,520,000	832,000	29,300		
Mean of the Average m³	5,788	3,365	182	Total	
				9,335	Pass

Occupancy State at time of test: DYNAMIC

Result of Particle Count Test: PASS

RESULTS OF NON-VIABLE PARTICLE COUNT TEST

H.D. Prep Room					
ISO 14644-1 Class 8 Environment					
Sample Location	Size Sampled: 0.5 micron	Size Sampled 1.0 micron	Size Sampled 5.0 micron	Day/ Time	Pass/ Fail
Control	0	0	0	07/02/2025 10:02	Pass
21	4,527	2,670	134	07/02/2025 11:08	Pass
22	2,479	1,130	21	07/02/2025 11:14	Pass
23	9,040	2,606	99	07/02/2025 11:19	Pass
Mean of the Average Ft.³	152	60	2		
Maximum Concentration Limit	3,520,000	832,000	29,300		
Mean of the Average m³	5,349	2,135	85	Total	
				7,569	Pass

Occupancy State at time of test: DYNAMIC

Result of Particle Count Test: PASS

Summary of Particle Count Test Procedure

The purpose of this test is to demonstrate compliance of the clean zone tested to the requirements specified in the International Organization for Standardization document ISO 14644-1:2015.

USP <797> requires all buffer zones to be ISO Class 7 or cleaner. The ante rooms may be an ISO Class 8 unless the ante room is adjacent to a negative ISO Class 7, then the ante room must also be an ISO Class 7 environment.

This test is also referred to as a Particle Count Survey or an Airborne Particle Count.

The number of sample locations was determined by utilizing table A.1 which is located in ISO 14644-1:2015, a copy of which may be found in section 6 of this report.

In this case:

Buffer Room = minimum of 6 locations.
165.25" x 114.25" = 18,879.81in² ÷ 144 = 131.11ft² x 0.093 = 12.19m²
Minus: 20.00" x 14.25" = 285.00in² ÷ 144 = 1.98ft² x 0.093 = 0.18m².
Minus: 20.25" x 14.50" = 293.63in² ÷ 144 = 2.04ft² x 0.093 = 0.19m².
Equals: 11.82m² = **6** locations.

Ante Gown In Room = minimum of 2 locations.
52.00" x 95.25" = 4,953.00n² ÷ 144 = 34.40ft² x 0.093 = 3.20m²
Minus: 12.25" x 16.00" = 196.00in² ÷ 144 = 1.36ft² x 0.093 = 0.13m².
Equals: 3.07m² = **2** locations.

Buffer H.D. Room = minimum of 4 locations.
109.50" x 113.50" = 12,428.25in² ÷ 144 = 86.31ft² x 0.093 = 8.03m²
Minus: 48.25" x 13.50" = 651.38in² ÷ 144 = 4.52ft² x 0.093 = 0.42m².
Equals: 7.61m² = **4** locations.

H.D Gown In Room = minimum of 2 locations.
61.50" x 95.00" = 5,842.50in² ÷ 144 = 40.57ft² x 0.093 = 3.77m²
Minus: 11.00" x 18.00" = 198.00in² ÷ 144 = 1.38ft² x 0.093 = 0.13m².
Minus: 6.00" x 18.00" = 108.00in² ÷ 144 = 0.75ft² x 0.093 = 0.07m².
Equals: 3.57m² = **2** locations.

Sterile Prep Room = minimum of 4 locations.
111.50" x 95.00" = 10,592.50in² ÷ 144 = 73.56ft² x 0.093 = 6.84m²
Minus: 23.75" x 11.25" = 267.19in² ÷ 144 = 1.86ft² x 0.093 = 0.17m².
Equals: 6.67m² = **4** locations.

H.D. Prep Room = minimum of 3 locations.
92.00" x 95.00" = 8,740.00in² ÷ 144 = 60.69ft² x 0.093 = 5.64m²
Minus: 19.00" x 6.25" = 118.75in² ÷ 144 = 0.82ft² x 0.093 = 0.08m².
Minus: 22.00" x 11.75" = 258.50in² ÷ 144 = 1.80ft² x 0.093 = 0.17m².
Equals: 5.39m² = **3** locations.

The location of the samples taken was determined by dissecting the room into equal grids and sampling in the center of each grid, as illustrated in Section 4 of this report.

The amount of air sampled at each location was 5.0 cubic feet, or 141.6 cubic liters, which exceeds the minimum volume required at each sample location determined by the following equation:

$$V_s = \frac{20}{Cn,m} \times 1{,}000$$

Where: V_S is the minimum single sample per location expressed in liters.
$C_{n,m}$ is the class limit (number of particles per cubic meter) for the largest considered particle size specified.
20 The defined number of particles that could be counted if the particle concentration were at the class limit.

For ISO Class 5: Vs = 24.04 liters
[20 ÷ 832 x 1,000 = 24.04]

For ISO Class 6: Vs = 68.26 liters
[20 ÷ 293 x 1,000 = 68.26]

For ISO Class 7: Vs = 6.83 liters
[20 ÷ 2,930 x 1,000 = 6.83]

For ISO Class 8: Vs = 0.68 liters
[20 ÷ 29,300 x 1,000 = 0.68]

The particle counter sampled at a rate of 1.0 cfm through an isokinetic probe which was oriented upward and held in a stand located at a height of 32 inches above the floor and attached to the counter by HYTREL PVC tubing which does not exceed 10 feet in length. Each location was sampled for a period of five minutes and the readings were then normalized to represent a cubic foot and a cubic meter.

The first equipment used is a discrete-particle counter (DPC) manufactured by Particle Measuring Systems, Inc. the model Lasair III_310C serial #103782 which was last calibrated on April 29, 2025 and due for recalibration on April 28, 2026. The most recent calibration report is located in Section 6.

The second equipment used is a discrete-particle counter (DPC) manufactured by Particle Measuring Systems, Inc. the model Lasair III_310C serial #171352 which was last calibrated on July 08, 2024 and due for recalibration on July 07, 2025. The most recent calibration report is located in Section 6.

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-21 which is available upon request.

The above referenced testing procedure meets test methods outlined in the following documents:

IEST-G-CC1001	Counting Airborne Particles for Classification and Monitoring of Cleanrooms and Clean Zones
IEST-RP-CC006.3	Testing Cleanroom
IEST-RP-CC013	Calibration Procedures and Guidelines for Select Equipment Used in Testing Cleanrooms and Other Controlled Environments
ISO 14644-1:2015	Classification of air cleanliness
ISO 14644-2:2015	Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
ISO 14644-3:2019	Test Methods
USP <800>	Hazardous Drugs
USP <797>	Guidebook to Pharmaceutical Compounding-Sterile Preparations
64B16-27.797	The Standards of Practice for Compounding Sterile Products
CAG-003	CETA Certification Guide for Sterile Compounding Facilities
CAG-008	CETA Certification Matrix for Sterile Compounding Facilities

RESULTS OF HEPA FILTER AIRFLOW TEST

Buffer Room ISO 14644-1 Class 7 Environment				
HEPA Filter	Measured Filter Velocity	Area of HEPA Filter	*K* correction factor	Measured Filter Volume
A	--	7.028ft²	--	161 cfm
B	--	7.028ft²	--	204 cfm
C	--	7.028ft²	--	126 cfm

Total Airflow Volume	491 cfm

RESULTS OF HEPA FILTER AIRFLOW TEST

Ante Gown-In Room				
ISO 14644-1 Class 8 Environment				
HEPA Filter	Measured Filter Velocity	Area of HEPA Filter	*K* correction factor	Measured Filter Volume
D	--	7.028ft²	--	119 cfm

Total Airflow Volume	119 cfm

RESULTS OF HEPA FILTER AIRFLOW TEST

Buffer H.D. Room				
ISO 14644-1 Class 7 Environment				
HEPA Filter	Measured Filter Velocity	Area of HEPA Filter	*K* correction factor	Measured Filter Volume
E	--	7.028ft²	--	365 cfm
F	--	3.361ft²	--	208 cfm

Total Airflow Volume	573 cfm

RESULTS OF HEPA FILTER AIRFLOW TEST

H.D. Gown-In Room				
ISO 14644-1 Class 7 Environment				
HEPA Filter	Measured Filter Velocity	Area of HEPA Filter	*K* correction factor	Measured Filter Volume
"G	--	7.028ft²	--	171 cfm

Total Airflow Volume	171 cfm

RESULTS OF HEPA FILTER AIRFLOW TEST

Sterile Prep Room				
ISO 14644-1 Class 8 Environment				
HEPA Filter	Measured Filter Velocity	Area of HEPA Filter	*K* correction factor	Measured Filter Volume
H	---	3.361ft²	--	182 cfm

Total Airflow Volume	182 cfm

RESULTS OF HEPA FILTER AIRFLOW TEST

H.D. Prep Room				
ISO 14644-1 Class 8 Environment				
HEPA Filter	Measured Filter Velocity	Area of HEPA Filter	*K* correction factor	Measured Filter Volume
I	--	3.361ft²	--	180 cfm

Total Airflow Volume	180 cfm

RESULTS OF HEPA FILTER AIRFLOW TEST

Non-Sterile H.D. Room				
Unclassified Environment				
HEPA Filter	Measured Filter Velocity	Area of HEPA Filter	*K* correction factor	Measured Filter Volume
J	---	7.028ft²	--	224 cfm

Total Airflow Volume	224 cfm

Summary of Airflow Test Procedure

The purpose of this test is to accurately measure the total volume of HEPA filtered air entering the clean zone. This volume will then be utilized to determine the air exchange rate within the clean zone. The HEPA filtered air is measured in one of two ways dependent upon accessibility.

While volume measurement is the preferred method because it is the most accurate, it may not be possible when access is hindered. In that case velocity readings are performed.

1) Each HEPA filter or HEPA supplied diffuser located within the clean zone is tested for volume by placing a flow hood over the entire surface of the filter or diffuser. A series of 5 readings are taken over a span of 30 seconds and recorded. These readings are averaged and the resulting average volume in cfm is recorded.

2) Velocity readings are taken by dividing the area of the HEPA filter into grids roughly 12" square. A single reading is taken within each grid by placing either a thermoanemometer probe or a multipoint sensor six inches below the filter face. Each measurement is at least 5 seconds in length. This reading is recorded. All subsequent readings are averaged per filter and each average recorded. The effective filter area is then determined by multiplying the length and width of the filter medium. The volume per filter is determined by multiplying the average velocity by the effective filter area.

A *k* correction factor may be used to normalize velocity measurements when some HEPA filters in a clean zone cannot be measured using a flow hood. The formula to determine the *k* factor is:

$$K_v = \frac{\text{Actual filter airflow volume}}{\text{Calculated filter airflow volume}}$$

The first device used to measure airflow volume was a flow hood manufactured by Alnor/TSI, Inc. the model EBT731 serial #EBT732226001 last calibrated on February 13, 2025 and due for recalibration on February 12, 2026. The most recent calibration report is located in Section 6.

The second device used to measure airflow volume was a flow hood manufactured by Alnor/TSI, Inc. the model EBT731 serial #EBT731503016 last calibrated on August 19, 2024 and due for recalibration on August 18, 2025. The most recent calibration report is located in Section 6.

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-23 which is available upon request.

The above referenced testing method meets test methods outlined in the following documents:

IEST-RP-CC006.3	Testing Cleanrooms
ISO 14644-1:2015	Classification of air cleanliness
ISO 14644-2:2015	Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
ISO 14644-3:2019	Test Methods
USP <800>	Hazardous Drugs
USP <797>	Guidebook to Pharmaceutical Compounding-Sterile Preparations
64B16-27.797	The Standards of Practice for Compounding Sterile Products
CAG-003	CETA Certification Guide for Sterile Compounding Facilities
CAG-008	CETA Certification Matrix for Sterile Compounding Facilities

RESULTS OF EXHAUST REGISTER AIRFLOW TEST

Non-Sterile H.D. Room				
Unclassified Environment				
Exhaust Register	Measured Exhaust Register Velocity	Area of Exhaust Register	*K* correction factor	Measured Exhaust Register Volume
8	314 fpm	1.816ft²	--	570 cfm

Total Airflow Volume	570 cfm

Summary of Airflow Test Procedure

The purpose of this test is to accurately measure the total volume of air exiting the room. This volume will then be utilized to determine the air exchange rate within the room. The air is measured in one of two ways:

While volume measurement is the preferred method because it is the most accurate, it may not be possible when access is hindered. In that case velocity readings are performed.

1) Each diffuser located within the room is tested for volume by placing a flow hood over the entire surface of the filter or diffuser. A series of 5 readings are taken over a span of 30 seconds and recorded. These readings are averaged and the resulting average volume in cfm is recorded.

2) Velocity readings are taken by dividing the area of the register into grids roughly 12" square. A single reading is taken within each grid by placing either a thermo-anemometer probe or a multipoint sensor six inches below the register opening. Each measurement is at least 5 seconds in length. This reading is recorded. All subsequent readings are averaged per register and each average recorded. The effective register area is then determined by multiplying the length and width of the register opening. The volume per register is determined by multiplying the average velocity by the effective register opening.

A *k* correction factor may be used to normalize velocity measurements when some registers filters in a room cannot be measured using a flow hood. The formula to determine the *k* factor is:

$$K_v = \frac{\text{Actual register airflow volume}}{\text{Calculated register airflow volume}}$$

The device used to measure airflow velocity was a thermoanemometer manufactured by Alnor/TSI, Inc. the model AVM440-A serial #AVM441045003 which was last calibrated on July 17, 2024 and due for recalibration on July 16, 2025. The most recent calibration report is located in Section 6.

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-23 which is available upon request.

The above referenced testing method meets test methods outlined in the following documents:

USP <795>	Non-Sterile Compounding
USP <800>	Hazardous Drugs
CAG-008	CETA Certification Matrix for Sterile Compounding Facilities

RESULTS OF AIR EXCHANGE RATE CALCULATIONS

Buffer Room ISO 14644-1 Class 7 Environment			
Total HEPA Air Volume	Room Volume	Minimum Acceptable Rate	Room Air Exchange Rate
491 cfm	1,018.11ft³	>30 ACPH	28.94 ACPH

Adjusted Air Exchange Rate					
Room HEPA Air Volume	*Device HEPA Air Volume	Total HEPA Air Volume	Room Volume	Minimum Acceptable Rate	Room Air Exchange Rate
491 cfm	962 cfm	1,453 cfm	1,018.11ft³	>30 ACPH	85.63 ACPH

*Includes airflow from device Model #HLF-72-A (UA) (S# HLF000645)

Occupancy State at time of test: DYNAMIC

Result of Air Exchange Calculations: PASS

RESULTS OF AIR EXCHANGE RATE CALCULATIONS

Ante Gown-In Room			
ISO 14644-1 Class 8 Environment			
Total HEPA Air Volume	Room Volume	Minimum Acceptable Rate	Room Air Exchange Rate
119 cfm	264.64ft³	>20 ACPH	26.98 ACPH

Occupancy State at time of test: DYNAMIC

Result of Air Exchange Calculations: PASS

RESULTS OF AIR EXCHANGE RATE CALCULATIONS

Buffer H.D. Room			
ISO 14644-1 Class 7 Environment			
Total HEPA Air Volume	Room Volume	Minimum Acceptable Rate	Room Air Exchange Rate
573 cfm	654.27ft³	>30 ACPH	52.55 ACPH

Occupancy State at time of test: DYNAMIC

Result of Air Exchange Calculations: PASS

RESULTS OF AIR EXCHANGE RATE CALCULATIONS

H.D. Gown-In Room			
ISO 14644-1 Class 7 Environment			
Total HEPA Air Volume	Room Volume	Minimum Acceptable Rate	Room Air Exchange Rate
171 cfm	307.58ft³	>30 ACPH	33.36 ACPH

Occupancy State at time of test: DYNAMIC

Result of Air Exchange Calculations: PASS

RESULTS OF AIR EXCHANGE RATE CALCULATIONS

Sterile Prep Room			
ISO 14644-1 Class 8 Environment			
Total HEPA Air Volume	Room Volume	Minimum Acceptable Rate	Room Air Exchange Rate
182 cfm	573.63ft³	>20 ACPH	19.04 ACPH

Adjusted Air Exchange Rate					
Room HEPA Air Volume	*Device HEPA Air Volume	Total HEPA Air Volume	Room Volume	Minimum Acceptable Rate	Room Air Exchange Rate
182 cfm	193 cfm	375 cfm	573.63ft³	>20 ACPH	39.22 ACPH

*Includes airflow from device Model #P5-48-HEAD-A (S# PB003500)

Occupancy State at time of test: DYNAMIC

Result of Air Exchange Calculations: PASS

RESULTS OF AIR EXCHANGE RATE CALCULATIONS

H.D. Prep Room			
ISO 14644-1 Class 8 Environment			
Total HEPA Air Volume	Room Volume	Minimum Acceptable Rate	Room Air Exchange Rate
180 cfm	464.60ft³	>20 ACPH	23.25 ACPH

Adjusted Air Exchange Rate					
Room HEPA Air Volume	*Device HEPA Air Volume	Total HEPA Air Volume	Room Volume	Minimum Acceptable Rate	Room Air Exchange Rate
180 cfm	207 cfm	387 cfm	464.60ft³	>20 ACPH	49.98 ACPH

*Includes airflow from device Model #P5-48-HEAD-A (S# PB003503)

Occupancy State at time of test: DYNAMIC

Result of Air Exchange Calculations: PASS

Summary of Air Exchange Rate Calculations

The purpose of this test is to determine the number of air changes per hour (ACPH).

For an ISO Class 7 environment, the ACPH should be >30. At least 15 ACPH must come from the facility ventilation system. When 15 ACPH is achieved from the HEPA filtered facility system but the ACPH is less than 30, then the HEPA filtered airflow from any devices within the facility may be utilized to achieve >30 ACPH.

The volume of HEPA filtered air entering the room is converted from cubic feet per minute (CFM) to cubic feet per hour (CFH) by multiplying by 60. This result is then divided by the room volume in cubic feet.

The room volume is determined by multiplying the area of the room by the ceiling height.

To achieve the air exchange rate or Air Changes per Hour (ACPH) the following formula is used:

ACPH= (CFM x 60) ÷ Room Volume

Individual room volumes and Air Exchange Rates in this case:

In this case:

Buffer Room ACPH = 28.94 (Does not include device airflow)
18,301.18in^2 (room area) x 96.13" (ceiling height) = 1,759,292.43in^3÷1,728 = 1,018.11ft^3
491 cfm x 60 = 29,460 cfh ÷ 1,018.11 = 28.94

Ante Gown In Room ACPH = 26.98
4,757.00in^2 (room area) x 96.13" (ceiling height) = 457,290.41in^3÷1,728 = 264.64ft^3
119 cfm x 60 = 7,140 cfh ÷ 264.64 = 26.98

Buffer H.D. Room ACPH = 52.55
11,776.87in^2 (room area) x 96.00" (ceiling height) = 1,130,579.52in^3÷1,728 = 654.27ft^3
573 cfm x 60 = 34,380 cfh ÷ 654.27 = 52.55

H.D Gown In Room ACPH = 33.36
5,536.50in^2 (room area) x 96.00" (ceiling height) = 531,504.00in^3÷1,728 = 307.58ft^3
171 cfm x 60 = 10,260 cfh ÷ 307.58 = 33.36

Sterile Prep Room ACPH = 19.04(Does not include device airflow)
10,325.31in^2 (room area) x 96.00" (ceiling height) = 991,229.76in^3÷1,728 = 573.63ft^3
182 cfm x 60 = 10,920 cfh ÷ 573.63 = 19.04

H.D. Prep Room ACPH = 23.25(Does not include device airflow)
8,362.75in² (room area) x 96.00" (ceiling height) = 802,824.00in³÷1,728 = 464.60ft³
180 cfm x 60 = 10,800 cfh ÷ 464.60 = 23.25

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-18 which is available upon request.

The above referenced testing method meets test methods outlined in the following documents:

IEST-RP-CC006.3	Testing Cleanrooms
ISO 14644-2:2015	Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
USP <800>	Hazardous Drugs
USP <797>	Guidebook to Pharmaceutical Compounding-Sterile Preparations
64B16-27.797	The Standards of Practice for Compounding Sterile Products
CAG-003	CETA Certification Guide for Sterile Compounding Facilities
CAG-008	CETA Certification Matrix for Sterile Compounding Facilities

RESULTS OF AIR EXCHANGE RATE CALCULATIONS

Non-Sterile – Hazardous Drug Room Unclassified Environment			
Exhausted Air Volume	Room Volume	Minimum Acceptable Rate	Room Air Exchange Rate
570 cfm	1,147.75ft³	12 ACPH	29.80 ACPH

Occupancy State at time of test: DYNAMIC

Result of Air Exchange Calculations: PASS

Summary of Air Exchange Rate Calculations

The purpose of this test is to determine the number of air changes per hour (ACPH).

For an unclassified negative pressure environment the ACPH must be at least 12.

The volume of air exhausted from the room is converted from cubic feet per minute (CFM) to cubic feet per hour (CFH) by multiplying by 60. This result is then divided by the room volume in cubic feet.

The room volume is determined by multiplying the area of the room by the ceiling height.

To achieve the air exchange rate or Air Changes per Hour (ACPH) the following formula is used:

ACPH= (CFM x 60) ÷ Room Volume

Individual room volumes and Air Exchange Rates in this case:

In this case:

Non-Sterile H.D. Room ACPH = 29.80
20,685.31in² (room area) x 95.88" (ceiling height) = 1,983,307.52in³÷1,728 = 1,147.75ft³
570 cfm x 60 = 34,200 cfh ÷ 1,147.75 = 29.80

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-18 which is available upon request.

The above referenced testing method meets test methods outlined in the following documents:

USP<795>	Non-Sterile Compounding
USP<800>	Hazardous Drugs
CAG-008	CETA Certification Matrix for Sterile Compounding Facilities

RESULTS OF HEPA FILTER INTEGRITY TEST

Buffer Room ISO 14644-1 Class 7 Environment			
HEPA Filter	% Penetration	Comment	Pass/Fail
A	<0.01%	--	Pass
B	<0.01%	--	Pass
C	<0.01%	--	Pass

Occupancy State at time of test: DYNAMIC

Result of HEPA Filter Integrity Test: PASS

RESULTS OF HEPA FILTER INTEGRITY TEST

Ante Gown-In Room			
ISO 14644-1 Class 8 Environment			
HEPA Filter	% Penetration	Comment	Pass/Fail
D	<0.01%	--	Pass

Occupancy State at time of test: DYNAMIC

Result of HEPA Filter Integrity Test: PASS

RESULTS OF HEPA FILTER INTEGRITY TEST

Buffer H.D. Room			
ISO 14644-1 Class 7 Environment			
HEPA Filter	% Penetration	Comment	Pass/Fail
E	<0.01%	--	Pass
F	<0.01%	--	Pass

Occupancy State at time of test: DYNAMIC

Result of HEPA Filter Integrity Test: PASS

RESULTS OF HEPA FILTER INTEGRITY TEST

H.D. Gown-In Room			
ISO 14644-1 Class 7 Environment			
HEPA Filter	% Penetration	Comment	Pass/Fail
G	<0.01%	--	Pass

Occupancy State at time of test: DYNAMIC

Result of HEPA Filter Integrity Test: PASS

RESULTS OF HEPA FILTER INTEGRITY TEST

Sterile Prep Room			
ISO 14644-1 Class 8 Environment			
HEPA Filter	% Penetration	Comment	Pass/Fail
H	<0.01%	--	Pass

Occupancy State at time of test: DYNAMIC

Result of HEPA Filter Integrity Test: PASS

RESULTS OF HEPA FILTER INTEGRITY TEST

H.D. Prep Room			
ISO 14644-1 Class 8 Environment			
HEPA Filter	% Penetration	Comment	Pass/Fail
I	<0.01%	--	Pass

Occupancy State at time of test: DYNAMIC

Result of HEPA Filter Integrity Test: PASS

Summary of HEPA Filter Integrity Test

The purpose of this test is to confirm that the HEPA, or ULPA, filter system is properly sealed by verifying the absence of by-pass leakage in the installation and that the filters are intact and free of defects. This test is also known as the HEPA and ULPA filter installation leak test and also the installed filter system leakage test.

This test is performed by generating a challenge aerosol upstream of the filter(s) to be tested. Each filter is then tested for leaks by scanning the face of the filter, the seal and the frame for penetrations using an aerosol photometer. Minor leaks may be repaired. Any by-pass not corrected will result in failure.

Filters installed within a filter housing located within the ventilation system are tested using the probe system where a single downstream reading is taken to verify the overall efficiency of the filter, gasket seating and housing.

The challenge liquid used was Poly Alpha Olefin (PAO). The challenge aerosol was generated by multiple Laskin nozzles supplied by a compressor(s) providing 100 liters per minute at 20 psi per nozzle.

The challenge aerosol was introduced into ports testing the HEPA filters individually.

The first aerosol photometer used was a calibrated linear photometer manufactured by TEC Services, Inc. the model PH-4 serial #1944 last calibrated on February 11, 2025 and due for recalibration on February 10, 2026. The most recent calibration report is located in Section 6. The photometer probe is an isokinetic probe.

The second aerosol photometer used was a calibrated linear photometer manufactured by TEC Services, Inc. the model PH-4 serial #4520 last calibrated on June 09, 2025 and due for recalibration on June 08, 2026. The most recent calibration report is located in Section 6. The photometer probe is an isokinetic probe.

An upstream challenge could not be measured because of inaccessibility. Therefore, an internal calibration of the aerosol photometer was utilized using the following formula:

$$C_2 = NC_1 \quad \frac{Q_1}{Q_2}$$

Where: C_2 is the full scale photometer setting based upon manufacturers calibration data.
N is the number of Laskin nozzles used.
C_1 µg/L per nozzle when discharged into a flow rate of Q_1 (38 m^3/min).
Q_1 38 m^3/min
Q_2 Volume of air measured in m^3/min

In this case*:
*The values shown here for Q_2 and C_2 for each calculation are rounded for brevity.

HEPA Filter "A"
Full scale reading represents 167µg/L
(2) x (10) x 38 ÷ 4.56 = 166.71

HEPA Filter "B"
Full scale reading represents 132µg/L
(2) x (10) x 38 ÷ 5.78 = 131.57

HEPA Filter "C"
Full scale reading represents 213µg/L
(2) x (10) x 38 ÷ 3.57 = 213.02

HEPA Filter "D"
Full scale reading represents 226µg/L
(2) x (10) x 38 ÷ 3.37 = 225.55

HEPA Filter "E"
Full scale reading represents 74µg/L
(2) x (10) x 38 ÷ 10.34 = 73.53

HEPA Filter "F"
Full scale reading represents 82µg/L
(2) x (10) x 38 ÷ 9.30 = 81.72

HEPA Filter "G"
Full scale reading represents 157µg/L
(2) x (10) x 38 ÷ 4.84 = 156.96

HEPA Filter "I"
Full scale reading represents 149µg/L
(2) x (10) x 38 ÷ 5.10 = 149.11

The filter was then scan tested approximately 1 inch below the face of the filter at a rate of 2 inches per second with the photometer on the 0.10% scale. Any result above 0.01% is unacceptable and results in failure.

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-11 and MEDREP-Proc-25 which is available upon request.

The above referenced testing method meets test methods outlined in the following documents:

IEST-RP-CC006.3	Testing Cleanrooms
IEST-RP-CC034.5	HEPA and ULPA Filter Leak Tests
ISO 14644-2:2015	Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
ISO 14644-3:2019	Test Methods
USP <800>	Hazardous Drugs
USP <797>	Guidebook to Pharmaceutical Compounding-Sterile Preparations
64B16-27.797	The Standards of Practice for Compounding Sterile Products
CAG-003	CETA Certification Guide for Sterile Compounding Facilities
CAG-008	CETA Certification Matrix for Sterile Compounding Facilities

RESULTS OF ROOM SEGREGATION TEST

Buffer Room						
ISO 14644-1 Class 7 Environment						
Zone	Adjacent Zone	Allowable Pressure	Monitor Indicates	Measured	Pass/Fail	Visual Confirmation
Buffer Room	Ante Gown In Room	≥ +0.020"wc	+0.040"wc (G-3)	+0.023"wc	Pass	Pass Unidirectional

Occupancy State at time of test: DYNAMIC

Result of Room Segregation Test: PASS

RESULTS OF ROOM SEGREGATION TEST

Ante Gown In Room						
ISO 14644-1 Class 8 Enviironment						
Zone	Adjacent Zone	Allowable Pressure	Monitor Indicates	Measured	Pass/Fail	Visual Confirmation
Ante Gown In Room	Buffer Room	≥ -0.020"wc	-0.040"wc (G-3)	-0.023"wc	Pass	Pass Unidirectional
Ante Gown In Room	Sterile Prep Room	≥ +0.020"wc	+0.060"wc (G-2)	+0.021"wc	Pass	Pass Unidirectional

Occupancy State at time of test: DYNAMIC

Result of Room Segregation Test: PASS

RESULTS OF ROOM SEGREGATION TEST

Buffer H.D. Room						
ISO 14644-1 Class 7 Environment						
Zone	Adjacent Zone	Allowable Pressure	Monitor Indicates	Measured	Pass/Fail	Visual Confirmation
Buffer H.D. Room	H.D. Gown In Room	-0.010" to -0.030"wc	--	-0.019"wc	Pass	Pass Unidirectional

Occupancy State at time of test: DYNAMIC

Result of Room Segregation Test: PASS

RESULTS OF ROOM SEGREGATION TEST

H.D. Gown In Room						
ISO 14644-1 Class 7 Environment						
Zone	Adjacent Zone	Allowable Pressure	Monitor Indicates	Measured	Pass/Fail	Visual Confirmation
H.D. Gown In Room	Buffer H.D. Room	+0.010" to +0.030"wc	--	+0.019"wc	Pass	Pass Unidirectional
H.D. Gown In Room	H.D. Prep Room	+0.010" to +0.030"wc	+0.040"wc (G-4)	+0.023"wc	Pass	Pass Unidirectional
H.D. Gown In Room	Outside	+0.010" to +0.030"wc	--	+0.020"wc	Pass	Pass Unidirectional

Occupancy State at time of test: DYNAMIC

Result of Room Segregation Test: PASS

RESULTS OF ROOM SEGREGATION TEST

Sterile Prep Room ISO 14644-1 Class 8 Environment						
Zone	Adjacent Zone	Allowable Pressure	Monitor Indicates	Measured	Pass/Fail	Visual Confirmation
Sterile Prep Room	Ante Gown In Room	≥ -0.020"wc	-0.060"wc (G-2)	-0.021"wc	Pass	Pass Unidirectional
Sterile Prep Room	Outside	≥ +0.020"wc	+0.050"wc (G-1)	+0.021"wc	Pass	Pass Unidirectional

Occupancy State at time of test: DYNAMIC

Result of Room Segregation Test: PASS

RESULTS OF ROOM SEGREGATION TEST

H.D. Prep Room						
ISO 14644-1 Class 8 Environment						
Zone	Adjacent Zone	Allowable Pressure	Monitor Indicates	Measured	Pass/Fail	Visual Confirmation
H.D. Prep Room	H.D. Gown In Room	-0.010" to -0.030"wc	-0.040"wc (G-4)	-0.023"wc	Pass	Pass Unidirectional

Occupancy State at time of test: DYNAMIC

Result of Room Segregation Test: PASS

RESULTS OF ROOM SEGREGATION TEST

Non-Sterile H.D. Room						
Unclassified Environment						
Zone	Adjacent Zone	Allowable Pressure	Monitor Indicates	Measured	Pass/Fail	Visual Confirmation
Non-Sterile H.D. Room	Outside	-0.010" to -0.030"wc	--	-0.024"wc	Pass	Pass Unidirectional

Occupancy State at time of test: DYNAMIC

Result of Room Segregation Test: PASS

Summary of Room Segregation Test

The purpose of this test is to document the ability of the cleanroom ventilation system to maintain a specific pressure difference between the cleanroom and its surrounding environments. This test is also known as the Air Pressure Difference Test, the Differential Pressure Test or the Room Pressurization Test.

With all doors closed, the pressure difference is measured at each door and opening which contains a method of closure.

For most portals, a minimum pressure difference of 0.020" water column, and a maximum pressure differential of 0.050" is recommended. This difference should be outward from the cleanest zone to the less clean zone.

For hazardous drug rooms, the range required is -0.010" to -0.030" water column. Hazardous drug rooms must be negative to the surrounding areas which also must be of the same ISO Class.

The first device used to measure the pressure difference was a micromanometer manufactured by Alnor/TSI, Inc. the model EBT731 serial #EBT732226001 last calibrated on February 12, 2025 and due for recalibration on February 11, 2026. The most recent calibration report is located in Section 6.

The second device used to measure the pressure difference was a micromanometer manufactured by Alnor/TSI, Inc. the model EBT731 serial #EBT731503016 last calibrated on August 19, 2024 and due for recalibration on August 18, 2025. The most recent calibration report is located in Section 6.

The measurement was taken by connecting two 8 foot norprene tubes onto the micromanometer, extending each tube into adjoining rooms and recording the reading. If an existing pressure monitor is present, that reading is recorded for comparison.

Additionally, a visual confirmation of the air direction is performed by using a "smoke" generating device containing high purity food grade, kosher USP propylene glycol and distilled water.

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-24 which is available upon request.

The above referenced testing method meets test methods outlined in the following documents:

IEST-RP-CC006.3	Testing Cleanrooms
ISO 14644-2:2015	Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
ISO 14644-3:2019	Test Methods
USP <800>	Hazardous Drugs
USP <797>	Guidebook to Pharmaceutical Compounding-Sterile Preparations
64B16-27.797	The Standards of Practice for Compounding Sterile Products
CAG-003	CETA Certification Guide for Sterile Compounding Facilities
CAG-008	CETA Certification Matrix for Sterile Compounding Facilities

RESULTS OF TEMPERATURE TEST

Buffer Room ISO 14644-1 Class 7 Environment	
Sample Location	Temperature °Fahrenheit
1	70.0°f
2	70.0°f
3	70.1°f
4	70.1°f
5	70.1°f
6	70.1°f
Mean of The Average	70.1°f
Maximum Reading	70.1°f
Minimum Reading	70.0°f

Occupancy State at time of test: DYNAMIC

RESULTS OF TEMPERATURE TEST

Ante Gown In Room ISO 14644-1 Class 8 Environment	
Sample Location	Temperature °Fahrenheit
7	70.1°f
8	70.3°f
Mean of The Average	70.2°f
Maximum Reading	70.3°f
Minimum Reading	70.1°f

Occupancy State at time of test: DYNAMIC

RESULTS OF TEMPERATURE TEST

Buffer H.D. Room ISO 14644-1 Class 7 Environment	
Sample Location	Temperature °Fahrenheit
9	68.2°f
10	68.2°f
11	68.2°f
12	68.2°f
Mean of The Average	68.2°f
Maximum Reading	68.2°f
Minimum Reading	68.2°f

Occupancy State at time of test: DYNAMIC

RESULTS OF TEMPERATURE TEST

H.D. Gown In Room	
ISO 14644-1 Class 7 Environment	
Sample Location	Temperature °Fahrenheit
13	68.2°f
14	68.2°f
Mean of The Average	68.2°f
Maximum Reading	68.2°f
Minimum Reading	68.2°f

Occupancy State at time of test: DYNAMIC

RESULTS OF TEMPERATURE TEST

Double Interlock Pass Through #1 ISO 14644-1 Class 7 Environment	
Sample Location	Temperature °Fahrenheit
15	70.0°f
Mean of The Average	70.0°f
Maximum Reading	70.0°f
Minimum Reading	70.0°f

Occupancy State at time of test: DYNAMIC

RESULTS OF TEMPERATURE TEST

Double Interlock Pass Through #2	
ISO 14644-1 Class 7 Environment	
Sample Location	Temperature °Fahrenheit
16	68.4°f
Mean of The Average	68.4°f
Maximum Reading	68.4°f
Minimum Reading	68.4°f

Occupancy State at time of test: DYNAMIC

RESULTS OF TEMPERATURE TEST

Sterile Prep Room	
ISO 14644-1 Class 8 Environment	
Sample Location	Temperature °Fahrenheit
17	70.0°f
18	70.2°f
19	70.2°f
20	70.0°f
Mean of The Average	70.1°f
Maximum Reading	70.2°f
Minimum Reading	70.0°f

Occupancy State at time of test: DYNAMIC

RESULTS OF TEMPERATURE TEST

H.D. Prep Room	
ISO 14644-1 Class 8 Environment	
Sample Location	Temperature °Fahrenheit
21	68.4°f
22	68.4°f
23	68.4°f
Mean of The Average	68.4°f
Maximum Reading	68.4°f
Minimum Reading	68.4°f

Occupancy State at time of test: DYNAMIC

Summary of Temperature Test Procedure

The purpose of this test is to document the room operating temperature and to demonstrate the capability of the air handling system to maintain the temperature. This test is also known as the General Temperature Test.

The number of sample locations was determined by utilizing table A.1 which is located in ISO 14644-1:2015, a copy of which may be found in section 6 of this report.

In this case:

Buffer Room = minimum of 6 locations.
165.25" x 114.25" = 18,879.81in² ÷ 144 = 131.11ft² x 0.093 = 12.19m²
Minus: 20.00" x 14.25" = 285.00in² ÷ 144 = 1.98ft² x 0.093 = 0.18m².
Minus: 20.25" x 14.50" = 293.63in² ÷ 144 = 2.04ft² x 0.093 = 0.19m².
Equals: 11.82m² = **6** locations.

Ante Gown In Room = minimum of 2 locations.
52.00" x 95.25" = 4,953.00in² ÷ 144 = 34.40ft² x 0.093 = 3.20m²
Minus: 12.25" x 16.00" = 196.00in² ÷ 144 = 1.36ft² x 0.093 = 0.13m².
Equals: 3.07m² = **2** locations.

Buffer H.D. Room = minimum of 4 locations.
109.50" x 113.50" = 12,428.25in² ÷ 144 = 86.31ft² x 0.093 = 8.03m²
Minus: 48.25" x 13.50" = 651.38in² ÷ 144 = 4.52ft² x 0.093 = 0.42m².
Equals: 7.61m² = **4** locations.

H.D Gown In Room = minimum of 2 locations.
61.50" x 95.00" = 5,842.50in² ÷ 144 = 40.57ft² x 0.093 = 3.77m²
Minus: 11.00" x 18.00" = 198.00in² ÷ 144 = 1.38ft² x 0.093 = 0.13m².
Minus: 6.00" x 18.00" = 108.00in² ÷ 144 = 0.75ft² x 0.093 = 0.07m².
Equals: 3.57m² = **2** locations.

Sterile Prep Room = minimum of 4 locations.
111.50" x 95.00" = 10,592.50in² ÷ 144 = 73.56ft² x 0.093 = 6.84m²
Minus: 23.75" x 11.25" = 267.19in² ÷ 144 = 1.86ft² x 0.093 = 0.17m².
Equals: 6.67m² = **4** locations.

H.D. Prep Room = minimum of 3 locations.
92.00" x 95.00" = 8,740.00in² ÷ 144 = 60.69ft² x 0.093 = 5.64m²
Minus: 19.00" x 6.25" = 118.75in² ÷ 144 = 0.82ft² x 0.093 = 0.08m².
Minus: 22.00" x 11.75" = 258.50in² ÷ 144 = 1.80ft² x 0.093 = 0.17m².
Equals: 5.39m² = **3** locations.

The location of the samples taken was determined by dissecting the room into equal grids and sampling in the center of each grid, as illustrated in Section 4 of this report. Each temperature reading is averaged over the duration of sampling.

The first device used to measure temperature was a thermoanemometer manufactured by Alnor/TSI, Inc. the model AVM440-A serial #AVM441045003 which was last calibrated on July 17, 2024 and due for recalibration on July 16, 2025. The most recent calibration report is located in Section 6.

The second device used to measure temperature was a thermoanemometer manufactured by Alnor/TSI, Inc. the model AVM440-A serial #AVM442332003 which was last calibrated on February 17, 2025 and due for recalibration on February 16, 2026. The most recent calibration report is located in Section 6.

The acceptable temperature is determined by the customer, but typically temperatures in a cleanroom should be between 66° and 70° Fahrenheit.

This test is considered a secondary test and is performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-27 which is available upon request.

The above referenced testing procedure meets test methods outlined in the following documents:

IEST-RP-CC006.3	Testing Cleanroom
IEST-RP-CC013	Calibration Procedures and Guidelines for Select Equipment Used in Testing Cleanrooms and Other Controlled Environments
ISO 14644-1:2015	Classification of air cleanliness
ISO 14644-3:2019	Test Methods
USP <800>	Hazardous Drugs
USP <797>	Guidebook to Pharmaceutical Compounding-Sterile Preparations
64B16-27.797	The Standards of Practice for Compounding Sterile Products
CAG-003	CETA Certification Guide for Sterile Compounding Facilities
CAG-008	CETA Certification Matrix for Sterile Compounding Facilities

RESULTS OF RELATIVE HUMIDITY TEST

Buffer Room ISO 14644-1 Class 7 Enviironment	
Sample Location	Relative Humidity
1	58.7%
2	58.4%
3	58.2%
4	58.0%
5	57.9%
6	57.9%
Mean of The Average	58.2%
Maximum Reading	58.7%
Minimum Reading	57.9%

Occupancy State at time of test: DYNAMIC

RESULTS OF RELATIVE HUMIDITY TEST

Ante Gown In Room	
ISO 14644-1 Class 8 Environment	
Sample Location	Relative Humidity
7	59.2%
8	60.6%
Mean of The Average	59.9%
Maximum Reading	60.6%
Minimum Reading	59.2%

Occupancy State at time of test: DYNAMIC

RESULTS OF RELATIVE HUMIDITY TEST

Buffer H.D. Room ISO 14644-1 Class 7 Environment	
Sample Location	Relative Humidity
9	52.3%
10	52.8%
11	52.6%
12	52.9%
Mean of The Average	52.7%
Maximum Reading	52.9%
Minimum Reading	52.3%

Occupancy State at time of test: DYNAMIC

RESULTS OF RELATIVE HUMIDITY TEST

H.D. Gown In Room	
ISO 14644-1 Class 7 Environment	
Sample Location	Relative Humidity
13	59.3%
14	59.3%
Mean of The Average	59.3%
Maximum Reading	59.3%
Minimum Reading	59.3%

Occupancy State at time of test: DYNAMIC

RESULTS OF RELATIVE HUMIDITY TEST

Double Interlock Pass Through #1 ISO 14644-1 Class 7 Environment	
Sample Location	Relative Humidity
15	58.0%
Mean of The Average	58.0%
Maximum Reading	58.0%
Minimum Reading	58.0%

Occupancy State at time of test: DYNAMIC

RESULTS OF RELATIVE HUMIDITY TEST

Double Interlock Pass Through #2	
ISO 14644-1: Class 7 Environment	
Sample Location	Relative Humidity
16	53.1%
Mean of The Average	53.1%
Maximum Reading	53.1%
Minimum Reading	53.1%

Occupancy State at time of test: DYNAMIC

RESULTS OF RELATIVE HUMIDITY TEST

Sterile Prep Room ISO 14644-1 Class 8 Environment	
Sample Location	Relative Humidity
17	59.8%
18	59.6%
19	59.2%
20	59.1%
Mean of The Average	59.4%
Maximum Reading	59.8%
Minimum Reading	59.1%

Occupancy State at time of test: DYNAMIC

RESULTS OF RELATIVE HUMIDITY TEST

H.D. Prep Room	
ISO 14644-1 Class 8 Environment	
Sample Location	Relative Humidity
21	57.3%
22	57.4%
23	57.8%
Mean of The Average	57.5%
Maximum Reading	57.8%
Minimum Reading	57.3%

Occupancy State at time of test: DYNAMIC

Summary of Relative Humidity Test Procedure

The purpose of this test is to document the room operating humidity and to demonstrate the capability of the air handling system to maintain the humidity. This test is also known as the General Moisture Uniformity Test.

The number of sample locations was determined by utilizing table A.1 which is located in ISO 14644-1:2015, a copy of which may be found in section 6 of this report.

In this case:

Buffer Room = minimum of 6 locations.
165.25" x 114.25" = 18,879.81in² ÷ 144 = 131.11ft² x 0.093 = 12.19m²
Minus: 20.00" x 14.25" = 285.00in² ÷ 144 = 1.98ft² x 0.093 = 0.18m².
Minus: 20.25" x 14.50" = 293.63in² ÷ 144 = 2.04ft² x 0.093 = 0.19m².
Equals: 11.82m² = **6** locations.

Ante Gown In Room = minimum of 2 locations.
52.00" x 95.25" = 4,953.00n² ÷ 144 = 34.40ft² x 0.093 = 3.20m²
Minus: 12.25" x 16.00" = 196.00in² ÷ 144 = 1.36ft² x 0.093 = 0.13m².
Equals: 3.07m² = **2** locations.

Buffer H.D. Room = minimum of 4 locations.
109.50" x 113.50" = 12,428.25in² ÷ 144 = 86.31ft² x 0.093 = 8.03m²
Minus: 48.25" x 13.50" = 651.38in² ÷ 144 = 4.52ft² x 0.093 = 0.42m².
Equals: 7.61m² = **4** locations.

H.D Gown In Room = minimum of 2 locations.
61.50" x 95.00" = 5,842.50in² ÷ 144 = 40.57ft² x 0.093 = 3.77m²
Minus: 11.00" x 18.00" = 198.00in² ÷ 144 = 1.38ft² x 0.093 = 0.13m².
Minus: 6.00" x 18.00" = 108.00in² ÷ 144 = 0.75ft² x 0.093 = 0.07m².
Equals: 3.57m² = **2** locations.

Sterile Prep Room = minimum of 4 locations.
111.50" x 95.00" = 10,592.50in² ÷ 144 = 73.56ft² x 0.093 = 6.84m²
Minus: 23.75" x 11.25" = 267.19in² ÷ 144 = 1.86ft² x 0.093 = 0.17m².
Equals: 6.67m² = **4** locations.

H.D. Prep Room = minimum of 3 locations.
92.00" x 95.00" = 8,740.00in² ÷ 144 = 60.69ft² x 0.093 = 5.64m²
Minus: 19.00" x 6.25" = 118.75in² ÷ 144 = 0.82ft² x 0.093 = 0.08m².
Minus: 22.00" x 11.75" = 258.50in² ÷ 144 = 1.80ft² x 0.093 = 0.17m².
Equals: 5.39m² = **3** locations.

The location of the samples taken was determined by dissecting the room into equal grids and sampling in the center of each grid, as illustrated in Section 4 of this report. Each humidity reading is averaged over the duration of sampling.

The first device used to measure humidity was a thermoanemometer manufactured by Alnor/TSI, Inc. the model AVM440-A serial #AVM441045003 which was last calibrated on July 17, 2024 and due for recalibration on July 16, 2025. The most recent calibration report is located in Section 6.

The second device used to measure humidity was a thermoanemometer manufactured by Alnor/TSI, Inc. the model AVM440-A serial #AVM442332003 which was last calibrated on February 17, 2025 and due for recalibration on February 16, 2026. The most recent calibration report is located in Section 6.

The acceptable relative humidity level is determined by the customer, but typical readings in a cleanroom should be between <60%.

This test is considered a secondary test and is performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-28 which is available upon request.

The above referenced testing procedure meets test methods outlined in the following documents:

IEST-RP-CC006.3	Testing Cleanroom
IEST-RP-CC013	Calibration Procedures and Guidelines for Select Equipment Used in Testing Cleanrooms and Other Controlled Environments
ISO 14644-1:2015	Classification of air cleanliness
ISO 14644-3:2019	Test Methods
USP <800>	Hazardous Drugs
USP <797>	Guidebook to Pharmaceutical Compounding-Sterile Preparations
64B16-27.797	The Standards of Practice for Compounding Sterile Products
CAG-003	CETA Certification Guide for Sterile Compounding Facilities
CAG-008	CETA Certification Matrix for Sterile Compounding Facilities

Section 3B

DEVICE TEST DATA

RESULTS OF NON-VIABLE PARTICLE COUNT TEST

Buffer Room				
Horizontal Laminar Airflow Clean Bench (Static)				
Purair Model #HLF-72-A (UV) Serial #HLF000645				
ISO 14644-1 Class 5 Environment				
Sample Location	Size Sampled 0.5 micron	Size Sampled 1.0 micron	Day/ Time	Pass/ Fail
Control	0	0	07/02/2025 10:10	Pass
1	0	0	07/02/2025 10:15	Pass
2	0	0	07/02/2025 10:17	Pass
3	0	0	07/02/2025 10:18	Pass
4	0	0	07/02/2025 10:20	Pass
5	0	0	07/02/2025 10:21	Pass
6	0	0	07/02/2025 10:23	Pass
Mean of the Average Ft.³	0	0		
Maximum Concentration Limit	3,520	832		
Mean of the Average m³	0	0	Total	
			0	Pass

Result of Particle Count Test: PASS

RESULTS OF NON-VIABLE PARTICLE COUNT TEST

Buffer Room				
Horizontal Laminar Airflow Clean Bench (Dynamic)				
Purair Model #HLF-72-A (UV) Serial #HLF000645				
ISO 14644-1 Class 5 Environment				
Sample Location	Size Sampled 0.5 micron	Size Sampled 1.0 micron	Day/ Time	Pass/ Fail
Control	0	0	07/02/2025 10:10	Pass
1	0	0	07/02/2025 10:24	Pass
Mean of the Average Ft.³	0	0		
Maximum Concentration Limit	3,520	832		
Mean of the Average m³	0	0	Total	
			0	Pass

Result of Particle Count Test: PASS

Summary of Laminar Flow Clean Bench Particle Count Test Procedure

The purpose of this test is to demonstrate compliance of the laminar flow clean bench clean air device tested to the requirements specified in the International Organization for Standardization document ISO 14644-1:2015.

USP <797> requires all biological safety cabinets, laminar flow clean benches and isolators used for compounding to be an ISO Class 5 environment. This test is also referred to as a Particle Count Survey or an Airborne Particle Count.

In the case of horizontal laminar airflow clean benches, the number of sample locations is 6. One sample at each side of the work surface, six inches from the sidewall, and four more samples taken down the center of the work surface equally separated to represent the entire work zone. This number far exceeds the minimum number required by using the formula referenced in ISO 14644-1:2015.

USP <797> requires that non-viable particle counts be sampled within all PECs under dynamic operating conditions. In this case, the number of sample locations was 1. This sample is taken within close proximity to the direct compounding area.

The amount of air sampled at each location was 1.0 cubic foot, or 28.3 cubic liters, which exceeds the minimum volume required at each sample location determined by the following equation:

$$V_s = \frac{20}{C_{n,m}} \times 1{,}000$$

Where: V_S is the minimum single sample per location expressed in liters.

$C_{n,m}$ is the class limit (number of particles per cubic meter) for the largest considered particle size specified.

20 The defined number of particles that could be counted if the particle concentration were at the class limit.

For ISO Class 5: Vs = 24.04 liters
[20 ÷ 832 x 1,000 = 24.04]

The particle counter sampled at a rate of 1.0 cfm through an isokinetic probe which was oriented horizontal toward the face of the HEPA filter and held in a stand located at a height of 6 inches above the work surface and attached to the counter by HYTREL PVC tubing which does not exceed 10 feet in length. Each location was sampled for a period of one minute and the readings were then normalized to represent a cubic foot and a cubic meter.

The equipment used is a discrete-particle counter (DPC) manufactured by Particle Measuring Systems, lnc. the model Lasair III_310C serial #171352 which was last calibrated on July 08, 2024 and due for recalibration on July 07, 2025. The most recent calibration report is located in Section 6.

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-48 which is available upon request.

The above referenced testing procedure meets test methods outlined in the following documents:

IEST-G-CCI001	Counting Airborne Particles for Classification and Monitoring of Cleanrooms and Clean Zones
IEST-RP-CC002.4	Unidirectional-Flow, Clean Air Devices
IEST-RP-CC013	Calibration Procedures and Guidelines for Select Equipment Used in Testing Cleanrooms and Other Controlled Environments
ISO 14644-1:2015	Classification of air cleanliness
ISO 14644-2:2015	Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
ISO 14644-3:2019	Test Methods
USP <797>	Guidebook to Pharmaceutical Compounding-Sterile Preparations
64B16-27.797	The Standards of Practice for Compounding Sterile Products
CAG-003	CETA Certification Guide for Sterile Compounding Facilities
CAG-008	CETA Certification Matrix for Sterile Compounding Facilities

Summary of Laminar Flow Clean Bench Certification Procedure

The purpose of this sequence of tests is to demonstrate compliance of the Laminar Flow Clean Bench(s) to the requirements set forth by the manufacturer of the cabinet. Additionally, USP <797> requires all biological safety cabinets, laminar flow clean benches and isolators used for compounding to be an ISO Class 5 environment.

There are a number of tests performed to comply with these requirements. In addition to the non-viable particle count test, these are:

1. Supply Velocity Profile Test

The velocity of the air moving outward through the work area is measured in a plane 6 inches from the face of the HEPA filter. This plane is divided into a grid and the downflow is measured using a thermoanemometer held in place by a ring stand. The individual readings are recorded on a numbered report; the readings are averaged and compared to the acceptable range listed by the manufacturer, but is generally between 80 fpm and 100 fpm.

The device used to measure airflow velocity was a thermoanemometer manufactured by Alnor/TSI, Inc. the model AVM440-A serial #AVM442332003 which was last calibrated on February 17, 2025 and due for recalibration on February 16, 2026. The most recent calibration report is located in Section 6.

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-1 which is available upon request.

2. HEPA Filter Leak Test

This test is performed by generating a challenge aerosol at the intake of the cabinet. This aerosol is provided as a challenge to the HEPA filter within the cabinet. The HEPA filter is then tested for leaks by scanning the face of the filter, the seal and the frame for penetrations using an aerosol photometer. Minor leaks may be repaired. Any by-pass not corrected will result in failure.

The challenge liquid used was Poly Alpha Olefin (PAO). The challenge aerosol was generated by multiple Laskin nozzles supplied by a compressor(s) providing 100 liters per minute at 20 psi per nozzle.

The aerosol photometer used was a calibrated linear photometer manufactured by TEC Services, Inc. the model PH-4 serial #1944 last calibrated on February 11, 2025 and due for recalibration on February 10, 2026. The most recent calibration report is located in Section 6. The photometer probe is an isokinetic probe.

An upstream challenge could not be measured because of inaccessibility. Therefore, an internal calibration of the aerosol photometer was utilized using the following formula:

$$C_2 = NC_1 \quad \frac{Q_1}{Q_2}$$

Where: C_2 is the full scale photometer setting based upon manufacturers calibration data.
N is the number of Laskin nozzles used.
C_1 µg/L per nozzle when discharged into a flow rate of Q_1 (38 m^3/min).
Q_1 38 m^3/min
Q_2 Volume of air measured in m^3/min

In this case*:
*The values shown here for Q_2 and C_2 for each calculation are rounded for brevity.

HLF-72-A (UA) (S# HLF000645)
Full scale reading represents 28µg/L
(2) x (10) x 38 ÷ 27.25 = 27.89

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-9 which is available upon request.

3. Visual Smoke Pattern Test

This test is designed to give a visual confirmation of the air direction, and airflow patterns. It is considered acceptable when the smoke exhibits a smooth unidirectional laminar flow of air, with no dead spots or reflux.

This test is designed to give a visual confirmation of airflow patterns. There are two separate and distinct tests. Induction Leak/Backstreaming Test and Airflow Smoke Pattern Test. The overall result is considered to be acceptable only if each individual test is acceptable.

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-7 which is available upon request.

4. Illumination and Sound Tests

These tests are related to worker comfort and do not require a Pass/Fail.

They are considered secondary tests. More specific testing criteria are documented in MEDREP-Proc-4 and MEDREP-Proc-6 which are available upon request.

Summary of Containment Ventilated Enclosure Certification Procedure

The purpose of this sequence of tests is to demonstrate safe, consistent operation of the ventilated enclosure . That the device is capable of capturing, containing and carrying away fumes generated in the work area.

There are a number of tests performed to confirm safe operation, these are:

1. Face Velocity

With the sash placed at the sash stop, (at 7.25") the face of the ventilated enclosure opening is divided into a grid pattern that is 12" square. A single velocity reading is taken in the center of each square foot along the vertical plane of the front opening. The individual readings are recorded and averaged. The most widely requested target average face velocity is 100 fpm. This test is also known as the Inflow velocity or face velocity grid test.

The device used to measure airflow velocity was a thermoanemometer manufactured by Alnor/TSI, Inc. the model AVM440-A serial #AVM442332003 which was last calibrated on February 17, 2025 and due for recalibration on February 16, 2026. The most recent calibration report is located in Section 6.

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-1 which is available upon request.

2. HEPA Filter Leak Tests

This test is performed by generating a challenge aerosol within the work area of the device. This aerosol is provided as a challenge to the exhaust HEPA filter. The HEPA filter is then tested for leaks by scanning the face of the filter, the seal and the frame for penetrations using an aerosol photometer. Minor leaks may be repaired. Any by-pass not corrected will result in failure.

The challenge liquid used was Poly Alpha Olefin (PAO). The challenge aerosol was generated by multiple Laskin nozzles supplied by a compressor(s) providing 100 liters per minute at 20 psi per nozzle.

The aerosol photometer used was a calibrated linear photometer manufactured by TEC Services, Inc. the model PH-4 serial #1944 last calibrated on February 11, 2025 and due for recalibration on February 10, 2026. The most recent calibration report is located in Section 6. The photometer probe is an isokinetic probe.

An upstream challenge could not be measured because of inaccessibility. Therefore, an internal calibration of the aerosol photometer was utilized using the following formula:

$$C_2 = NC_1 \quad \frac{Q_1}{Q_2}$$

Where: C_2 is the full scale photometer setting based upon manufacturers calibration data.
N is the number of Laskin nozzles used.
C_1 µg/L per nozzle when discharged into a flow rate of Q_1 (38 m^3/min).
Q_1 38 m^3/min
Q_2 Volume of air measured in m^3/min

In this case*:
*The values shown here for Q_2 and C_2 for each calculation are rounded for brevity.

P5-48-HEAD-A (S# PB003500)
Full scale reading represents 139µg/L
(2) x (10) x 38 ÷ 5.46 = 139.07

P5-48-HEAD-A (S# PB003503)
Full scale reading represents 130µg/L
(2) x (10) x 38 ÷ 5.86 = 129.66

P5-48-HEAD-A (S# PB003501)
Full scale reading represents 179ug/L
(2) x (10) x 38 ÷ 4.25 = 178.93

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-9 which is available upon request.

3. Smoke Visualization

This test is designed to give a visualization of the hood's ability to contain vapors. Using an ampule containing titanium tetrachloride, four distinct air patterns are evaluated.

1. The operation of the bottom air foil is tested by running the ampule under the air foil from one side to the other.
2. Smoke shall be discharged from the ampule along both walls and the floor of the hood in a line parallel to the hood face and 6 inches behind the face and along the top of the face opening
3. A stream of smoke is discharged from the ampule in an 8 inch diameter circle on the back of the ventilated enclosure. Air movement toward the front shall be defined as reverse flow and the lack of air movement shall be defined as dead air space.
4. Smoke shall be generated by the ampule at the work surface and along all equipment in the hood. All smoke shall be carried to the back of the hood and exhausted out.

If there is any visible smoke flow out of the front of the ventilated enclosure, the hood fails the test. This test is also known as the Flow Visualization test and the Local Visualization Challenge.

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-44 which is available upon request.

4. Illumination and Sound Tests

These tests are related to worker comfort and do not require a Pass/Fail.

They are considered secondary tests. More specific testing criteria are documented in MEDREP-Proc-4 and MEDREP-Proc-6 which are available upon request.

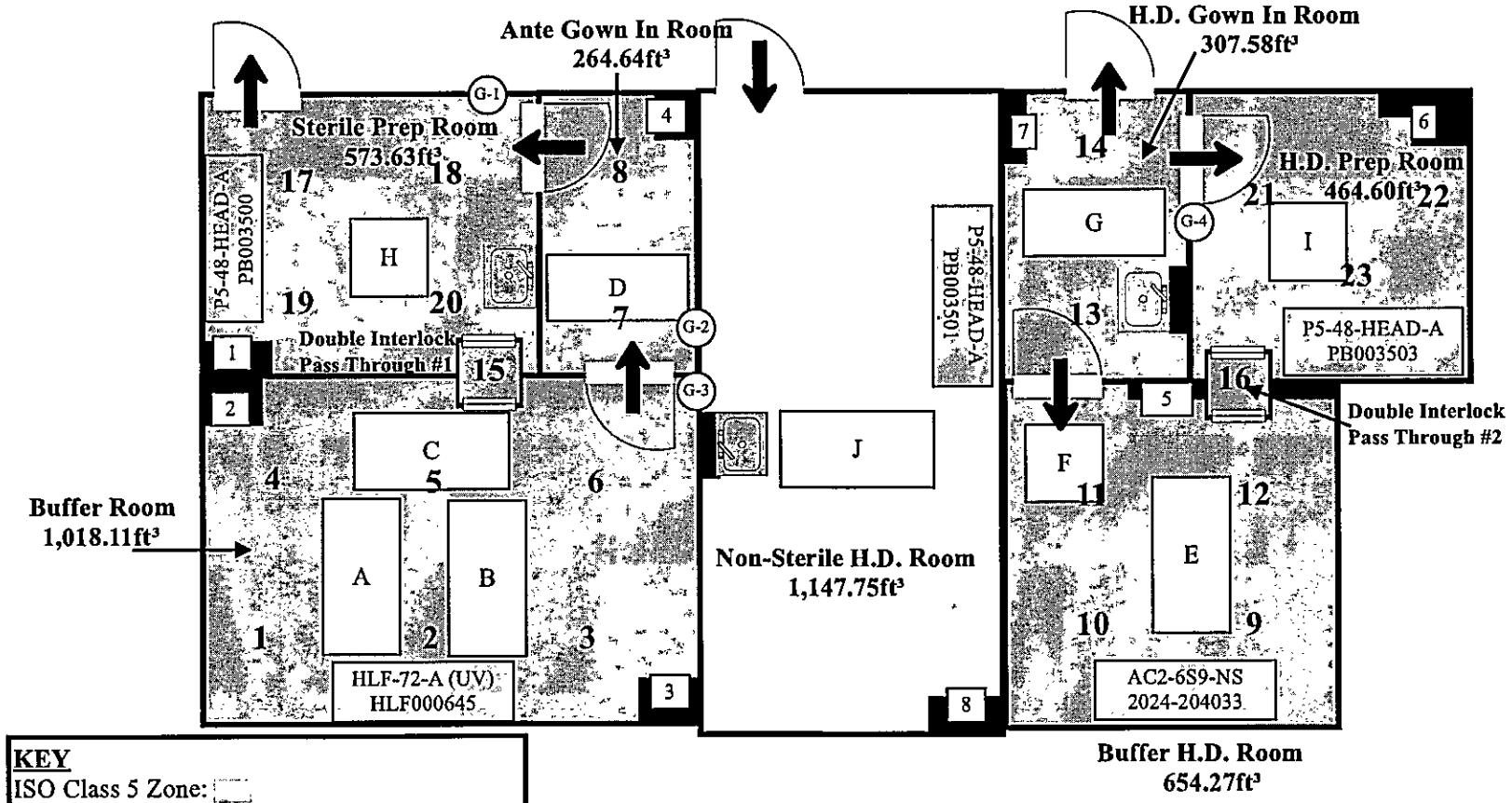
Section 4

SAMPLE LOCATIONS

St. Luke Compounding Pharmacy

New Port Richey, Florida

Pharmacy ISO Class 7 Facility



KEY

ISO Class 5 Zone:

ISO Class 7 Zone:

ISO Class 8 Zone:

Particle Count Locations: **1-23**

Differential Pressure Directions: ←↑↓→

Supply HEPA Filters: A through J

Return Registers 1 through 8

Gages: G-1 through G-4

This drawing is not to scale and is to be used for the purposes of comparison only.

MEDREP TECHNOLOGIES, INC. 12/2024

Section 5

SERVICE REPORTS

MEDREP TECHNOLOGIES, INC

Post Office Box 494273
Port Charlotte, Florida 33949-4273
Phone: 941-627-8858 Fax: 941-629-9698 Web: www.medrep.us

St Luke Pharmacy

Customer Pharmacy Location Pharmacy Date 7/2/25

FACILITY TEST REPORT

APPLICABLE	TEST	REFERENCE
Yes__No✓	Smoke Pattern	MEDREP-Proc-7
Yes__No✓	HVAC System HEPA Leak Test	MEDREP-Proc-11
Yes__No✓	Biological Decontamination	MEDREP-Proc-14
Yes✓No__	Air Exchange Rate	MEDREP-Proc-18
Yes✓No__	Non-Viable Particle Counts	MEDREP-Proc-21
Yes__No✓	HEPA Filter Velocity	MEDREP-Proc-23
Yes✓No__	HEPA Filter Volume	MEDREP-Proc-23
Yes✓No__	Segregation Pressure	MEDREP-Proc-24
Yes✓No__	Terminal HEPA Leak Test	MEDREP-Proc-25
Yes✓No__	Temperature/Uniformity	MEDREP-Proc-27
Yes✓No__	Relative Humidity/Uniformity	MEDREP-Proc-28
Yes__No✓	Sound Level/Pressure	MEDREP-Proc-29
Yes__No✓	Vibration	MEDREP-Proc-30
Yes__No✓	Lighting	MEDREP-Proc-31
Yes__No✓	Recovery Test	MEDREP-Proc-34
Yes__No✓	Facility Pressurization Test	MEDREP-Proc-42
Yes__No✓	Viable Particle Counts	MEDREP-Proc-46
Yes✓No__	Check/Adjust Gages	MEDREP-Proc-61
Yes__No✓	Isolation/Reverse-Isolation Room	MEDREP-Proc-62
Yes__No✓	Displacement Airflow	MEDREP-Proc-67
Yes__No✓	Smoke Study	MEDREP-Proc-78

Facility: ____Containment Facility ✓ Clean Room Environment Other____

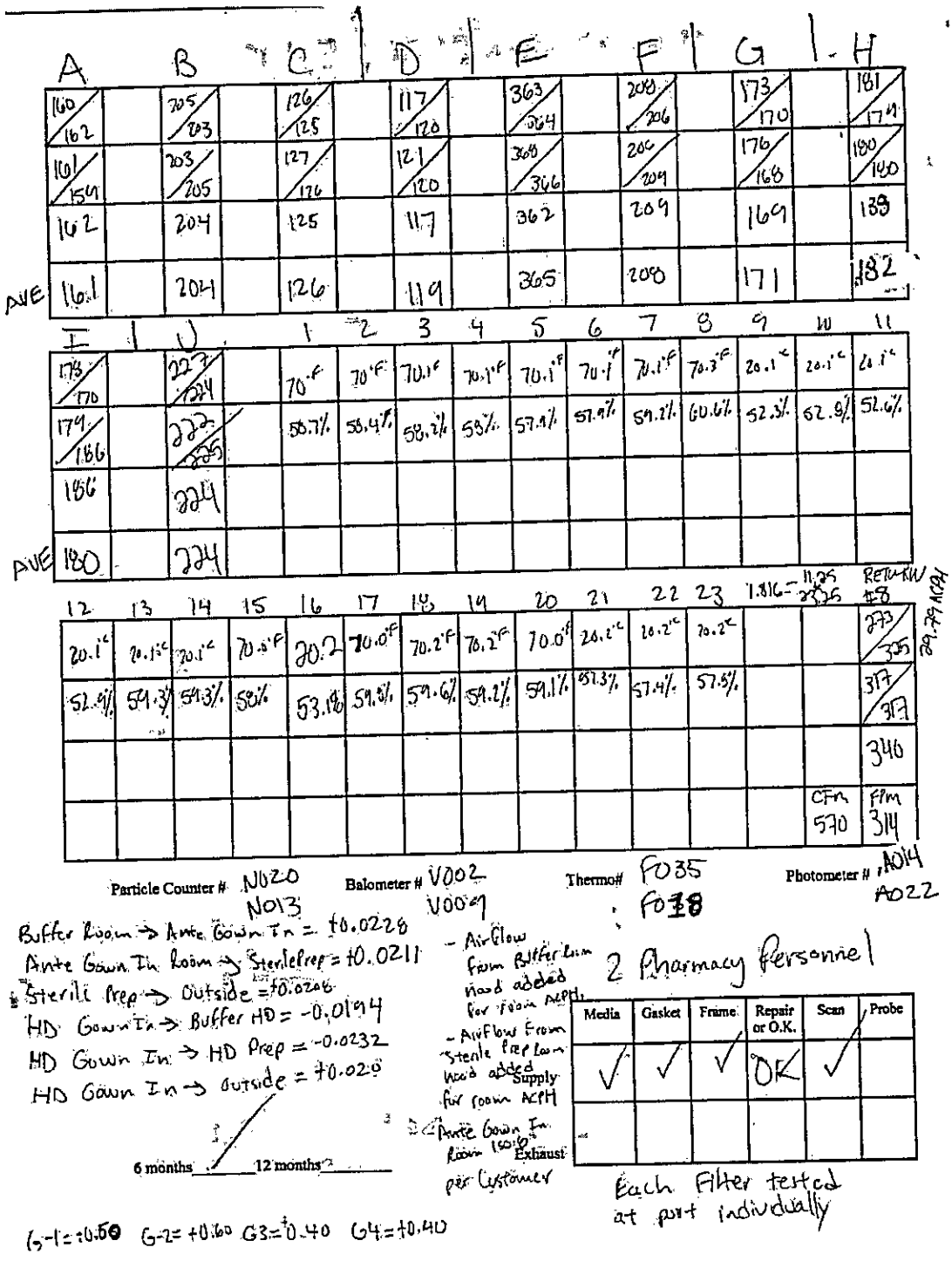
TEST CONDITION: ____As-Built ____At-Rest ✓ Operational

TEST RESULTS UNDER SEPARATE COVER

Test Performed by: Work Accepted By:

Protocols available upon request

Eric Jones 2427 001


A B C D E F G H
160/162 205/203 126/125 117/120 363/364 208/206 173/170 181/174
161/159 203/205 127/126 121/120 360/366 206/209 176/168 180/180
162 204 125 117 362 209 169 139
AVE 161 204 126 119 365 208 171 182
I J 1 2 3 4 5 6 7 8 9 10 11
178/170 227/224 70°F 70°F 70.1°F 70.1°F 70.1°F 70.1°F 70.1°F 70.3°F 20.1°C 20.1°C 20.1°C
179/166 222/225 56.7% 58.4% 58.2% 58% 57.9% 57.9% 59.2% 60.6% 52.3% 62.9% 52.6%
186 224
AVE 180 224
12 13 14 15 16 17 18 19 20 21 22 23
20.1°C 20.1°C 20.1°C 70.3°F 20.2 70.0°F 70.2°F 70.2°F 70.0°F 20.2°C 20.2°C 20.2°C
52.9% 59.3% 59.3% 58% 53.1% 59.5% 59.6% 59.2% 59.1% 57.3% 57.4% 57.5%
1.816 - 11.25 = 3355
RETURN #8
273/305
317/317
346
CFm 570
Fm 314
Particle Counter # N020 N013
Balometer # V002 V004
Thermo# F035 F038
Photometer # A014 A022
Buffer Room → Ante Gown In = +0.0228
Ante Gown In Room → Sterileprep = +0.0211
Sterili Prep → Outside = +0.0206
HD Gown In → Buffer HD = -0.0194
HD Gown In → HD Prep = -0.0232
HD Gown In → Outside = +0.0209
6 months 12 months
- Airflow from Buffer Room need added for room ACPH.
- Airflow from Sterile Prep Room need added Supply for room ACPH
Ante Gown In Room 150% Exhaust per Customer
2 Pharmacy Personnel
Media Gasket Frame Repair or O.K. Scan Probe
✓ ✓ ✓ OK ✓
Each Filter tested at port individually
G-1 = +0.50 G-2 = +0.60 G3 = +0.40 G4 = +0.40

MEDREP TECHNOLOGIES, INC

Post Office Box 494273
Port Charlotte, Florida 33949-4273
Phone: 941-627-8858 Fax: 941-629-9698 Web: www.medrep.us

Customer ST LUKE'S Location [illegible] Date 3/7th/2015
PHASE-WALL

FACILITY TEST REPORT

APPLICABLE		TEST	REFERENCE
Yes__No_/		Smoke Pattern	MEDREP-Proc-7
Yes__No_/	MEDREP RECOMMENDS	HVAC System HEPA Leak Test	MEDREP-Proc-11
Yes__No_/		Biological Decontamination	MEDREP-Proc-14
Yes_/No__	A GAUGE FOR SET	Air Exchange Rate	MEDREP-Proc-18
Yes__No_/	PRESSURE AT DOOR	Non-Viable Particle Counts	MEDREP-Proc-21
Yes__No_/		HEPA Filter Velocity	MEOREP-Proc-23
Yes__No_/		HEPA Filter Volume	MEDREP-Proc-23
Yes_/No__		Segregation Pressure	MEDREP-Proc-24
Yes__No_/		Terminal HEPA Leak Test	MEDREP-Proc-25
Yes__No_/		Temperature/Uniformity	MEDREP-Proc-27
Yes__No_/		Relative Humidity/Uniformity	MEDREP-Proc-28
Yes__No_/		Sound Level/Pressure	MEDREP-Proc-29
Yes__No_/		Vibration	MEDREP-Proc-30
Yes__No_/		Lighting	MEDREP-Proc-31
Yes__No_/		Recovery Test	MEDREP-Proc-34
Yes__No_/		Facility Pressurization Test	MEDREP-Proc-42
Yes__No_/		Viable Particle Counts	MEDREP-Proc-46
Yes__No__		Check/Adjust Gages	MEDREP-Proc-61
Yes__No_/		Isolation/Reverse-Isolation Room	MEOREP-Proc-62
Yes__No_/		Displacement Airflow	MEDREP-Proc-67
Yes__No_/		Smoke Study	MEDREP-Proc-78

Facility: _/_ Containment Facility _____ Clean Room Environment Other_____

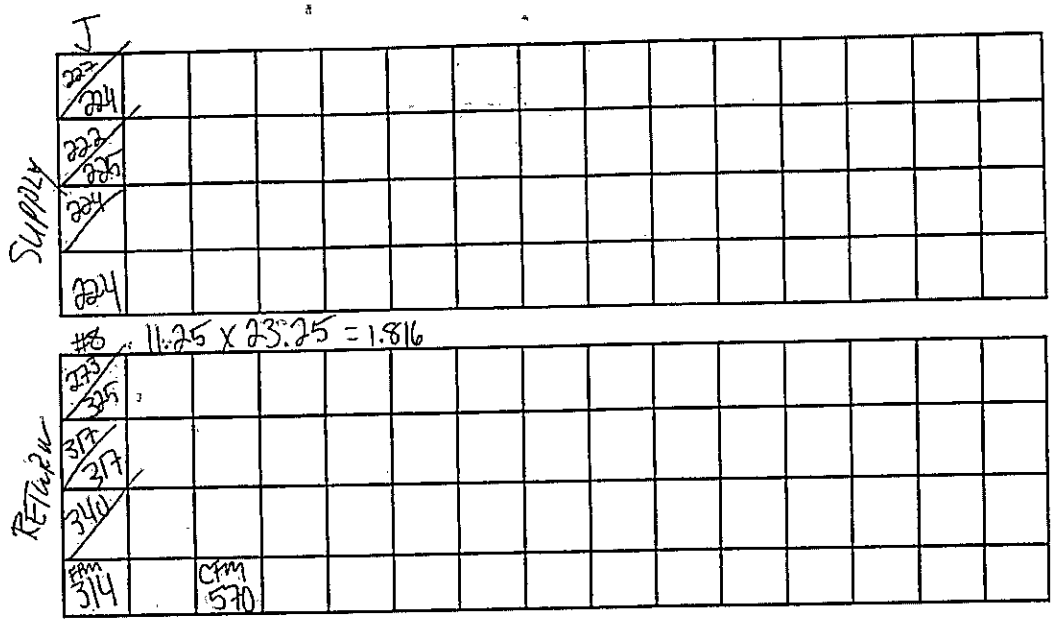
TEST CONDITION: _____ As-Built _____ At-Rest _/_ Operational

TEST RESULTS UNDER SEPARATE COVER

Test Performed by: [signature]

Work Accepted By: [signature]

Protocols available upon request



Particle Counter # — Balometer # 9 Thermo# 18 Photometer #

MM	FROM	TO	GAUGE
0.0243	~~NS-HD ROOM~~ OUTSIDE	NS-HD ROOM	MA

	Media	Gasket	Frame	Repair or O.K.	Scan	Probe
Supply	—	—	—	—	—	—
Exhaust	—	—	—	—	—	—

6 months ___ 12 months ___

MEDREP TECHNOLOGIES, INC

Report 109459

Post Office Box 494273
Port Charlotte, Florida 33949-4273
Phone: 941-627-8858 Fax: 941-629-9698 Web: www.medrep.us

Customer ST LUKE'S [illegible] Location HZ BUFFER ROOM Phone _____

Model # NC2 6A8-4S-G18" Ser # 3001-2011033 Cust # _____ Date 2/11/2025

BSC TEST REPORT

APPLICABLE	TEST	REFERENCE	RESULTS	ACCEPTABLE
Yes / No	Airflow: Supply Velocity	MEDREP-Proc-1	111 fpm	Yes / No
Yes / No	Airflow: Intake Velocity	MEDREP-Proc-1	____ fpm	Yes / No
Yes / No	Check/Adjust Gage	MEDREP-Proc-1	____"wg	Yes / No
Yes / No	Duct Status	MEDREP-Proc-2	____"wg	Yes / No
Yes / No	Illumination Level Test	MEDREP-Proc-4	____ fc	Yes / No
Yes / No	UV Output Test	MEDREP-Proc-5	____ µw/cm²	Yes / No
Yes / No	Sound Level Test	MEDREP-Proc-6	____ dB A	Yes / No
Yes / No	Smoke Pattern	MEDREP-Proc-7		Yes / No
Yes / No	Check Leveling	MEDREP-Proc-8		Yes / No
Yes / No	Leak Test: Supply HEPA	MEDREP-Proc-9	____ %	Yes / No
Yes / No	Leak Test: Exhaust HEPA	MEDREP-Proc-9	____ %	Yes / No
Yes / No	Class I / Class III Requirements	MEDREP-Proc-10		Yes / No
Yes / No	Electrical Safety Test	MEDREP-Proc-15		Yes / No
Yes / No	Smoke Study	MEDREP-Proc-79		Yes / No
Yes / No	Biological Decontamination	MEDREP-Proc-17		Yes / No
Yes / No	Site Assessment	MEDREP-Proc-39		Yes / No
Yes / No	Check Alarm(s)	MEDREP-Proc-40		Yes / No
Yes / No	Viable Counts	MEDREP-Proc-47		results to follow
Yes / No	Non-Viable Counts	MEDREP-Proc-48		results to follow

MEDREP FOUND UNIT WITH LOW AIR FLOW/DOWN FLOW. MEDREP RECOMMENT TO ADJ BLOWER MOTOR FOR PROPER AIR FLOW BALANCE BUT UNIT NEED A G4 UPGRADE. MAY STILL BE IN WARRANTY.

/ Unit Certified
___ Months
___ Unit NOT Certified

Unit Type: ___ Class I ___ Class II Type B1
___ Class II Type A1 ___ Class II Type B2
/ Class II Type A2 ___ Class III

TEST CRITERIA: _____ NSF 49 _____ ISO 14644 _____ Manufacturer _____ USP <797> _____ Other

G4 UPGRADE WILL SOLVE CFM ISSUE

Tests Performed By: [signature] Work Accepted By: [signature]

All Protocols available upon request

I.D #: 2022-0006

SUPPLY AIRFLOW

Acceptable Range: 55-65

40	40	36	36	36	35	35	37	36	37	38				
40	40	39	40	43	41	42	41	44	44	44				
42	43	43	46	48	45	50	47	46	47	46				

Gage/Max Ave: NA

Nominal Ave: 41 fpm

Highest Reading: 50 fpm

Lowest Reading: 35 fpm

DECONTAMINATION:

Paraformaldehyde ___ gms. @ ___ hrs.

Ammonium Carbonate ___ gms

Temperature ___ °f-Humidity ___ %

Counter 13 Thermo # 18 Photometer # 22

Supply HEPA 16 X 72

Exhaust HEPA ___

Pre-filter ___

EXHAUST AIRFLOW

Ave: ___ fpm Calculated Inflow: ___ fpm Measured Inflow: ___ fpm

Exhaust Volume: ___ cfm Acceptable Range: ___ fpm

Duct: ___ "wg Thimble Status: ___ Room Pressure: ___ "wg

Exhaust Opening: ___ Front Opening: ___

DIM: ___

UV OUTPUT

Old Lamp						
New Lamp						
Ave.			Ave.			

HEPA LEAK TEST

	Media	Gasket	Frame	Repair/ O.K	Scan	Probe
Supl.						
Exh.						

MOTOR SETTING

Incr.	Norm.	Decr.

ELECTRICAL LEAKAGE

	Norm.	Rev.
On	µa	µa
Off	µa	µa

Ground Circuit Resistance ___ Ω

ILLUMINATION

On								
Off								

VIBRATION

SOUND

On	Off	Next

Could not increase air flow. Error code popped up.

MEDREP TECHNOLOGIES, INC

Post Office Box 494273
Port Charlotte, Florida 33949-4273
Phone: 941-627-8858 Fax: 941-629-9698 Web: www.medrep.us

at Lake Compounding . Non Haz

Customer Sarasota Location Buffer Room Phone ——

Model # HLF-72-A (UV) Ser # HLFJ30645 Cust # —— Date 7/2/25

CLEAN-AIR DEVICE TEST REPORT

APPLICABLE	TEST	REFERENCE	RESULTS	ACCEPTABLE
Yes ✓ No	Airflow: Supply Velocity	MEDREP-Proc-3	911 fpm	Yes ✓ No
Yes ✓ No	Illumination Level Test	MEDREP-Proc-4	119 fc	Yes No
Yes ✓ No	Sound Level Test	MEDREP-Proc-6	75 dbA	Yes ✓ No
Yes ✓ No	Check Leveling	MEDREP-Proc-8		Yes No
Yes ✓ No	Leak Test: Supply HEPA	MEDREP-Proc-12	<0.01 %	Yes No
Yes No ✓	Electrical Safety Test	MEDREP-Proc-15		Yes No
Yes ✓ No	Site Assessment	MEDREP-Proc-39		Yes ✓ No
Yes No ✓	Air Visualization Study	MEDREP-Proc-45		results to follow
Yes No ✓	Viable Particle Counts	MEDREP-Proc-47		results to follow
Yes ✓ No	Check/Adjust Gage	MEDREP-Proc-61	0.025 wg	Yes No
Yes ✓ No	Non-Viable Counts	MEDREP-Proc-48		results to follow
Yes ✓ No	Static			
Yes ✓ No	Dynamic			

✓ Unit Certified 10 Months Unit Type: ✓ Clean Bench Housing Other

Unit NOT Certified

TEST CRITERIA: ✓ ISO 14644 ✓ Manufacturer ✓ USP <797> Other

Tests Performed By: Work Accepted By:

Protocols available upon request Ernst Wyss I.D.# 7922 05

SUPPLY AIRFLOW

Acceptable Range: 80-100

97	90	84	104	114	102	81	123	109	95	112				
97	96	80	105	74	69	60	76	65	84	89				
94	70	85	89	97	83	98	86	85	84	96				

Gage/Max Ave: 0.625

Nominal Ave: 90 fpm

Highest Reading: 123 fpm

Lowest Reading: 60 fpm

DECONTAMINATION:

Paraformaldehyde ___ gms. @ ___ hrs.

Ammonium Carbonate ___ gms

Temperature ___ °F Humidity ___ %

Counter: 1620 Thermo.#: F035 Photometer #: A014

Supply HEPA: 24x72

Pre-filter: ___

HEPA LEAK TEST

	Media	Gasket	Frame	Repair/ D.P.	Scan	Probe
Supl.	✓	✓	✓	✓	✓	

27%

MOTOR SETTING

Incr.	Norm.	Decr.

ELECTRICAL LEAKAGE

	Norm.	Rev.
On	µa	µa
Off	µa	µa

Ground Circuit Resistance ___ Ω

ILLUMINATION

On	99	125	156	135	110			119
Off	42	27	26	27	22			

SOUND

On	Off	Next
75	66	75

Medrep Technologies

Post Office Box 494273
Port Charlotte, Florida 33949
www.medrep.us
941-627-8858v
941-979-8089f

FUME HOOD TEST REPORT

CUSTOMER St Luke's Compounding LOCATION Non Haz Room Prairie

MANUFACTURER A Science MODEL 5FT TEAD-A SERIAL 2B003500 DATE 7/2/25

APPLICABLE	TEST	REFERENCE	RESULT	Acceptable
YES__NO✓	Airflow: Face Velocity – Full Open	MEDREP-Proc-13	N/A fpm	YES✓NO__
YES✓NO__	Airflow: Face Volume -Operating Height	MEDREP-Proc-13	102 cfm	YES✓NO__
YES__NO✓	Airflow: Auxiliary Airflow Volume	MEDREP-Proc-13	____ cfm	YES__NO__
YES__NO✓	Check/Adjust Gage	MEDREP-Proc-1	____ "wg	YES__NO__
YES✓NO__	Illumination Level	MEDREP-Proc-4	79 fc	YES✓NO__
YES✓NO__	Sound Level	MEDREP-Proc-6	72 dbA	YES__NO__
YES✓NO__	Airflow Pattern Test	MEDREP-Proc-7		YES__NO__
YES__NO✓	Variable Air Volume Control	MEDREP-Proc-13		YES__NO__
YES✓NO__	Penetration Leak Test - Exhaust	MEDREP-Proc-11	0.005 %	YES✓NO__
YES✓NO__	Site Assesement	MEDREP-Proc-39		YES__NO__
YES__NO✓	Check Monitor	MEDREP-Proc-40	____ fpm	YES__NO__

TESTING CRITERIA:

✓ OSHA (60-110 fpm) ___ NIOSH (100-150 fpm)

✓ ANSI (80-120 fpm) ___ NRC (100+ fpm)

✓ SEFA (75-125 fpm)

___ In-House

NOTES:

DEVICE: Passed: ✓ Failed: ___

Retest Due 1/31/26

Device Type:			
___ Vertical Sash	___ Horizontal Sash	___ Combination Sash	___ Radioisotope
___ Perchloric	___ Floor Mounted	___ Auxiliary Air	___ Bypass
___ Distillation	___ Demonstration	✓ Ductless	___ Canopy
___ Slots	___ Grossing Table	___ Powder	___ Snorkel

Tested by: _____ signature
Frank Vargas print.

Accepted by: _____ signature
Barbara Mc. Br print

PROCEDURES AVAILABLE UPON REQUEST

DEVICE ID: 2022102

FACE VELOCITY READINGS

1/4" x 44 1/2"	92	88	81	93	90	93										

Indicate in left column if maximum sash height, nominal sash height, 50% sash height, 25% sash height, horizontal or vertical readings, etc.

Draw lines to indicate boundaries.

Monitor: —

Average at max. opening: — fpm

Average at nominal opening: 86 fpm

Max. nominal reading: 93 fpm

Min. nominal reading: 90 fpm

Auxiliary air volume: — cfm @ % —

Average at 50% sash opening: — fpm @ — inches

Average at 25% sash opening: — fpm @ — inches

Sash height at full opening: 7 1/4 inches

Sash height at nominal opening: 44 1/2 inches 7 1/4

Width of opening: 44 1/2 inches

Areas of opening: 2.24 sq ft

ILLUMINATION LEVEL TEST average 29 fc

on	23	36	30				
off	7	8	10				—

HEPA LEAK TEST

	media	gasket	frame	ok	Max %	scan	probe	nozzles
exhaust	/	✓	✓	ok	0		/	1

Thermo: F035 Photometer: A014

SOUND LEVEL TEST result 72 dbA

on	off	net
73	70	72

Notes:

Medrep Technologies
Post Office Box 494273
Port Charlotte, Florida 33949
www.medrep.us
941-627-8858v
941-979-8089f

FUME HOOD TEST REPORT

CUSTOMER [illegible] LOCATION H7 Rm [illegible]

MANUFACTURER ATR SYSTEMS MODEL PRIMEFLEX-II SERIAL PR0125A3 DATE 2/[illegible]

APPLICABLE	TEST	REFERENCE	RESULT	Acceptable
YES / NO	Airflow: Face Velocity – Full Open	MEDREP-Proc-13	95 fpm	YES / NO
YES / NO	Airflow: Face Volume -Operating Height	MEDREP-Proc-13	202 cfm	YES / NO
YES NO /	Airflow: Auxiliary Airflow Volume	MEDREP-Proc-13	_____ cfm	YES NO
YES NO /	Check/Adjust Gage	MEDREP-Proc-1	_____ "wg	YES NO
YES / NO	Illumination Level	MEDREP-Proc-4	60 fc	YES / NO
YES / NO	Sound Level	MEDREP-Proc-6	66 dbA	YES / NO
YES / NO	Airflow Pattern Test	MEDREP-Proc-7		YES / NO
YES NO /	Variable Air Volume Control	MEDREP-Proc-13		YES NO
YES / NO	Penetration Leak Test - Exhaust	MEDREP-Proc-11	[illegible] %	YES / NO
YES / NO	Site Assessment	MEDREP-Proc-39		YES / NO
YES NO /	Check Monitor	MEDREP-Proc-40	_____ fpm	YES NO

TESTING CRITERIA:

/ OSHA (60-110 fpm)
/ ANSI (80-120 fpm)
/ SEFA (75-125 fpm)
/ In-House
___ NIOSH (100-150 fpm)
___ NRC (100+ fpm)

NOTES:

DEVICE: Passed / Failed ___

Retest Due 3/[illegible]/2026

Device Type:				
	___ Vertical Sash	___ Horizontal Sash	___ Combination Sash	___ Radioisotope
	___ Perchloric	___ Floor Mounted	___ Auxiliary Air	___ Bypass
	___ Distillation	___ Demonstration	___ Ductless	___ Canopy
	___ Slots	___ Grossing Table	/ Powder	___ Snorkel

Tested by: [illegible] signature
[illegible] print

Accepted by: [illegible] signature
[illegible] print

PROCEDURES AVAILABLE UPON REQUEST

DEVICE ID 3929.083

FACE VELOCITY READINGS

7.25X44.5	84	80	90	86												

Indicate in left column if maximum sash height, nominal sash height, 50% sash height, 25% sash height, horizontal or vertical readings, etc.

Draw lines to indicate boundaries.

Monitor: —

Average at max. opening: — fpm

Average at nominal opening: 85 fpm

Max. nominal reading: 90 fpm

Min. nominal reading: 80 fpm

~~Auxiliary air~~ volume: 207 cfm @ % —

Average at 50% sash opening: — fpm @ — inches

Average at 25% sash opening: — fpm @ — inches

Sash height at full opening: — inches

Sash height at nominal opening: 7.25 inches

Width of opening: 44.5 inches

Area of opening: 2.44 sq ft

ILLUMINATION LEVEL TEST average 60 fc

on	54	58	67	62			60
off	13	17	19	23			

HEPA LEAK TEST

	media	gasket	frame	ok	Max %	scan	probe	nozzles
exhaust	✓	✓	✓	OK			✓	✓

Thermo: 18 Photometer: 22

SOUND LEVEL TEST result 69 dbA

on	off	net
69	53	69

Notes:

Medrep Technologies

Post Office Box 494273
Port Charlotte, Florida 33949
www.medrep.us
941-627-8858v
941-979-8089f

FUME HOOD TEST REPORT

CUSTOMER St. Luke's Compounding Pharmacy LOCATION Non sterile HD Room

MANUFACTURER A.S. Genie MODEL PS48-HCBD-A SERIAL P800350T DATE 7/2/25

APPLICABLE	TEST	REFERENCE	RESULT	Acceptable
YES NO	Airflow: Face Velocity – Full Open	MEDREP-Proc-13	107 fpm	YES NO
YES NO	Airflow: Face Volume - Operating Height	MEDREP-Proc-13	1512 cfm	YES NO
YES NO	Airflow: Auxiliary Airflow Volume	MEDREP-Proc-13	____ cfm	YES NO
YES NO	Check/Adjust Gage	MEDREP-Proc-1	____ "wg	YES NO
YES NO	Illumination Level	MEDREP-Proc-4	54 fc	YES NO
YES NO	Sound Level	MEDREP-Proc-6	69 dbA	YES NO
YES NO	Airflow Pattern Test	MEDREP-Proc-7		YES NO
YES NO	Variable Air Volume Control	MEDREP-Proc-13		YES NO
YES NO	Penetration Leak Test – Exhaust	MEDREP-Proc-11	0.005 %	YES NO
YES NO	Site Assessment	MEDREP-Proc-39	____	YES NO
YES NO	Check Monitor	MEDREP-Proc-40	____ fpm	YES NO

TESTING CRITERIA:

OSHA (60-110 fpm) NIOSH (100-150 fpm)

ANSI (80-120 fpm) NRC (100+ fpm)

SEFA (75-125 fpm)

In-House

NOTES:

DEVICE: Passed Failed

Retest Due 1 year

Device Type:

Vertical Sash	Horizontal Sash	Combination Sash	Radioisotope
Perchloric	Floor Mounted	Auxiliary Air	Bypass
Distillation	Demonstration	Ductless	Canopy
Slots	Grossing Table	Powder	Snorkel

Tested by: [signature] signature

C. Edward Hayes print

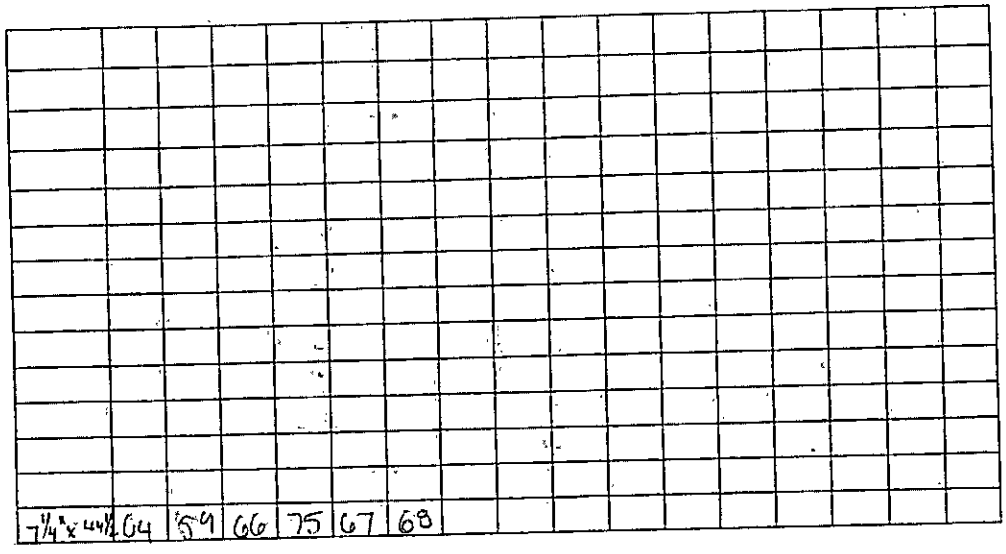
Accepted by: [signature] signature

[illegible] print

PROCEDURES AVAILABLE UPON REQUEST

DEVICE ID 2072.004

FACE VELOCITY READINGS



Indicate in left column if maximum sash height, nominal sash height, 50% sash height, 25% sash height, horizontal or vertical readings, etc.

Draw lines to indicate boundaries.

Monitor: ———

Average at max. opening: ——— fpm

Average at nominal opening: 67 fpm

Max. nominal reading: 75 fpm

Min. nominal reading: 59 fpm

Auxiliary air volume: ——— cfm @ % ———

Average at 50% sash opening: ——— fpm @ ——— inches

Average at 25% sash opening: ——— fpm @ ——— inches

Sash height at full opening: ——— inches

Sash height at nominal opening: 7¼ inches

Width of opening: 44½ inches

Areas of opening: 2.24 sq ft

ILLUMINATION LEVEL TEST average 54 fc

on	39	66	56				
off	8	10	10				—

HEPA LEAK TEST

	media	gasket	frame	ok	Max %	scan	probe	nozzles
exhaust	✓	✓	✓	OK	0		✓	1

Thermo: F055 Photometer: A014

SOUND LEVEL TEST result 69 dbA

on	off	net
69	59	69

Notes: Double HEPA's into room

increased S/C

Section 6

TEST EQUIPMENT CALIBRATION DATA

TEST EQUIPMENT CALIBRATION DATA

Equipment	Manufacturer	Model	Serial #	Last Calibration	Calibration Due
Thermoanemometer	Alnor	AVM440-A	AVM441045003	July 17, 2024	July 16, 2025
Thermoanemometer	Alnor	AVM440-A	AVM442332003	February 17, 2025	February 16, 2026
Aerosol Photometer	TEC	PH-4	1944	February 11, 2025	February 10, 2026
Aerosol Generator [Calibration not applicable; dates denote equipment servicing.]	ATI	4B Lite	70984	February 11, 2025	February 10, 2026
Compressor [Calibration not applicable; dates denote equipment servicing.]	Teich-Aire	KM-200c	01526	February 11, 2025	February 10, 2026
Aerosol Photometer	TEC	PH-4	4520	June 09, 2025	June 08, 2026
Aerosol Generator [Calibration not applicable; dates denote equipment servicing.]	ATI	4B Lite	70978	June 09, 2025	June 08, 2026
Compressor [Calibration not applicable; dates denote equipment servicing.]	Teich - Aire	KM-200c	01587	June 09, 2025	June 08, 2026
Particle Counter	PMS	Lasair III_310C	103782	April 29, 2025	April 28, 2026
Particle Counter	PMS	Lasair III_310C	171352	July 08, 2024	July 07, 2025
Balometer	Alnor	EBT731	EBT732226001	February 13, 2025	February 12, 2026
Micromanometer	Alnor	EBT731	EBT732226001	February 13, 2025	February 12, 2026
Balometer	Alnor	EBT731	EBT731503016	August 19, 2024	August 18, 2025
Micromanometer	Alnor	EBT731	EBT731503016	August 19, 2024	August 18, 2025

Customer: St. Luke Compounding Pharmacy
Dates: July 02 & 03, 2025
Technicians: Gene Formanek & Frank Vargas

Current Calibration Reports Attached

TSI P/N 2330137

ALNOR CERTIFICATE OF CALIBRATION AND TESTING

TSI Incorporated, 500 Cardigan Road, Shoreview, MN 55126 USA
Tel: 1-800-874-2811 1-651-490-2811 Fax: 1-651-490-3824 http://www.tsi.com

Environment Conditions		
Temperature	73.6 (23.1)	°F (°C)
Relative Humidity	41	%RH
Barometric Pressure	29.19 (988.5)	inHg (hPa)

Model	AVM440-A
Serial Number	AVM441045003

☒ As Left ☐ As Found
☒ In Tolerance ☐ Out of Tolerance

– Calibration Verification Results –

Humidity Verification — System H-120 — *Unit: %RH*

#	Standard	Measured	Allowable Range	#	Standard	Measured	Allowable Range
1	10.0	10.4	7.0~13.0	4	70.0	70.7	67.0~73.0
2	30.0	30.6	27.0~33.0	5	90.0	89.7	87.0~93.0
3	50.0	51.0	47.0~53.0				

Temperature Verification — System T-101 — *Unit: °F (°C)*

#	Standard	Measured	Allowable Range	#	Standard	Measured	Allowable Range
1	32.0 (0.0)	32.2 (0.1)	31.5~32.5 (-0.3~0.3)	2	139.9 (59.9)	140.2 (60.1)	139.3~140.4 (59.6~60.2)

TSI does hereby certify that the above described instrument conforms to the original manufacturer's specification (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the United States National Institute of Standards and Technology (NIST) or has been verified with respect to instrumentation whose accuracy is traceable to NIST, or is derived from accepted values of physical constants. TSI's calibration system is registered to ISO-9001:2015.

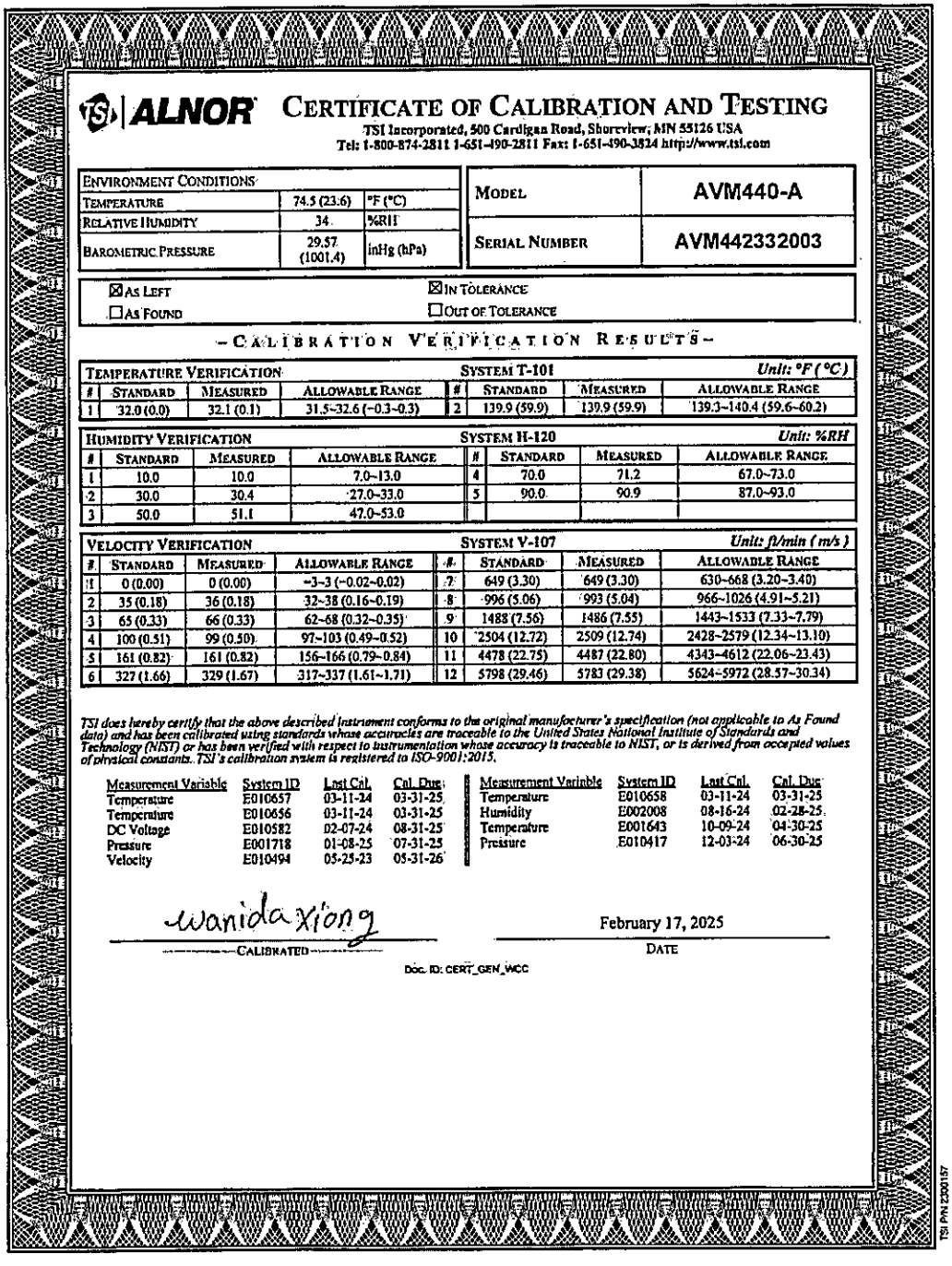
Measurement Variable	System ID	Last Cal.	Cal. Due
Humidity	E002008	02-16-24	08-31-24
Temperature	E010658	03-11-24	03-31-25
DC Voltage	E010582	02-07-24	08-31-25
Pressure	E001718	07-12-24	01-31-25
Velocity	E010408	12-14-21	12-31-24

Measurement Variable	System ID	Last Cal.	Cal. Due
Temperature	E010657	03-11-24	03-31-25
Temperature	E010656	03-11-24	03-31-25
Temperature	E001643	04-10-24	10-31-24
Pressure	E010417	06-18-24	12-31-24

Huda Mohammed — Calibrated

July 17, 2024 — Date

Doc. ID: CERT_GEN_WCC



ALNOR CERTIFICATE OF CALIBRATION AND TESTING

TSI Incorporated, 500 Cardigan Road, Shoreview, MN 55126 USA
Tel: 1-800-874-2811 1-651-490-2811 Fax: 1-651-490-3824 http://www.tsi.com

Environment Conditions		
Temperature	74.5 (23.6)	°F (°C)
Relative Humidity	34	%RH
Barometric Pressure	29.57 (1001.4)	inHg (hPa)

Model	AVM440-A
Serial Number	AVM442332003

☒ As Left ☒ In Tolerance
☐ As Found ☐ Out of Tolerance

– Calibration Verification Results –

Temperature Verification — System T-101 — *Unit: °F (°C)*

#	Standard	Measured	Allowable Range	#	Standard	Measured	Allowable Range
1	32.0 (0.0)	32.1 (0.1)	31.5~32.6 (-0.3~0.3)	2	139.9 (59.9)	139.9 (59.9)	139.3~140.4 (59.6~60.2)

Humidity Verification — System H-120 — *Unit: %RH*

#	Standard	Measured	Allowable Range	#	Standard	Measured	Allowable Range
1	10.0	10.0	7.0~13.0	4	70.0	71.2	67.0~73.0
2	30.0	30.4	27.0~33.0	5	90.0	90.9	87.0~93.0
3	50.0	51.1	47.0~53.0				

Velocity Verification — System V-107 — *Unit: ft/min (m/s)*

#	Standard	Measured	Allowable Range	#	Standard	Measured	Allowable Range
1	0 (0.00)	0 (0.00)	-3~3 (-0.02~0.02)	7	649 (3.30)	649 (3.30)	630~668 (3.20~3.40)
2	35 (0.18)	36 (0.18)	32~38 (0.16~0.19)	8	996 (5.06)	993 (5.04)	966~1026 (4.91~5.21)
3	65 (0.33)	66 (0.33)	62~68 (0.32~0.35)	9	1488 (7.56)	1486 (7.55)	1443~1533 (7.33~7.79)
4	100 (0.51)	99 (0.50)	97~103 (0.49~0.52)	10	2504 (12.72)	2509 (12.74)	2428~2579 (12.34~13.10)
5	161 (0.82)	161 (0.82)	156~166 (0.79~0.84)	11	4478 (22.75)	4487 (22.80)	4343~4612 (22.06~23.43)
6	327 (1.66)	329 (1.67)	317~337 (1.61~1.71)	12	5798 (29.46)	5783 (29.38)	5624~5972 (28.57~30.34)

TSI does hereby certify that the above described instrument conforms to the original manufacturer's specification (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the United States National Institute of Standards and Technology (NIST) or has been verified with respect to instrumentation whose accuracy is traceable to NIST, or is derived from accepted values of physical constants. TSI's calibration system is registered to ISO-9001:2015.

Measurement Variable	System ID	Last Cal.	Cal. Due
Temperature	E010657	03-11-24	03-31-25
Temperature	E010656	03-11-24	03-31-25
DC Voltage	E010582	02-07-24	08-31-25
Pressure	E001718	01-08-25	07-31-25
Velocity	E010494	05-25-23	05-31-26

Measurement Variable	System ID	Last Cal.	Cal. Due
Temperature	E010658	03-11-24	03-31-25
Humidity	E002008	08-16-24	02-28-25
Temperature	E001643	10-09-24	04-30-25
Pressure	E010417	12-03-24	06-30-25

wanida xiong — Calibrated

February 17, 2025 — Date

Doc. ID: CERT_GEN_WCC

TSI P/N 2300157

TEC Services, Inc.
25 Little Avenue
New Oxford, PA 17350
Phone: 717-624-3191
Fax: 717-624-3549
www.tecservicesinc.com

Controlled Environment Products
Calibration & Services

EQUIPMENT CALIBRATION REPORT

Date Received:	2/11/25	Date Shipped:	2/11/25
Customer:	Medrep Technologies, Inc.	Contact:	Liz Ossmann
Address:	25250 Sandhill Blvd.	Phone #:	941-627-8858
	Punta Gorda, FL 33983	Customer PO #:	7153
Manufacturer:	TEC Services	Model #:	PH-4
Instrument Type:	Aerosol Photometer	Serial #:	1944

NIST Traceable calibration performed to the above instrument per IEST-RP-CC013 and TEC Services' SOP's.

INSTRUMENT DATA

		As Found	Final	Mfg. Tolerances
Straylight	(N/A)	.172%	.078%	Not Applicable
Sample Flow	(1)	29.5	29.0	28.3 ± 2.8 SLPM
V1	(1)	5.14	5.15	5.15V ± .05V
V2	(1)	12.49	12.48	12.0V ± 1V
V3	(1)	-11.94	-11.94	-12.0V ± .5V
V4	(1)	24.16	24.16	24.0V ± .5V
U5	(1)	5.001	5.001	5.000 ± .010V

(1) In Tolerance (2) Out of Tolerance (3) No effect on instrument operation (N/A) Not Applicable
Received In Tolerance: ☒ Yes ☐ No ☐ Not Operable
☐ Not Applicable – NEW INSTRUMENT

Calibrated for: ☒ PAO Temperature: 20.4 ° C. Relative Humidity: 37.0 %

MAINTENANCE PERFORMED

☒ Clean / Rebuild Chamber ☒ Realign Optics ☒ Flush Hoses
☒ Check Wiring & Hardware ☐ Replace Gaskets ☐ Update Software Version ____
☐ Not Applicable - NEW INSTRUMENT

Notes: ____

FINAL VERIFICATION PERFORMED

☒ Leak Test Sampling System ☐ Test Scanning Probe ☒ Perform Voltage Check
☒ Verify Max Gain Stability ☒ Performance Test

NIST TRACEABLE EQUIPMENT USED

Description	Model	Serial #	Certificate #	Cal Date	Due Date
Digital Multimeter	Fluke 87-V	64740006	U476015-00-01	04 APR 24	04 APR 25
Thermohygrometer	Extech 445715	CP244467	1756326	17 MAY 24	17 MAY 25
Flowmeter	TSI 4043	40431911011	N/A	03 OCT 24	03 OCT 25

Calibrated per Procedure: ☒ TEC001 ☐ TEC002 ☒ TEC003 ☐ TEC004 ☒ TEC005
☐ TEC006 ☒ TEC007 ☒ TEC008 ☒ TEC009 ☐ TEC010

CALIBRATION BY: George Dolan DATE: 2/11/25 DUE DATE: 2/11/26

TEC Services, Inc.
25 Little Avenue
New Oxford, PA 17350
Phone: 717-624-3191
Fax: 717-624-3549
www.tecservicesinc.com

Controlled Environment Products
Calibration & Services

EQUIPMENT CALIBRATION REPORT

Date Received:	6/6/25	Date Shipped:	6/9/25
Customer:	Medrep technologies, Inc.	Contact:	Liz Ossmann
Address:	25250 Sandhill Blvd.	Phone #:	941-627-8858
	Punta Gorda, FL 33983	Customer PO #:	7204
Manufacturer:	TEC Services	Model #:	PH-4
Instrument Type:	Aerosol Photometer	Serial #:	4520 Customer ID#: N/A

NIST Traceable calibration performed to the above instrument per IEST-RP-CC013 and TEC Services' SOP's.

INSTRUMENT DATA

		As Found	Final	Mfg. Tolerances
Straylight	(N/A)	.109%	.083%	Not Applicable
Sample Flow	(1)	28.2	28.0	28.3 ± 2.8 SLPM
V1	(1)	5.15	5.15	5.15V ± .05V
V2	(1)	11.63	11.63	12.0V ± 1V
V3	(1)	-12.26	-12.26	-12.0V ± .5V
V4	(1)	24.16	24.15	24.0V ± .5V
U5	(1)	5.001	5.001	5.000 ± .010V

(1) In Tolerance (2) Out of Tolerance (3) No effect on instrument operation (N/A) Not Applicable
Received In Tolerance: ☒ Yes ☐ No ☐ Not Operable
☐ Not Applicable – NEW INSTRUMENT

Calibrated for: ☒ PAO Temperature: 21.4 °C Relative Humidity: 43.6 %

MAINTENANCE PERFORMED

☒ Clean / Rebuild Chamber ☒ Realign Optics ☒ Flush Hoses
☒ Check Wiring & Hardware ☐ Replace Gaskets ☐ Update Software Version _____
☐ Not Applicable - NEW INSTRUMENT

Notes: _____

FINAL VERIFICATION PERFORMED

☒ Leak Test Sampling System ☒ Test Scanning Probe ☒ Perform Voltage Check
☒ Verify Max Gain Stability ☒ Performance Test

NIST TRACEABLE EQUIPMENT USED

Description	Model	Serial #	Certificate #	Cal Date	Due Date
Digital Multimeter	Fluke 87-V	67030001	U540637-00-01	14 MAR 25	14 MAR 26
Thermohygrometer	Control Co. 4154	250180426	4154-15800279	24 MAR 25	24 MAR 27
Flowmeter	TSI 4043	40431911011	N/A	03 OCT 24	03 OCT 25

Calibrated per Procedure: ☒ TEC001 ☐ TEC002 ☒ TEC003 ☐ TEC004 ☒ TEC005
☐ TEC006 ☒ TEC007 ☒ TEC008 ☒ TEC009 ☐ TEC010

CALIBRATION BY: _____ DATE: 6/9/25 DUE DATE: 6/9/26

PARTICLE MEASURING SYSTEMS
a spectris company

5475 Airport Boulevard, Boulder, Colorado 80301-2339
303.443.7100 800.238.1801

Certificate of Calibration

Date: Apr-29-2025 11:29:13

Work Order:	WO523700
Customer Name:	Medrep Tech Inc
Customer Address:	25250 Sandhill Boulevard, Punta Gorda, FL 33983 UNITED STATES
Date Received:	Apr-03-2025
Calibration Lab:	5475 Airport Blvd. Boulder, CO 80301

Unit Under Test

Instrument:	Lasairlll_310C	Serial Number:	103782
Firmware Version:	PCE: B2B53624 1.9	Calibration Due:	Apr-29-2026

Certification

Particle Measuring Systems certifies that the instrument listed above meets or exceeds manufacturing specifications and meets the requirements of ISO 21501-4:2018. It has been calibrated using equipment and/or standards whose accuracies are traceable to the National Institute of Standards and Technology (NIST), or have been derived from acceptable values of natural physical constants, or by the ratio type of self-calibration. Counting Efficiency determined by digital output.

This instrument was calibrated in accordance with the Particle Measuring Systems quality system documentation which meets ISO 9001:2015 requirements. The results contained within this calibration certificate relate only to the item calibrated. This certificate may not be reproduced, except in full, without written consent from Particle Measuring Systems.

Particle Measuring Systems meets applicable requirements set forth in ISO/IEC 17025:2017 (as accredited by A2LA, certificate # 3952.01). Reported uncertainties have been calculated in accordance with the principals expressed in the GUM and represent expanded uncertainties expressed at approximately the 95% confidence level using a coverage factor of K=2. Expanded uncertainties for 17025 accredited parameters are marked accordingly. Statements of conformity are based upon a binary decision rule, as defined in ILAC G8, where the acceptance limit is equal to the specification limit and a PASS indicates the measured value is within the acceptance limit and a FAIL indicates the measured value is outside the acceptance limit and the associated measurement uncertainty does not exceed the specification limit.

Instrument Condition As Found

☐ In-Tolerance ☑ Out-of-Tolerance ☐ Operational Failure

Condition As Left

☑ In-Tolerance

Calibration Standards

Procedura Used:	2793G	Program Used:	1000013097 Rev R

Performed by

Technician Name:	Veronica Padilla
Administrator Name:	Calvin Bauge

Veronica Padilla

PARTICLE MEASURING SYSTEMS
a spectris company

5475 Airport Boulevard, Boulder, Colorado 80301-2339
303.443.7100 800.238.1801

Certificate of Calibration

Date: Jul-08-2024 06:34:20

Work Order: 495159
Customer Name: Medrep Tech Inc
Calibration Lab: 5475 AIRPORT BLVD BOULDER CO 80301

Unit Under Test

Instrument:	LasairIII_310C	Serial Number:	171352
Firmware Version:	PCE: B2B53624 1.9	Calibration Due:	Jul-08-2025

Certification

Particle Measuring Systems certifies that the instrument listed above meets or exceeds manufacturing specifications and meets the requirements of ISO 21501-4:2018. It has been calibrated using equipment and/or standards whose accuracies are traceable to the National Institute of Standards and Technology (NIST), or have been derived from acceptable values of natural physical constants, or by the ratio type of self-calibration. Counting Efficiency determined by digital output.

This instrument was calibrated in accordance with the Particle Measuring Systems quality system documentation which meets ISO 9001:2015 requirements. The results contained within this calibration certificate relate only to the item calibrated. This certificate may not be reproduced, except in full, without written consent from Particle Measuring Systems.

Instrument Condition As Found

☑ In-Tolerance ☐ Out-of-Tolerance ☐ Operational Failure

Condition As Left

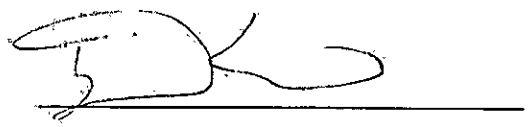
☑ In-Tolerance

Calibration Standards

Procedure Used: 2793 G Program Used: 1000013097 Rev N

Performed by

Technician Name: Tyson Keuma



CERTIFICATE OF CALIBRATION

TSI Incorporated, Alnor Products, 500 Cardigan Road, Shoreview, MN 55126 USA
TEL: 1-800-874-2811 1-651-490-2811 FAX: 1-651-490-3824 www.alnor.com

Environment Condition		
Temperature	73.1	°F
Relative Humidity	30.0	% RH
Barometric Pressure	29.1	inHg

Model	EBT™ Balometer® EBT731
Serial No.	EBT732226001

Calibration Standards Used
Capture Hood Calibration System 2

☒ As Left ☒ In Tolerance
☐ As Found ☐ Out of Tolerance

Calibration Data

Tolerance: ± (3% of reading + 7.0 cfm)

Testing Points	Supply Data Measured in ft³/min			Return Data Measured in ft³/min		
	Calibration Standard	Instrument Output	Allowable Range	Calibration Standard	Instrument Output	Allowable Range
1	1901	1908	1837 ~ 1965	1894	1875	1831 ~ 1957
2	1500	1502	1448 ~ 1552	1498	1488	1447 ~ 1549
3	1200	1200	1157 ~ 1243	1198	1207	1156 ~ 1240
4	899	899	865 ~ 932	900	910	866 ~ 934
5	599	603	575 ~ 623	599	607	575 ~ 623
6	300	299	284 ~ 316	300	305	284 ~ 316
7	101	99	91 ~ 111	99	105	90 ~ 108

* *Indicates out of tolerance condition*

TSI Incorporated does hereby certify that the above described instrument conforms to the original manufacturer's specifications (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the National Institute of Standards and Technology within the limitations of NIST's calibration services or have been derived from accepted values of natural physical constants or have been derived by the ratio type of self calibration techniques. The calibration ratio for this instrument is at least 1.40:1 at 100 ft³/min (170 m³/hr, 47 l/s) and 2.0:1 at all other points. TSI is registered to ISO-9001:2015, Quality Assurance Requirements. This report may not be reproduced, except in full, unless permission for the publication of an approved abstract is obtained in writing from the calibration organization issuing this report.

Measurement Variable	System ID Number	Date Last Calibrated	Calibration Due Date
DC Voltage	E010585	06-10-24	06-30-25
Thermometer	E003392	08-28-24	02-28-25
Pressure	E002082	09-10-24	03-31-25
Pressure	E010937	09-10-24	03-31-25
Flow	E005774	10-06-21	10-31-25
Flow	E005773	10-06-21	10-31-25
Barometric Pressure	E003782	06-24-24	06-30-25

Calibration procedure used: 1000022699

Thuy Xing
Calibrated By

Feb. 13, 2025
Calibration Date

1083503A

TSI P/N 2300167

CERTIFICATE OF CALIBRATION

TSI Incorporated, Alnor Products, 500 Cardigan Road, Shoreview, MN 55126 USA
TEL:1-800-874-2811 1-651-490-2811 FAX: 1-651-490-3824 www.alnor.com

ENVIRONMENT CONDITION		
TEMPERATURE	74.7	°F
RELATIVE HUMIDITY	30.0	% RH
BAROMETRIC PRESSURE	29.08	inHg

MODEL	EBT™ Micromanometer EBT731
SERIAL NO.	EBT732226001

CALIBRATION STANDARDS USED
Manometer Calibration Bench 1

☒ AS LEFT ☐ AS FOUND
☒ IN TOLERANCE ☐ OUT OF TOLERANCE

CALIBRATION DATA

TESTING POINTS	BAROMETRIC PRESSURE MEASURED IN in.Hg			DIFFERENTIAL PRESSURE MEASURED IN in.H2O		
	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE
1	19.97	19.96	19.58 ~ 20.36	0.0970	0.0972	0.0950 ~ 0.0990
2	29.09	29.09	28.51 ~ 29.67	0.495	0.496	0.485 ~ 0.505
3	34.50	34.49	33.81 ~ 35.19	3.01	3.02	2.95 ~ 3.07
4	-	-	-	12.1	12.1	11.9 ~ 12.3
5	-	-	-	14.6	14.6	14.3 ~ 14.9

TESTING POINTS	TEMPERATURE MEASURED IN °F[1]		
	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE
1	5.0	5.0	4.5 ~ 5.5
2	77.0	77.0	76.5 ~ 77.5
3	158.0	157.9	157.5 ~ 158.5

* *Indicates out of tolerance condition*

[1]Circuit portion of temperature measurement only, not including probe

TSI Incorporated does hereby certify that the above described instrument conforms to the original manufacturer's specifications (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the National Institute of Standards and Technology within the limitations of NIST's calibration services or have been derived from accepted values of natural physical constants or have been derived by the ratio type of self calibration techniques. The following ratios express the expanded uncertainty at a confidence level of 95% (i.e. with a coverage factor k=2) of the calibration facilities with respect to the instrument being calibrated: for barometric pressure ≥ 6.7:1; for differential pressure ≥ 3:1; for temperature ≥ 1.16:1. TSI is registered to ISO-9001:2015, Quality Assurance Requirements. This report may not be reproduced, except in full, unless permission for the publication of an approved abstract is obtained in writing from the calibration organization issuing this report.

Measurement Variable	System ID Number	Date Last Calibrated	Calibration Due Date
DC Voltage	E002798	02-07-24	08-31-25
DC Voltage	E002797	08-23-22	08-31-27
Pressure	E002124	09-18-24	09-30-25
Pressure	E002447	06-24-24	06-30-25

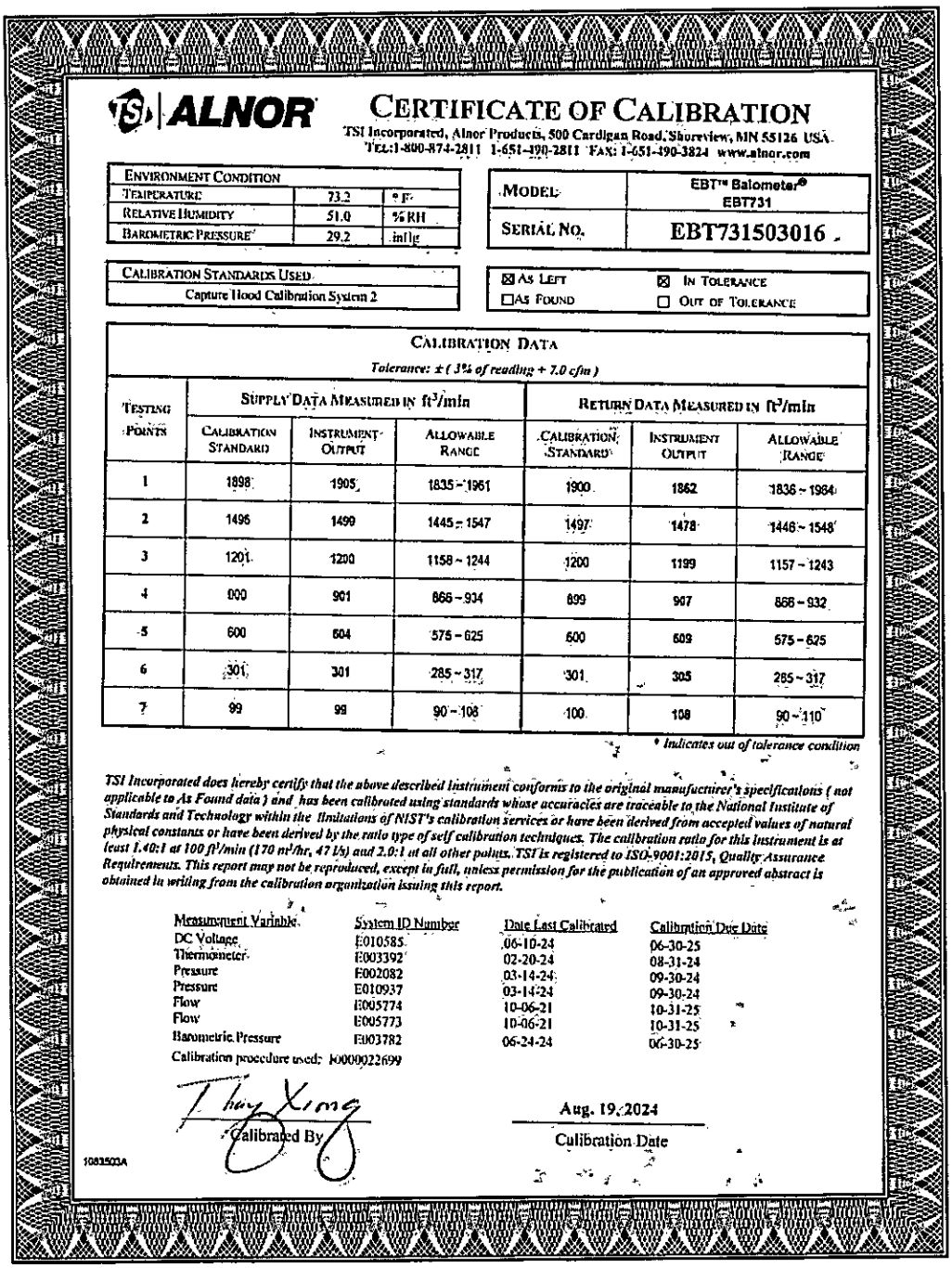
Calibration procedure used: 10000022697

Thay Xmg
Calibrated By

Feb. 12, 2025
Calibration Date

1083501A

TSI P/N 2300157



CERTIFICATE OF CALIBRATION

TSI Incorporated, Alnor Products, 500 Cardigan Road, Shoreview, MN 55126 USA
Tel:1-800-874-2811 1-651-490-2811 Fax: 1-651-490-3824 www.alnor.com

Environment Condition		
Temperature	73.2	°F
Relative Humidity	51.0	%RH
Barometric Pressure	29.2	inHg

Model	EBT™ Balometer® EBT731
Serial No.	EBT731503016

Calibration Standards Used:
Capture Hood Calibration System 2

☒ As Left ☒ In Tolerance
☐ As Found ☐ Out of Tolerance

Calibration Data

Tolerance: ± (3% of reading + 7.0 cfm)

Testing Points	Supply Data Measured in ft³/min			Return Data Measured in ft³/min		
	Calibration Standard	Instrument Output	Allowable Range	Calibration Standard	Instrument Output	Allowable Range
1	1898	1905	1835 ~ 1961	1900	1862	1836 ~ 1964
2	1496	1499	1445 ~ 1547	1497	1478	1446 ~ 1548
3	1201	1200	1158 ~ 1244	1200	1199	1157 ~ 1243
4	900	901	866 ~ 934	899	907	868 ~ 932
5	600	604	575 ~ 625	600	609	575 ~ 625
6	301	301	285 ~ 317	301	305	285 ~ 317
7	99	99	90 ~ 108	100	108	90 ~ 110

* *Indicates out of tolerance condition*

TSI Incorporated does hereby certify that the above described instrument conforms to the original manufacturer's specifications (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the National Institute of Standards and Technology within the limitations of NIST's calibration services or have been derived from accepted values of natural physical constants or have been derived by the ratio type of self calibration techniques. The calibration ratio for this instrument is at least 1.40:1 at 100 ft³/min (170 m³/hr, 47 l/s) and 2.0:1 at all other points. TSI is registered to ISO-9001:2015, Quality Assurance Requirements. This report may not be reproduced, except in full, unless permission for the publication of an approved abstract is obtained in writing from the calibration organization issuing this report.

Measurement Variable	System ID Number	Date Last Calibrated	Calibration Due Date
DC Voltage	E010585	06-10-24	06-30-25
Thermometer	E003392	02-20-24	08-31-24
Pressure	E002082	03-14-24	09-30-24
Pressure	E010937	03-14-24	09-30-24
Flow	E005774	10-06-21	10-31-25
Flow	E005773	10-06-21	10-31-25
Barometric Pressure	E003782	06-24-24	06-30-25

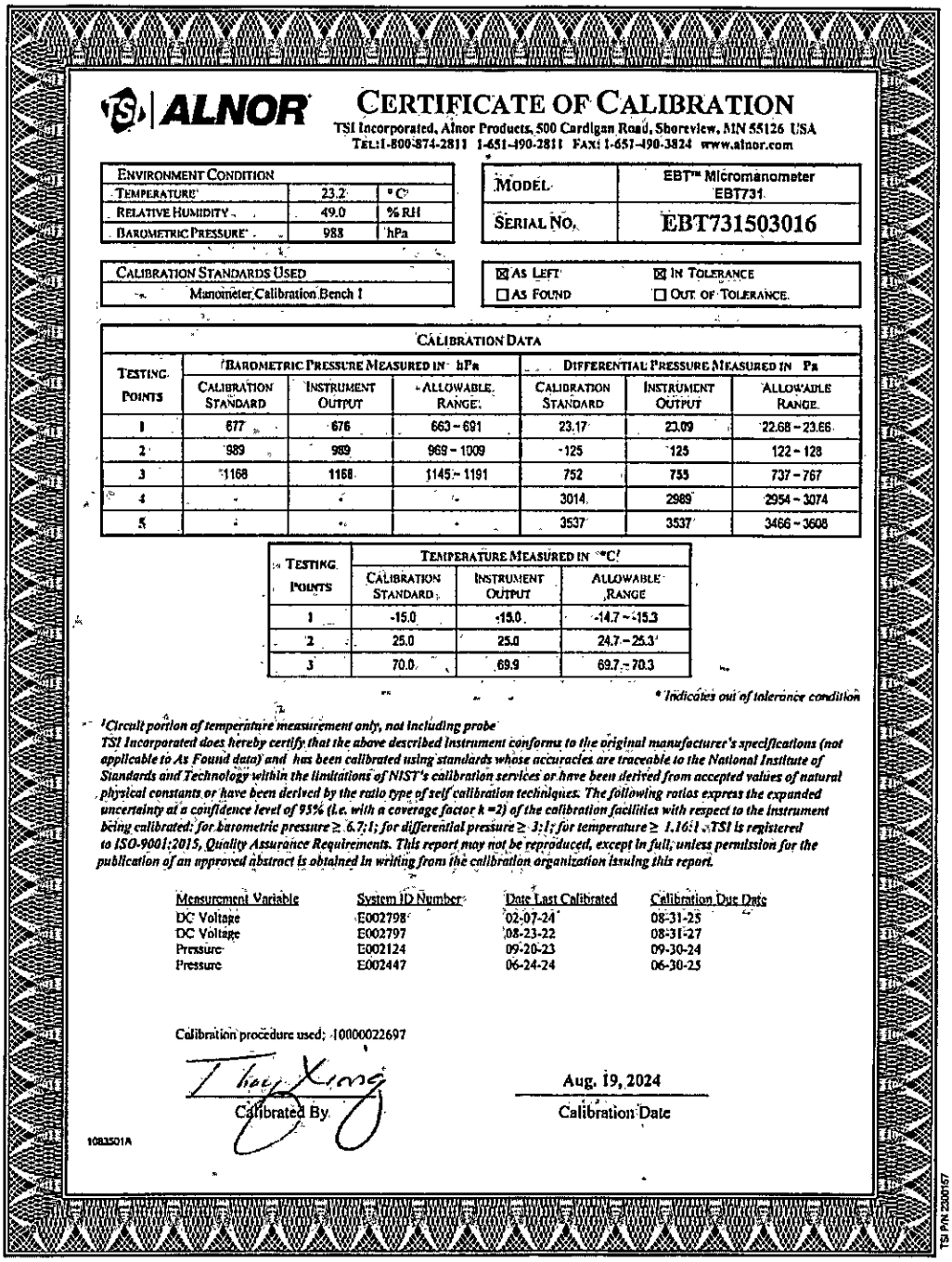
Calibration procedure used: 9000022699

Thuy Xing
Calibrated By

Aug. 19, 2024
Calibration Date

1003503A

TSI P/N 2300167



CERTIFICATE OF CALIBRATION

TSI Incorporated, Alnor Products, 500 Cardigan Road, Shoreview, MN 55126 USA
TEL:1-800-874-2811 1-651-490-2811 FAX: 1-651-490-3824 www.alnor.com

ENVIRONMENT CONDITION		
TEMPERATURE	23.2	°C
RELATIVE HUMIDITY	49.0	% RH
BAROMETRIC PRESSURE	988	hPa

MODEL	EBT™ Micromanometer EBT731
SERIAL NO.	EBT731503016

CALIBRATION STANDARDS USED
Manometer Calibration Bench 1

☒ AS LEFT ☒ IN TOLERANCE
☐ AS FOUND ☐ OUT OF TOLERANCE

CALIBRATION DATA

TESTING POINTS	BAROMETRIC PRESSURE MEASURED IN hPa			DIFFERENTIAL PRESSURE MEASURED IN Pa		
	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE
1	677	676	663 – 691	23.17	23.09	22.68 – 23.66
2	989	989	969 – 1009	125	125	122 – 128
3	1168	1168	1145 – 1191	752	755	737 – 767
4				3014	2989	2954 – 3074
5				3537	3537	3466 – 3608

TESTING POINTS	TEMPERATURE MEASURED IN °C[1]		
	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE
1	-15.0	-15.0	-14.7 – -15.3
2	25.0	25.0	24.7 – 25.3
3	70.0	69.9	69.7 – 70.3

* Indicates out of tolerance condition

[1]Circuit portion of temperature measurement only, not including probe

TSI Incorporated does hereby certify that the above described instrument conforms to the original manufacturer's specifications (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the National Institute of Standards and Technology within the limitations of NIST's calibration services or have been derived from accepted values of natural physical constants or have been derived by the ratio type of self calibration techniques. The following ratios express the expanded uncertainty at a confidence level of 95% (i.e. with a coverage factor k =2) of the calibration facilities with respect to the instrument being calibrated: for barometric pressure ≥ 6.7:1; for differential pressure ≥ 3:1; for temperature ≥ 1.16:1. TSI is registered to ISO-9001:2015, Quality Assurance Requirements. This report may not be reproduced, except in full, unless permission for the publication of an approved abstract is obtained in writing from the calibration organization issuing this report.

Measurement Variable	System ID Number	Date Last Calibrated	Calibration Due Date
DC Voltage	E002798	02-07-24	08-31-25
DC Voltage	E002797	08-23-22	08-31-27
Pressure	E002124	09-20-23	09-30-24
Pressure	E002447	06-24-24	06-30-25

Calibration procedure used: 10000022697

Thuy Xiong
Calibrated By

Aug. 19, 2024
Calibration Date

1083501A

TSI P/N 2300157

Section 7

CERTIFICATE OF COMPLIANCE

CERTIFICATE OF COMPLIANCE

We hereby certify that the cleanroom facility
Located at St. Luke Compounding Pharmacy,
New Port Richey, Florida has been fully inspected
July 02 & 03, 2025
for compliance
To the requirements set forth in:

ISO 14644-1:2015
USP<800>
USP<797>
64B16-27.797
CAG-003

We are pleased to announce that this facility
Meets the standards of compliance for an
ISO Class 7 & 8 environment.

This facility shall be retested prior to
January 31, 2025

We attest the above data to be true and correct.

Medrep Technologies

Frank Ossmann
President

DEVICE INSPECTION REPORT

September 2025

Prepared for:

ST. LUKE
COMPOUNDING PHARMACY

New Port Richey, Florida

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Contents

Section 1: Summary

Section 2: Results of Testing

Section 3: Test Data

Section 4: Sample Methodology

Section 5: Service Report

Section 6: Test Equipment Calibration Data

Section 1

SUMMARY

St. Luke Compounding Pharmacy
New Port Richey, Florida
ISO Class 5 Biological Safety Cabinet

SUMMARY

Of Testing Performed September 16, 2025

The purpose of this inspection was to prove continued compliance, after repairs were made within the device to the requirements of a laminar flow ISO Class 5 environment as defined by ISO 14644-1:2015, referenced in USP<797>, 64B16-27.797 and other applicable documents listed herein.

This scheduled inspection is part of an ongoing semi-annual monitoring and periodic test program designed to document long-term compliance. The most recent inspections were performed on December 20, 2024 & January 08, 2025.

Following the testing and based upon the results of those tests listed, the device was found to be in conformance and a certificate of compliance has been issued and affixed to the device.

Testing Performed by: Terry Lugviel
IEST Level 2 Technician

Report prepared by: Caroline Arnold
Tier 2 Compliance Officer

Report approved by: James Rice
Tier 2 Compliance Officer

Respectfully submitted: October 03, 2025

The tests performed upon the device were:

1. Airflow Adjustment for Class II BSCs	MEDREP-Proc-1
2. Testing Pressure and Airflow in a Duct	MEDREP-Proc-2
3. Testing Fluorescent Illumination Level	MEDREP-Proc-4
4. Testing Sound Level	MEDREP-Proc-6
5. Smoke Pattern in a Device	MEDREP-Proc-7
6. Check Leveling of a Device	MEDREP-Proc-8
7. Leak Testing HEPA Filters for BSCs	MEDREP-Proc-9
8. Performing the Site Installation Assessment	MEDREP-Proc-39
9. Testing Device Alarm Functions	MEDREP-Proc-40
10. Non-Viable Particle Counts in a Device	MEDREP-Proc-48
11. Check/Adjust Gages	MEDREP-Proc-61

Section 2

RESULTS OF TESTING

RESULTS OF CLEAN AIR DEVICE TEST

Buffer H.D. Room				
Class II Type A2 Biological Safety Cabinet				
Esco Model #AC2-6S9-NS Serial #2024-204033				
ISO 14644-1 Class 5 Environment				
Test	Criteria	Result	Pass/Fail	Comment
Non-Viable Particle Count (Static)	<3,520	0	Pass	
Non-Viable Particle Count (Dynamic)	<3,520	0	Pass	
Supply Airflow	55-65 fpm	58 fpm	Pass	
Inflow Velocity	100-110 fpm	107 fpm	Pass	
Supply HEPA Leak Test	<0.01%	<0.01%	Pass	
Exhaust HEPA Leak Test	<0.01%	<0.01%	Pass	
Site Assessment	See Methodology	Acceptable	Pass	
Visual Smoke Pattern Test		Acceptable	Pass	
Alarm Function		Operable	Pass	
Illumination Test	>45 fc	243 fc	--	
Sound Level Test	<70 dBA	65 dBA	--	
Exhaust Status	Vented Connection Negative	Thimble Connected Negative	Pass	

This device was tested to meet the requirements of an ISO Class 5 environment, the standards of the manufacturer, and the requirements of NSF/ANSI 49-2022.

Occupancy State at time of test: DYNAMIC

Date of test: September 16, 2025

Result of Device Tests: PASS

Section 3

TEST DATA

RESULTS OF NON-VIABLE PARTICLE COUNT TEST

Buffer H.D. Room				
Class II Type A2 Biological Safety Cabinet (Static)				
Esco Model #AC2-6S9-NS Serial #2024-204033				
ISO 14644-1 Class 5 Environment				
Sample Location	Size Sampled 0.5 micron	Size Sampled 1.0 micron	Day/ Time	Pass/ Fail
Control	0	0	09/16/2025 14:11	Pass
1	0	0	09/16/2025 14:16	Pass
2	0	0	09/16/2025 14:18	Pass
3	0	0	09/16/2025 14:19	Pass
4	0	0	09/16/2025 14:21	Pass
5	0	0	09/16/2025 14:22	Pass
6	0	0	09/16/2025 14:24	Pass
Mean of the Average $Ft.^3$	0	0		
Maximum Concentration Limit	3,520	832		
Mean of the Average m^3	0	0	Total	
			0	Pass

Result of Particle Count Test: PASS

RESULTS OF NON-VIABLE PARTICLE COUNT TEST

Buffer H.D. Room				
Class II Type A2 Biological Safety Cabinet (Dynamic)				
Esco Model #AC2-6S9-NS Serial #2024-204033				
ISO 14644-1 Class 5 Environment				
Sample Location	Size Sampled 0.5 micron	Size Sampled 1.0 micron	Day/ Time	Pass/ Fail
Control	0	0	09/16/2025 14:11	Pass
1	0	0	09/16/2025 14:28	Pass
Mean of the Average Ft.³	0	0		
Maximum Concentration Limit	3,520	832		
Mean of the Average m³	0	0	Total	
			0	Pass

Result of Particle Count Test: PASS

Summary of BSC Particle Count Test Procedure

The purpose of this test is to demonstrate compliance of the biological safety cabinet clean air device tested to the requirements specified in the International Organization for Standardization document ISO 14644-1:2015.

USP <797> requires all biological safety cabinets, laminar flow clean benches and isolators used for compounding to be an ISO Class 5 environment. This test is also referred to as a Particle Count Survey or an Airborne Particle Count.

The number of sample locations was 6. One sample in each corner of the work surface, six inches from each wall, and two more samples taken down the center of the work surface equally separated to represent the entire work zone. This number far exceeds the minimum number required by using the formula referenced in ISO 14644-1:2015.

USP <797> requires that non-viable particle counts be sampled within all PECs under dynamic operating conditions. In this case, the number of sample locations was 1. This sample is taken within close proximity to the direct compounding area.

The amount of air sampled at each location was 1.0 cubic foot, or 28.3 cubic liters, which exceeds the minimum volume required at each sample location determined by the following equation:

$$V_s = \frac{20}{Cn,m} \times 1{,}000$$

Where: Vs is the minimum single sample per location expressed in liters.

$C_{n,m}$ is the class limit (number of particles per cubic meter) for the largest considered particle size specified.

20 The defined number of particles that could be counted if the particle concentration were at the class limit.

For ISO Class 5: Vs = 24.04 liters
[20 ÷ 832 x 1,000 = 24.04]

The particle counter sampled at a rate of 1.0 cfm through an isokinetic probe which was oriented upward and held in a stand located at a height of 6 inches above the work surface and attached to the counter by HYTREL PVC tubing which does not exceed 10 feet in length. Each location was sampled for a period of one minute and the reading were then normalized to represent a cubic foot and a cubic meter.

The equipment used is a discrete-particle counter (DPC) manufactured by Particle Measuring Systems, Inc. the model Lasair III_310C serial #103435 which was last calibrated on June 23, 2025 and due for recalibration on June 22, 2026. The most recent calibration report is located in Section 6.

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-48 which is available upon request.

The above referenced testing procedure meets test methods outlined in the following documents:

IEST-G-CC1001	Counting Airborne Particles for Classification and Monitoring of Cleanrooms and Clean Zones
IEST-RP-CC002.4	Unidirectional-Flow, Clean Air Devices
IEST-RP-CC013	Calibration Procedures and Guidelines for Select Equipment Used in Testing Cleanrooms and Other Controlled Environments
ISO 14644-1:2015	Classification of air cleanliness
ISO 14644-2:2015	Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
ISO 14644-3:2019	Test Methods
USP <797>	Guidebook to Pharmaceutical Compounding-Sterile Preparations
64B16-27.797	The Standards of Practice for Compounding Sterile Products
CAG-003	CETA Certification Guide for Sterile Compounding Facilities
CAG-008	CETA Certification Matrix for Sterile Compounding Facilities

Section 4

SAMPLE METHODOLOGY

Summary of BSC Certification Procedure

The purpose of this sequence of tests is to demonstrate compliance of the Biological Safety Cabinet(s) to the requirements set forth by the manufacturer of the cabinet, NSF/ANSI 49-2022 and other requirements which may apply. Additionally, USP <797> requires all biological safety cabinets, laminar flow clean benches and isolators used for compounding to be an ISO Class 5 environment.

There are a number of tests performed to comply with these requirements. In addition to the non-viable particle count test, these are:

1. Downflow Velocity Profile Test

The velocity of the air moving downward through the work area is measured in a plane 4 inches above the working height of the front sash. This plane is divided into a grid and the downflow is measured using a thermoanemometer held in place by a ring stand. The individual readings are recorded on a numbered report; the readings are averaged and compared to the acceptable range listed by the manufacturer.

The device used to measure airflow velocity was a thermoanemometer manufactured by Alnor/TSI, Inc. the model AVM440-A serial #AVM441603001 which was last calibrated on June 02, 2025 and due for recalibration on June 01, 2026. The most recent calibration report is located in Section 6.

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-1 which is available upon request.

2. Inflow Velocity Test

The velocity is the air moving inward through the work access opening and this airflow may be measured or calculated. The individual readings are recorded on a numbered report; the readings are averaged and compared to the acceptable range listed by the manufacturer.

In this case, the airflow was measured in a grid pattern above the face of the exhaust HEPA filter. Multiple readings were taken. These velocity readings were recorded and averaged. This average, in fpm was multiplied by the size of the filter opening, in square feet, to determine the volume exiting the cabinet in cfm. This volume is then divided by the area of the front access opening to determine the calculated inflow velocity.

The device used to measure airflow velocity was a thermoanemometer manufactured by Alnor/TSI, Inc. the model AVM440-A serial #AVM441603001 which was last calibrated on June 02, 2025 and due for recalibration on June 01, 2026. The most recent calibration report is located in Section 6.

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-1 which is available upon request.

3. HEPA Filter Leak Tests

This test is performed by generating a challenge aerosol within the work area of the cabinet. This aerosol is provided as a challenge to the HEPA filters within the cabinet. The two HEPA filters present are then tested for leaks by scanning the face of the filter, the seal and the frame for penetrations using an aerosol photometer. Minor leaks may be repaired. Any by-pass not corrected will result in failure.

The challenge liquid used was Poly Alpha Olefin (PAO). The challenge aerosol was generated by multiple Laskin nozzles supplied by a compressor(s) providing 100 liters per minute at 20 psi per nozzle.

The aerosol photometer used was a calibrated linear photometer manufactured by TEC Services, Inc. the model PH-4 serial #2149 last calibrated on March 24, 2025 and due for recalibration on March 23, 2026. The most recent calibration report is located in Section 6. The photometer probe is an isokinetic probe.

An upstream challenge could not be measured because of inaccessibility. Therefore, an internal calibration of the aerosol photometer was utilized using the following formula:

$$C_2 = NC_1 \quad \frac{Q_1}{Q_2}$$

Where: C_2 is the full scale photometer setting based upon manufacturers calibration data.
N is the number of Laskin nozzles used.
C_1 µg/L per nozzle when discharged into a flow rate of Q_1 (38 m^3/min).
Q_1 38 m^3/min
Q_2 Volume of air measured in m^3/min

In this case*:
*The values shown here for Q_2 and C_2 for each calculation are rounded for brevity.

AC2-6S9-NS (S# 2024-204033)
Full scale reading represents 31µg/L
(2) x (10) x 38 ÷ 24.55 = 30.95

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-9 which is available upon request.

4. Visual Smoke Pattern Test

This test is designed to give a visual confirmation of the air direction, and airflow patterns. It is considered acceptable when the smoke exhibits a smooth unidirectional laminar flow of air, with no dead spots or reflux.

It is separated into four separate and distinct tests:

1. Downflow test
2. View screen retention test
3. Work opening edge retention test
4. Sash/window seal test

The overall result is considered to be acceptable only if each individual test is acceptable.

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-7 which is available upon request.

5. Illumination and Sound Tests

These tests are related to worker comfort and do not require a Pass/Fail.

They are considered secondary tests. More specific testing criteria are documented in MEDREP-Proc-4 and MEDREP-Proc-6 which are available upon request.

6. Alarm Test

Biological Safety Cabinets with sliding sash (view screens) also contain an alarm to signal when the sash is not at the recommended height.

Biological Safety Cabinets which are connected to an exhaust duct are required to have an audible/visual alarm to warn in the event of exhaust system failure. The alarm present must be tested as such:

Type A biological safety cabinets:

Reduce the exhaust airflow gradually until the alarm sounds. The alarm must sound before canopy containment is lost by visual confirmation using a smoke source.

Type B biological safety cabinets:

Once the cabinet has been set within the acceptable airflow range, reduce the exhaust volume by 20% and verify that the audible and visual alarms are activated within 15 seconds. At that point the internal supply fan must be interlocked to shut down.

This test is considered a primary test and should be performed semi-annually. More specific testing criteria are documented in MEDREP-Proc-40 which is available upon request.

Section 5

SERVICE REPORT

MEDREP TECHNOLOGIES, INC

Report 109393

Post Office Box 494273
Port Charlotte, Florida 33949-4273
Phone: 941-627-8858 Fax: 941-629-8698 Web: www.medrep.us

Customer [illegible] Location [illegible] Phone [illegible]

Model # [illegible] Ser # [illegible] Cust # [illegible] Date [illegible]

BSC TEST REPORT

APPLICABLE	TEST	REFERENCE	RESULTS	ACCEPTABLE
Yes__No__	Airflow: Supply Velocity	MEDREP-Proc-1	[illegible] fpm	Yes__No__
Yes__No__	Airflow: Intake Velocity	MEDREP-Proc-1	[illegible] fpm	Yes__No__
Yes__No__	Check/Adjust Gage	MEDREP-Proc-1	[illegible]	Yes__No__
Yes__No__	Duct Status	MEDREP-Proc-2	[illegible]	Yes__No__
Yes__No__	Illumination Level Test	MEDREP-Proc-4	[illegible] fc	Yes__No__
Yes__No__	UV Output Test	MEDREP-Proc-5	[illegible] µw/cm²	Yes__No__
Yes__No__	Sound Level Test	MEDREP-Proc-6	[illegible] dB A	Yes__No__
Yes__No__	Smoke Pattern	MEDREP-Proc-7		Yes__No__
Yes__No__	Check Leveling	MEDREP-Proc-8		Yes__No__
Yes__No__	Leak Test: Supply HEPA	MEDREP-Proc-9	[illegible]	Yes__No__
Yes__No__	Leak Test: Exhaust HEPA	MEDREP-Proc-9	[illegible]	Yes__No__
Yes__No__	Class I / Class III Requirements	MEDREP-Proc-10		Yes__No__
Yes__No__	Electrical Safety Test	MEDREP-Proc-15		Yes__No__
Yes__No__	Smoke Study	MEDREP-Proc-79		Yes__No__
Yes__No__	Biological Decontamination	MEDREP-Proc-17		Yes__No__
Yes__No__	Site Assessment	MEDREP-Proc-39		Yes__No__
Yes__No__	Check Alarm(s)	MEDREP-Proc-40		Yes__No__
Yes__No__	Viable Counts	MEDREP-Proc-47		results to follow
Yes__No__	Non-Viable Counts	MEDREP-Proc-48		results to follow

__Unit Certified __Months

__Unit NOT Certified

Unit Type: __Class I __Class II Type B1 __Class II Type A1 __Class II Type B2 __Class II Type A2 __Class III

TEST CRITERIA: __NSF 49 __ISO 14644 __Manufacturer __USP <797> __Other

Tests Performed By: [illegible]

Work Accepted By: [illegible]

All Protocols available upon request

I.D # [illegible]

3090

SUPPLY AIRFLOW

Acceptable Range: 55-65

58	60	54	51	49	50	52	53	52	52	57				
58	55	53	54	56	55	55	55	57	59	63				
66	62	63	62	62	60	62	64	62	64	71				

Gage/Max Ave: _____

Nominal Ave: 58 fpm

Highest Reading: _____ fpm

Lowest Reading: _____ fpm

DECONTAMINATION

Paraformaldehyde ____ gms. @ ____ hrs.

Ammonium Carbonate ____ gms

Temperature ____ °f Humidity ____ %

Counter 2611 Thermo # 5025 Photometer # AG16

Supply HEPA 18x72

Exhaust HEPA _____

Pre-filter _____

EXHAUST AIRFLOW

Tested @ P/S

286							285	
270							270	
281	279	279	277	268	271	270	275	277

Ave: 277 fpm Calculated Inflow: ____ fpm Measured Inflow: 107 fpm

Exhaust Volume: 416 cfm Acceptable Range: 100-110 fpm

Duct: ____ "wg Thimble Status: Yes Room Pressure: ____ "wg

Exhaust Opening: 1.5 Front Opening: 7.88.8

DIM: _____

UV OUTPUT

Old Lamp						
New Lamp						
Ave.			Ave.			

3½ hours/shor

HEPA LEAK TEST

	Media	Gasket	Frame	Repair OK	Scan	Probe
Supl.	✓	✓	—	ok	✓	
Exh.	✓	✓	—	ok		

MOTOR SETTING

Incr.	Norm.	Decr.
✓		

ELECTRICAL LEAKAGE

	Norm.	Rev.
On	µa	µa
Off	µa	µa

Ground Circuit Resistance _____ Ω

ILLUMINATION

On	322	342	340	321	323			285
Off								

VIBRATION

µin			

SOUND

On	Off	Next
67	62	65

Section 6

TEST EQUIPMENT CALIBRATION DATA

TEST EQUIPMENT CALIBRATION DATA

Equipment	Manufacturer	Model	Serial #	Last Calibration	Calibration Due
Thermoanemometer	Alnor	AVM440-A	AVM441603001	June 02, 2025	June 01, 2026
Aerosol Photometer	TEC	PH-4	2149	March 24, 2025	March 23, 2026
Aerosol Generator [Calibration not applicable; dates denote equipment servicing.]	ATI	4B Lite	70977	March 24, 2025	March 23, 2026
Compressor [Calibration not applicable; dates denote equipment servicing.]	Teich-Aire	KM-200c	01590	March 24, 2025	March 23, 2026
Particle Counter	PMS	Lasair III_310C	103435	June 23, 2025	June 22, 2026

Customer: St. Luke Compounding Pharmacy
Date: September 16, 2025
Technician: Terry Lugviel

Current Calibration Reports Attached

TSI P/N 2900157

ALNOR CERTIFICATE OF CALIBRATION AND TESTING

TSI Incorporated, 500 Cardigan Road, Shoreview, MN 55126 USA
Tel: 1-800-874-2811 1-651-490-2811 Fax: 1-651-490-3824 http://www.tsi.com

Environment Conditions		
Temperature	71.81 (22.1)	°F (°C)
Relative Humidity	52.8	%RH
Barometric Pressure	28.73 (972.9)	inHg (hPa)

Model	AVM440-A
Serial Number	AVM441603001

☒ As Left ☒ In Tolerance
☐ As Found ☐ Out of Tolerance

– Calibration Verification Results –

Humidity Verification — System H-102 — *Unit: %RH*

#	Standard	Measured	Allowable Range	#	Standard	Measured	Allowable Range
1	10.0	10.4	7.0~13.0	4	70.0	71.7	67.0~73.0
2	30.1	31.3	27.1~33.1	5	89.9	91.1	86.9~92.9
3	50.0	51.5	47.0~53.0				

Temperature Verification — System T-100 — *Unit: °F (°C)*

#	Standard	Measured	Allowable Range	#	Standard	Measured	Allowable Range
1	32.0 (0.0)	32.2 (0.1)	31.5~32.5 (-0.3~0.3)	2	140.0 (60.0)	140.1 (60.1)	139.5~140.5 (59.7~60.3)

Velocity Verification — System V-111 — *Unit: fl/min (m/s)*

#	Standard	Measured	Allowable Range	#	Standard	Measured	Allowable Range
1	0 (0.00)	0 (0.00)	-3~3 (-0.02~0.02)	7	647 (3.28)	650 (3.30)	627~666 (3.19~3.38)
2	35 (0.18)	36 (0.18)	32~38 (0.16~0.19)	8	998 (5.07)	998 (5.07)	968~1028 (4.92~5.22)
3	64 (0.33)	65 (0.33)	61~67 (0.31~0.34)	9	1479 (7.51)	1498 (7.61)	1434~1523 (7.29~7.74)
4	100 (0.51)	100 (0.51)	97~103 (0.49~0.52)	10	2491 (12.65)	2500 (12.70)	2416~2566 (12.28~13.03)
5	161 (0.82)	162 (0.82)	156~166 (0.79~0.84)	11	4486 (22.79)	4519 (22.96)	4351~4620 (22.10~23.47)
6	326 (1.65)	327 (1.66)	316~335 (1.60~1.70)	12	5808 (29.50)	5812 (29.52)	5634~5982 (28.62~30.39)

TSI does hereby certify that the above described instrument conforms to the original manufacturer's specification (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to the United States National Institute of Standards and Technology (NIST) or has been verified with respect to instrumentation whose accuracy is traceable to NIST, or is derived from accepted values of physical constants. TSI's calibration system is registered to ISO-9001:2015.

Measurement Variable	System ID	Last Cal.	Cal. Due	Measurement Variable	System ID	Last Cal.	Cal. Due
Humidity	E011511	04-15-25	10-31-25	Temperature	E003617	01-03-25	07-31-25
Temperature	E003305	01-03-25	07-31-25	DC Voltage	E004018	06-13-24	06-30-25
Temperature	E004398	04-03-25	10-31-25	Pressure	E003541	01-08-25	07-31-25
Pressure	E011250	01-08-25	07-31-25	Velocity	E010494	05-25-23	05-31-26

wanida xiong
Calibrated

June 2, 2025
Date

Doc. ID: CERT_GEN_WCC

TEC Services, Inc.
25 Little Avenue
New Oxford, PA 17350
Phone: 717-624-3191
Fax: 717-624-3549
www.tecservicesinc.com

Controlled Environment Products
Calibration & Services

EQUIPMENT CALIBRATION REPORT

Date Received:	*3/24/25*	Date Shipped:	*3/24/25*
Customer:	*Medrep Technologies, Inc.*	Contact:	*Liz Ossmann*
Address:	*25250 Sandhill Blvd.*	Phone #:	*941-627-8858*
	Punta Gorda, FL 33983	Customer PO #:	*7171*
Manufacturer:	*TEC Services*	Model #:	*PH-4*
Instrument Type:	*Aerosol Photometer*	Serial #:	*2149* Customer ID#: *N/A*

NIST Traceable calibration performed to the above instrument per IEST-RP-CC013 and TEC Services' SOP's.

INSTRUMENT DATA

		As Found	Final	Mfg. Tolerances
Straylight	*(N/A)*	*.574%*	*.375%*	Not Applicable
Sample Flow	*(1)*	*29.1*	*29.0*	28.3 ± 2.8 SLPM
V1	*(1)*	*5.15*	*5.15*	5.15V ± .05V
V2	*(1)*	*12.16*	*12.15*	12.0V ± 1V
V3	*(1)*	*-12.17*	*-12.17*	-12.0V ± .5V
V4	*(1)*	*24.09*	*24.10*	24.0V ± .5V
U5	*(1)*	*5.000*	*5.000*	5.000 ± .010V

(1) In Tolerance (2) Out of Tolerance (3) No effect on instrument operation (N/A) Not Applicable
Received in Tolerance: ☒ **Yes** ☐ **No** ☐ **Not Operable**
☐ **Not Applicable – NEW INSTRUMENT**

Calibrated for: ☒ PAO Temperature: *21.4* ° C Relative Humidity: *37.0* %

MAINTENANCE PERFORMED

☒ Clean / Rebuild Chamber ☒ Realign Optics ☒ Flush Hoses
☒ Check Wiring & Hardware ☐ Replace Gaskets ☐ Update Software Version ____
☐ Not Applicable - NEW INSTRUMENT

Notes: ____

FINAL VERIFICATION PERFORMED

☒ Leak Test Sampling System ☐ Test Scanning Probe ☒ Perform Voltage Check
☒ Verify Max Gain Stability ☒ Performance Test

NIST TRACEABLE EQUIPMENT USED

Description	Model	Serial #	Certificate #	Cal Date	Due Date
Digital Multimeter	Fluke 87-V	67030001	U540637-00-01	14 MAR 25	14 MAR 26
Thermohygrometer	Extech 445715	CP244467	1756326	17 MAY 24	17 MAY 25
Flowmeter	TSI 4043	40431911011	N/A	03 OCT 24	03 OCT 25

Calibrated per Procedure: ☒ TEC001 ☐ TEC002 ☒ TEC003 ☐ TEC004 ☒ TEC005
☐ TEC006 ☒ TEC007 ☒ TEC008 ☒ TEC009 ☐ TEC010

CALIBRATION BY: George Bolt DATE: *3/24/25* DUE DATE: *3/24/26*

PARTICLE MEASURING SYSTEMS
a spectris company

5475 Airport Boulevard, Boulder, Colorado 80301-2339
303.443.7100 800.238.1801

ACCREDITED

Certificate of Calibration

Date: Jun-23-2025 05:52:09

Work Order:	526617
Customer Name:	Medrep Tech Inc
Customer Address:	25250 Sandhill Boulevard, Punta Gorda, FL 33983 UNITED STATES
Date Received:	May-19-2025
Calibration Lab:	5475 Airport Boulevard, Boulder, CO 80301

Unit Under Test

Instrument:	LasairIII_310C	Serial Number:	103435
Firmware Version:	PCE: B2B53624 1.9	Calibration Due:	Jun-23-2026

Certification

Particle Measuring Systems certifies that the instrument listed above meets or exceeds manufacturing specifications and meets the requirements of ISO 21501-4:2018. It has been calibrated using equipment and/or standards whose accuracies are traceable to the National Institute of Standards and Technology (NIST), or have been derived from acceptable values of natural physical constants, or by the ratio type of self-calibration. Counting Efficiency determined by digital output.

This instrument was calibrated in accordance with the Particle Measuring Systems quality system documentation which meets ISO 9001:2015 requirements. The results contained within this calibration certificate relate only to the item calibrated. This certificate may not be reproduced, except in full, without written consent from Particle Measuring Systems.

Particle Measuring Systems meets applicable requirements set forth in ISO/IEC 17025:2017 (as accredited by A2LA, certificate # 3962.01). Reported uncertainties have been calculated in accordance with the principals expressed in the GUM and represent expanded uncertainties expressed at approximately the 95% confidence level using a coverage factor of K=2. Expanded uncertainties for 17025 accredited parameters are marked accordingly. Statements of conformity are based upon a binary decision rule, as defined in ILAC G8, where the acceptance limit is equal to the specification limit and a PASS indicates the measured value is within the acceptance limit and a FAIL indicates the measured value is outside the acceptance limit and the associated measurement uncertainty does not exceed the specification limit.

Instrument Condition As Found

☑ In-Tolerance ☐ Out-of-Tolerance ☐ Operational Failure

Condition As Left

☑ In-Tolerance

Calibration Standards

Procedure Used:	2793 G	Program Used:	1000013097 Rev R

Performed by

Technician Name:	Khane Panyachith
Administrator Name:	Calvin Bauge

4UU

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 03640	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Sterile and Non-Sterile Compounding	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #[redacted] ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: TMC Acquisition, LLC dba Tailor Made Compounding

Physical Address: 200 Moore Drive

City: Nicholasville State: KY Zip: 40356

Mailing Address (if different from physical address): Same as physical

City: _____ State: _____ Zip: _____

Telephone: 859-887-0013 Toll Free # (NAC 639.708, NRS 639.23286): 1-844-857-6233

Fax: 859-406-1242 Contact Email: lsparrow@tmcrx.com

Website: www.tailormadecompounding.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Blake McLeod

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21010

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Blake McLeod	NV Pharmacist Registration #: 21010
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Kentucky

Parent Company (if any): Noom Acquisition, LLC

Corporation/Organization Name: TMC Acquisition, LLC dba Tailor Made Compounding

Mailing Address: 200 Moore Drive

City: Nicholasville State: KY Zip: 40356

Telephone: 859-887-0013 Email: lsparrow@tmcrx.com

Contact Person Name: Leslie Sparrow

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

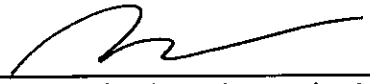
Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Chief Executive Officer (title) for Tailor Made Compounding (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Ross Jordan

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

1/22/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ross Jordan

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1/22/2026

Date

Board Use Only	Date Received: 1/23/26	Amount: 500.00/ V# 1683

Nevada Non-Resident Pharmacy Permit Application

Ownership Information

LLC Owner

Name: Noom Acquisition, LLC

Address: 1 Palmer Square, Suite 441 Princeton, NJ 08542

FEIN: 41-2890353

*The stockholder of the pharmacy is Noom Acquisition, LLC, which owns 100% of the pharmacy. Noom Acquisition, LLC holds 10% or more of the shares.

Officers:

Name: Ross Jordan

Title: Chief Executive Officer, Manager

Business Address: 200 Moore Drive Nicholasville, KY 40356

Name: Blake McLeod

Title: Chief Operating Officer, Pharmacist in Charge

Business Address: 200 Moore Drive Nicholasville, KY 40356

Name: Adam Woomer

Title: Chief Financial Officer

Business Address: 200 Moore Drive Nicholasville, KY 40356

Name: Geoff Cook

Title: Manager

Business Address: 1 Palmer Square, Suite 441 Princeton, NJ 08542

Name: Jean Clifton

Title: Manager

Business Address: 1 Palmer Square, Suite 441 Princeton, NJ 08542

Name: Norman Petty

Title: Manager

Business Address: 1 Palmer Square, Suite 441 Princeton, NJ 08542

Commonwealth of Kentucky
Michael G. Adams, Secretary of State

Michael G. Adams
Secretary of State
P. O. Box 718
Frankfort, KY 40602-0718
(502) 564-3490
http://www.sos.ky.gov

Certificate of Existence

Authentication number: 348651
Visit https://web.sos.ky.gov/ftshow/certvalidate.aspx to authenticate this certificate.

I, Michael G. Adams, Secretary of State of the Commonwealth of Kentucky, do hereby certify that according to the records in the Office of the Secretary of State,

TMC Acquisition, LLC

TMC Acquisition, LLC is a limited liability company duly organized and existing under KRS Chapter 14A and KRS Chapter 275, whose date of organization is October 1, 2020 and whose period of duration is perpetual.

I further certify that all fees and penalties owed to the Secretary of State have been paid; that articles of dissolution have not been filed; and that the most recent annual report required by KRS 14A.6-010 has been delivered to the Secretary of State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my Official Seal at Frankfort, Kentucky, this 31st day of October, 2025, in the 234th year of the Commonwealth.

Michael G. Adams
Secretary of State
Commonwealth of Kentucky
348651/1115094

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler TMC Acquisition, LLC dba Tailor Made Compounding

Pharmacy/Wholesaler License # (if applicable) PH03640

Physical Address 200 Moore Drive

City Nicholasville State KY Zip 40356

Mailing Address (if different from physical address) Same as physical

City _____ State _____ Zip _____

Telephone 859-887-0013 Website www.tailormadecompounding.com

Licensing Company Email lsparrow@tmcrx.com

Section 2: Personal Information

First Blake Middle Edward Last McLeod

Alias(es, nicknames, name changes, etc.) N/A

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Paul G. Blazer High School		08/05-05/09	
Address	City	State	Zip
1500 Blazer Blvd	Ashland	KY	41102
Diploma/Degree obtained, if any			
HIgh School Diploma			

School Name		From - To (MM/YY – MM/YY)	
University of Kentucky		08/09-05/12	
Address	City	State	Zip
410 Administration Dr	Lexington	KY	40506
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
University of Kentucky College of Pharmacy		08/12-05/16	
Address	City	State	Zip
789 S. Limestone St	Lexington	KY	40506
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
05/18-Present				
From - To (MM/YY – MM/YY)				
06/16-05/18				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
Tailor Made Comounding		05/18-Present	
Business Address	**City**	**State**	**Zip**
200 Moore Dr.	Nicholasville	KY	40356
Phone	**Title**	**Number of Employed Hours**	
8598870013	Pharmacist	15,000	

Description of Duties

- Responsible for all operations and personnel of the pharmacy
- Ensure full compliance of USP 795, USP 797, and USP 800
- Responsible for training and educating pharmacists on all requirements, standards, and regulations around USP 795, USP 797, and USP 800

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Blake McLeod, **certify that as the designated representative for**

TMC Acquisition, LLC dba Tailor Made Compounding,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BM I am at least 21 years of age;
3. BM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Blake McLeod

Print Name (First, Last)

Blake McL

Original Signature (electronic, copies or stamps not accepted)

1/22/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Blake McLeod

Print Name (First, Last)

Blake McL

Original Signature (electronic, copies or stamps not accepted)

1/22/24

Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Jessamine

I, Blake McLeod, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Blake McL

Original Signature

1/22/24

Date

Subscribed and Sworn to before me this 22nd day of January.

Leslie Sparrow

Notary Public Signature

LESLIE BROOKE SPARROW
Notary Public
Commonwealth of Kentucky
Commission Number KYNP15150
My Commission Expires Sep 16, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: TMC Acquisition, LLC dba Tailor Made Compounding

NV Pharmacy or Outsourcing facility license # (if applicable): PH03640

Physical Address: 200 Moore Drive

City: Nicholasville State: KY Zip: 40356

Mailing Address (if different from physical address): Same as physical

City: State: Zip:

Telephone: 859-887-0013 Toll Free # (NAC 639.708, NRS 639.23286): 1-844-857-6233

Fax: 859-406-1242 Contact Email: lsparrow@tmcrx.com

Website: www.tailormadecompounding.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Blake McLeod

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21010

Name of Designated Person(s) as defined by revised USP-797 guidelines: Blake McLeod

Email of Designated Person(s): bmcleod@tmcrx.com

Telephone of Designated Person(s): 859-887-0013

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ☐ Category 2 ■ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☐ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? Suite C: 8/20/2025; Suite A: 12/31/2025

6. What is the frequency of the recertification for the ISO classified areas? Biannually

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Not Applicable

10. Will you be performing sterile hazardous drug compounding? ■ Yes No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

See Attachment

12. What laboratory performs your sterility or endotoxin testing?

Name: See Attachment for Laboratories used for sterility and endotoxin testing.

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

13. What is your procedure for visual inspection of compounded sterile products?

TMC SOP 1050 - Review and Release of Product, outlines the procedure for the visual inspection of compounded sterile products. A visual inspection is performed by supervising pharmacists, where the following parameters are reviewed for product evaluation and approval for order fulfillment:
Inspect to ensure the labeling on the product matches the compounding record. Inspect to determine if physical appearance is as defined in the master formulation record. Inspect to ensure the product is free of foreign matter (e.g. particles or fibers), discoloration or other defects. Inspect container closure system for integrity (e.g. leakage, cracks in the container, improper seals).

14. How often do you perform glove fingertip and medial fill testing?

Garbing competency including a gloved fingertip thumb test (GFT), media fill with a post GFT, and surface sample of the direct compounding area are performed quarterly. GFTs post garbing are also performed weekly.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

See Attachment

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

See Attachment

17. Who performs the sterile compounding process at your facility?

Compounding Technicians under the supervision of Laboratory Management and Supervising Pharmacists.

18. Who is responsible and accountable for the sterile compounding process at your facility?

The Pharmacist-in-Charge has overall responsibility for the operation of the facility. Supervising pharmacists are responsible for the direct supervision of sterile compounding. Laboratory management is responsible for the direct oversight of sterile compounding to ensure compliance with applicable standards and regulations.

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

See Attachment.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? An externally vented containment ventilated enclosure (CVE) is used for manipulation, premixing/weighing, of non-sterile components and an externally vented Class II Biological Safety Cabinet (BSC) is used for all sterile operations.		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	■ No
9. If yes, list the name of the device: Not Applicable		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

For sterile compounded products there are three mechanisms for notifying the patient or consumer of the proper handling and disposal of hazardous drugs.

- The immediate container is labeled with the hazardous drug category and instruction to dispose of properly.
- The prescription label also has auxiliary labels that include the hazardous drug category and instruction to dispose of properly.
- A Pharmacy Information sheet is also supplied to the patient with each shipment that provides instructions and considerations for the use of chemotherapy rated gloves. The sheet also provides links to the FDA website for appropriate disposal of medications.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

The training program consists of didactic and performance competency-based activities. The Standard Operating Procedure (SOP) 1046 Hazardous Communication Program provides the general framework for this training, with supporting SOPs and competency training based on specific topics. Topics included below:

- Identification and acknowledgment of Hazardous Drugs (HDs) via and internal NIOSH list.
- Identification of Hazardous drugs via container labels for raw materials and compounded products.
- Identification of areas of the facility where HDs are present.
- Safety Data Sheets (SDS), including location and education of the various sections of the SDS.
- Proper use of Personal Protective equipment
- Proper usage of the Containment Primary Engineering Controls
- Cleaning Requirements and proper technique
- Spill Management
- Waste Management and proper disposal requirements for HDs
- Handling of HDs including potential routes of exposure.
- Response to known or suspected HD exposure.

Individuals are paired with trained staff for demonstration and observation of skills. Trainees are required to perform skills according to defined requirements prior to being able to work independently as verified through observational evaluation. Training activities are repeated annually and are documented in the electronic quality management system.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

See Attachment

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

Sterile compounding technicians are required to perform the following on a quarterly basis: Garbing competency including a gloved fingertip thumb test (GFT), media fill with a post GFT, and surface sample of the direct compounding area. Additionally, a GFT post garbing are performed on a weekly basis for active compounding technicians.

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ■ Yes No

4. What is the frequency for completing volumetric active air sampling?

Air sampling is conducted in compliance with USP <797> for compounding Category 3 sterile products. Identified locations within the ISO 8, ISO 7, and ISO 5 classified areas are sampled monthly.

5. What is the frequency for completing surface sampling? Surface sampling is conducted in compliance with USP <797> for compounding Category 3 sterile products. Identified locations within ISO 8, ISO 7 and ISO 5 classified areas are sampled weekly. Sampling of the direct compounding area is conducted after every batch.		
6. What is the frequency for using sporicidal agents? A Sporicidal agent (PeridoxRTU®) is utilized during weekly and monthly cleaning activities.		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	■ Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	■ Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Blake McLeod

Name of Person who Completed the Form

PIC

Title

Blake McL

Signature (copies or stamps not accepted)

1/22/24

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

TAILOR MADE COMPOUNDING

TMC Acquisition, LLC
dba Tailor Made Compounding
200 Moore Drive
Nicholasville, KY 40356

NEVADA STATE BOARD OF PHARMACY
Sterile Compounding Questionnaire Attachment

TMC Acquisition, LLC dba Tailor Made Compounding; PH03640

Section II
11. List the sterile compounded products that you will be compounding for Nevada patients or consumers.

Estradiol Cypionate (GSO) 10mg/mL Injectable
Glutathione 200mg/mL Injectable
Liraglutide/Glycine 6mg/5mg/mL Innjectable
Methionine/Inositol B12 (Cyanocobalamin) 25mg/50mg/1mg/mL Injectable
Methylcobalamin 10mg/mL Injectable
NAD+ 200mg/mL Injectable
Pentosan Polysulfate Sodium 250mg/mL Injectable
PT-141 (Bremelanotide) 10,000mcg/mL Injectable
Semaglutide 2.5mg/mL Injectable
Semaglutide 5mg/mL Injectable
Semaglutide/Glycine 1mg/5mg/mL Injectable
Semaglutide/Glycine 2.5mg/5mg/mL Injectable
Semaglutide/Glycine 5mg/5mg/mL Injectable
Sermorelin 2000mcg/mL Injectable
Sermorelin/Glycine 2000mcg/5mg/mL Injectable
Testosterone Cypionate (GSO) 200mg/mL Injectable
Testosterone Cypionate (MCT) 200mg/mL Injectable

12. What laboratory performs your sterility and endotoxin testing

Eagle Analytical
11111 S. Wilcrest Drive, Suite 1000
Houston, TX 77099
Phone: 800-745-8916

Prompt Praxis Laboratories
150 N. Fairway Drive, Suite 148
Vernon Hills, IL 60061
Phone: 847-859-3850

15. Describe your initial and ongoing training program for all personnel performing sterile compounding.

The training program consists of didactic and performance competency-based activities based on the Standard Operating Procedures. Individuals are paired with trained staff for demonstration and observation of skills. Trainees are required to perform skills according to defined requirements prior to being able to work independently. Training activities are repeated annually and are documented in an electronic quality management system.

Initial training specific to sterile compounders includes:

- Garbing and Hand hygiene. Garbing assessment is performed in triplicate supported by GFTs with each assessment.
- Cleaning and disinfection of the sterile preparation areas and cleanrooms
- Cleanroom Practices and Sterile Preparation Room Practices, including principles of movement of materials, movement of personnel, proper use of PECs, and principles of HEPA unidirectional airflow within the PECs
- Aseptic technique, including Media Fill completion with a post garbing GFT, post compounding GFT, and a surface sample of the direct compounding area.
- Various equipment SOPs
- Preparation of supplies for sterile compounding including sterilization and depyrogenation processes.
- Performance competency of compounding proactive including documentation of the compounding process, calculations, measuring, mixing.

Ongoing Training

- Garbing competency GFTs are repeated weekly
- Aseptic technique media fill is performed quarterly. This includes a Garbing GFT and a post compounding GFT with a surface sample of the direct compounding surface.
- All other trainings are repeated annually.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Cleaning Solutions

Cleaning, disinfecting solutions used within the PEC, C-PEC, and the SCA are sterile. Lint free wipers are used in application of all solutions.

- Cleaner/disinfecting: Contec® Healthcare TB1-3300™ Disinfectant with a dwell time of one (1) minute. This solution is used for daily cleaning in non-hazardous sterile cleanrooms.

- Sporicidal disinfectant: Contec® PeridoxRTU® with a dwell time of three (3) minutes. This solution is used for weekly and monthly cleanings in the non-hazardous
- Deactivation and decontamination solution: Contec® PeridoxRTU® with a dwell time of three (3) minutes.
- Sterile IPA with a sterility assurance of 10-6 SAL.

After dwell time has passed for each solution, all surfaces are cleaned with sterile 70% IPA.

Cleaning Procedure

- PEC and C-PEC work surfaces are cleaned:
  - Beginning of compounding day
  - Between batches
  - When visibly soiled
  - End of compounding day including the equipment inside the PEC or C-PEC.
- Under C-PEC work surface is cleaned monthly (limited to sterile hazardous compounding as PECs do not have a removable work tray)
- Secondary engineering controls non-hazardous
  - Cleaned daily and weekly including passthroughs, work surfaces outside of the PEC and floors
  - Cleaned monthly including ceilings, walls, doors, doorframes, storage shelving and bins, equipment outside of the PEC.
- Secondary engineering controls hazardous
  - Cleaned daily including passthroughs, work surfaces outside of the PEC and floors
  - Cleaned monthly including ceilings, walls, doors, doorframes, storage shelving and bins, equipment outside of the PEC.

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

The Pharmacy maintains written procedures to ensure compounded medications requiring special handling or temperature control are transported in a manner that preserves product integrity and patient safety. Compounded medications are transported in accordance with TMC SOP 1031 - Transporting of Compounded Products, which defines shipping requirements based on product-specific handling and temperature needs. All medications are secured within a dram or secured external product container to protect the product from leakage or breakage. Temperature studies on final shipping package configuration have been performed to determine suitability of the packaging configuration to maintain appropriate temperature for temperature sensitive products. Packaging configurations include insulated shippers and cold packs used as appropriate. Shipments are labeled with required handling instructions (e.g., "Refrigerate Upon Arrival") and sent via contracted carriers with tracking, with expedited delivery selected for refrigerated products.

Section IV

1. List the specific Category 3 sterile products that your facility compounds.

Estradiol Cypionate (GSO) 10mg/mL Injectable

Glutathione 200mg/mL Injectable

Liraglutide/Glycine 6mg/5mg/mL Innjectable

Methionine/Inositol B12 (Cyanocobalamin) 25mg/50mg/1mg/mL Injectable

Methylcobalamin 10mg/mL Injectable

NAD+ 200mg/mL Injectable

Pentosan Polysulfate Sodium 250mg/mL Injectable

PT-141 (Bremelanotide) 10,000mcg/mL Injectable

Semaglutide 2.5mg/mL Injectable

Semaglutide 5mg/mL Injectable

Semaglutide/Glycine 1mg/5mg/mL Injectable

Semaglutide/Glycine 2.5mg/5mg/mL Injectable

Semaglutide/Glycine 5mg/5mg/mL Injectable

Sermorelin 2000mcg/mL Injectable

Sermorelin/Glycine 2000mcg/5mg/mL Injectable

Testosterone Cypionate (GSO) 200mg/mL Injectable

Testosterone Cypionate (MCT) 200mg/mL Injectable

Kentucky Board of Pharmacy
125 Holmes St.
Frankfort, KY 40601

Inspection Report

Pharmacy

Name: *TMC ACQUISITION LLC* **Permit No.:** *P08150*

Address: *200 MOORE DRIVE, NICHOLASVILLE, KY 40356*

Phone: *(859) 887-0013* **Fax:** *(859) 406-1242* **Email:** *leslie@tailormadecompounding.com*

Current: *Permit,DEA Registration*

Inspection

Date: *05/30/2024* **Time In:** *10:24 AM* **Time Out:** *4:36 PM*

Type: *Routine*

Notes: *Inspection Report 1 of 2. See separate report for sterile compounding inspection.*

Pharmacist and Interns

Zachary Britton
License: *PT00381572* Status: *Active* PIC: *No*

Mary Littral
License: *PT00376177* Status: *Active* PIC: *No*

Thomas Stransky
License: *PT00378424* Status: *Lapsed* PIC: *No*

Garrett Cline
License: *PT00381039* Status: *Active* PIC: *No*

Kaylie N Thornton
License: *PT00377159* Status: *Active* PIC: *No*

Zachary M Marcum
License: *PT00347173* Status: *Active* PIC: *No*

Allison Current
License: *PT00382390* Status: *Active* PIC: *No*

Trinna S Banta
License: *PT00078160* Status: *Active* PIC: *No*

Max McClain

Pharmacist and Interns *(continued)*

License: *PT00369675* Status: *Active* PIC: *No*

Angelia D Shultz
License: *PT00385856* Status: *Active* PIC: *No*

Dalton Newman
License: *PT00373762* Status: *Active* PIC: *No*

Benjamin C Hempfling
License: *PT00386555* Status: *Active* PIC: *No*

Sara M Rodgers
License: *PT00380864* Status: *Lapsed* PIC: *No*

Cody Crank
License: *PT00361631* Status: *Active* PIC: *No*

Nicholas Clark
License: *PT00372185* Status: *Active* PIC: *No*

Tory J Newton
License: *PT00361687* Status: *Active* PIC: *No*

Malaya Turner
License: *PT00374380* Status: *Active* PIC: *No*

MacKaylah Figgs
License: *PT00373763* Status: *Active* PIC: *No*

Cazavion Joiner
License: *PT00382839* Status: *Active* PIC: *No*

michael a anthony
License: *PT00385491* Status: *Active* PIC: *No*

Erica Chambers
License: *PT00385198* Status: *Active* PIC: *No*

Amanda B Culver
License: *PT00361491* Status: *Active* PIC: *No*

Aidan W Green
License: *PT00385857* Status: *Active* PIC: *No*

Nicole Torrance

Pharmacist and Interns *(continued)*

License: *PT00382931* Status: *Active* PIC: *No*

Johanna Taylor Walker

License: *PT00371745* Status: *Active* PIC: *No*

Jeremy Brewer

License: *PT00381943* Status: *Lapsed* PIC: *No*

Nicholas Melgar

License: *PT00033815* Status: *Active* PIC: *No*

Dante Giannone

License: *PT00382623* Status: *Active* PIC: *No*

Joshua Cross

License: *PT00365981* Status: *Lapsed* PIC: *No*

Emily Middleton

License: *PT00382330* Status: *Active* PIC: *No*

Jeffery Corman

License: *PT00349829* Status: *Active* PIC: *No*

Collin A Elrod

License: *PT00385697* Status: *Active* PIC: *No*

Adam Carpenter

License: *PT00366126* Status: *Active* PIC: *No*

Amanda Steinhauser

License: *PT00372186* Status: *Active* PIC: *No*

Sadie Smith

License: *PT00382930* Status: *Lapsed* PIC: *No*

Jaylen Adaway

License: *PT00370058* Status: *Lapsed* PIC: *No*

Jessica Filbin

License: *PT00377974* Status: *Active* PIC: *No*

Zachary Chapman

License: *PT00376178* Status: *Active* PIC: *No*

Michael D Fassio

Pharmacist and Interns *(continued)*

License: *PT00361902* Status: *Active* PIC: *No*

Stacy Fryman

License: *PT00384381* Status: *Active* PIC: *No*

MARY RASCHICK

License: *PT00372706* Status: *Active* PIC: *No*

Shelby M. Dela Cruz

License: *021513* Status: *Active* PIC: *No*

Ross Jordan

License: *PT00368986* Status: *Active* PIC: *No*

Melanie Parrish

License: *PT00381660* Status: *Active* PIC: *No*

Amber Romaine

License: *PT00372184* Status: *Active* PIC: *No*

STACY Y BERTRAM

License: *PT00022209* Status: *Active* PIC: *No*

Caitlyn L Ledford

License: *PT00032670* Status: *Active* PIC: *No*

Cameron Simpson

License: *PT00382214* Status: *Active* PIC: *No*

Shawn Hall

License: *PT00385054* Status: *Active* PIC: *No*

Jennifer Hall

License: *PT00380143* Status: *Active* PIC: *No*

McKayla Scott

License: *PT00382389* Status: *Lapsed* PIC: *No*

ANTHONY SAYLOR

License: *PT00364489* Status: *Active* PIC: *No*

Audra Manning

License: *PT00364188* Status: *Active* PIC: *No*

Valarie Stone

Pharmacist and Interns *(continued)*

License: *PT00381883* Status: *Active* PIC: *No*

Kayla D Jones
License: *PT00361697* Status: *Active* PIC: *No*

Max Mosher
License: *PT00380317* Status: *Active* PIC: *No*

Rachel K. Blackburn
License: *019390* Status: *Active* PIC: *No*

William Callahan
License: *PT00361625* Status: *Active* PIC: *No*

NATHAN A BARB
License: *PT00375920* Status: *Active* PIC: *No*

Ashley Mills
License: *PT00364843* Status: *Active* PIC: *No*

Courtney A Ervin
License: *PT00347650* Status: *Lapsed* PIC: *No*

Lindsey Waford
License: *PT00371028* Status: *Active* PIC: *No*

Kaytlin e Peck
License: *PT00379132* Status: *Active* PIC: *No*

Evelyn Foster
License: *PT00381571* Status: *Active* PIC: *No*

Mark LeBlanc
License: *PT00384301* Status: *Active* PIC: *No*

Jessica S Collins
License: *PT00352506* Status: *Active* PIC: *No*

David McCarty
License: *PT00381392* Status: *Active* PIC: *No*

WILLIAM CODY FOSTER
License: *PT00384414* Status: *Active* PIC: *No*

Paul Joseph Sharpe

Pharmacist and Interns *(continued)*

License: *020950* Status: *Active* PIC: *No*

Tiffany C Teegarden

License: *PT00361901* Status: *Active* PIC: *No*

Ray Solis

License: *PT00385400* Status: *Active* PIC: *No*

Amber L Ritchie

License: *PT00361751* Status: *Active* PIC: *No*

Brian M. Williams

License: *022294* Status: *Active* PIC: *No*

Taryn L Yeast

License: *PT00026216* Status: *Active* PIC: *No*

Jamie Butler

License: *PT00383889* Status: *Active* PIC: *No*

Contessa Small

License: *PT00381391* Status: *Active* PIC: *No*

Morgan Montgomery

License: *PT00381658* Status: *Active* PIC: *No*

CHARITY DORATHEA ANDREWS

License: *012672* Status: *Active* PIC: *No*

ALLYSON L MULKEY

License: *PT00034327* Status: *Active* PIC: *No*

John Macklon Matthews III

License: *023716* Status: *Active* PIC: *No*

ALFONSO BROWN

License: *PT00362847* Status: *Active* PIC: *No*

Ashly C Taylor

License: *PT00361673* Status: *Lapsed* PIC: *No*

April Conn

License: *PT00385221* Status: *Active* PIC: *No*

Adam Woomer

Pharmacist and Interns *(continued)*

License: *PT00366533* Status: *Active* PIC: *No*

Joshua Stewart

License: *PT00368987* Status: *Active* PIC: *No*

RYAN HANEY

License: *I16531* Status: *Intern* PIC: *No*

Alexandra W Gavin

License: *PT00010764* Status: *Active* PIC: *No*

LINDSAY D GIURGEVICH

License: *PT00371484* Status: *Active* PIC: *No*

Austin Corman

License: *PT00356611* Status: *Active* PIC: *No*

anna Williams

License: *PT00346816* Status: *Active* PIC: *No*

Angel Sandusky

License: *PT00381886* Status: *Lapsed* PIC: *No*

Haley R Houp-May

License: *PT00385855* Status: *Active* PIC: *No*

Kristen M Nicholson

License: *PT00243918* Status: *Active* PIC: *No*

Shana Raines

License: *PT00382929* Status: *Active* PIC: *No*

Kristi Sims

License: *PT00382213* Status: *Active* PIC: *No*

Rebecca Fitchett

License: *PT00381019* Status: *Lapsed* PIC: *No*

Debbie Bates

License: *PT00383198* Status: *Lapsed* PIC: *No*

Nicholas Hardin

License: *PT00384927* Status: *Active* PIC: *No*

Deja Thomas

Pharmacist and Interns *(continued)*

License: *PT00361713* Status: *Active* PIC: *No*

John Thornton

License: *PT00382025* Status: *Active* PIC: *No*

Andrea G Williams

License: *PT00370007* Status: *Lapsed* PIC: *No*

Danielle M Walker

License: *PT00379525* Status: *Active* PIC: *No*

Leslie Sparrow

License: *PT00348733* Status: *Active* PIC: *No*

James Bailey

License: *PT00379801* Status: *Active* PIC: *No*

Tara Short

License: *PT00381887* Status: *Active* PIC: *No*

Amy D Kaylor

License: *PT00036262* Status: *Active* PIC: *No*

Tori Giurgevich

License: *PT00381219* Status: *Active* PIC: *No*

Josh Jones

License: *PT00380144* Status: *Active* PIC: *No*

Mason McAuliffe

License: *PT00380421* Status: *Active* PIC: *Na*

Shelby DiLeo

License: *PT00025583* Status: *Active* PIC: *No*

Taylor Adams

License: *PT00372278* Status: *Active* PIC: *No*

Ben Green

License: *PT00385399* Status: *Active* PIC: *No*

CRISTINA MARIE WILLIAMS

License: *019541* Status: *Active* PIC: *No*

Jonathan S Walker

Pharmacist and Interns *(continued)*

License: *PT00386021* Status: *Active* PIC: *No*

Hillary D Fredrick
License: *PT00368691* Status: *Active* PIC: *No*

JINA R GREENHILL
License: *PT00346952* Status: *Active* PIC: *No*

Jordan L Towery
License: *PT00024949* Status: *Active* PIC: *No*

Holly Nance
License: *PT00382331* Status: *Active* PIC: *No*

Stevie Parmley
License: *PT00363490* Status: *Active* PIC: *No*

LEAUNDRA WEST
License: *PT00364562* Status: *Active* PIC: *No*

SAMANTHA THORNTON
License: *PT00368461* Status: *Lapsed* PIC: *No*

Tracy D Ishmael
License: *PT00364553* Status: *Active* PIC: *No*

Joely Foster-Jacobs
License: *PT00378418* Status: *Lapsed* PIC: *No*

Gregory Parsons
License: *PT00377546* Status: *Active* PIC: *No*

JESSICA R JOHNSON
License: *PT00015660* Status: *Active* PIC: *No*

Gary Harris
License: *PT00381885* Status: *Lapsed* PIC: *No*

BLAKE EDWARD McLEOD
License: *018491* Status: *Active* PIC: *Yes*

Savannah Stevens
License: *PT00378735* Status: *Active* PIC: *No*

Anthony D Clayton

Pharmacist and Interns *(continued)*

License: *PT00023668* Status: *Active* PIC: *No*

Natasha R Garrett

License: *PT00119630* Status: *Active* PIC: *No*

Scott A Schrader

License: *PT00361669* Status: *Lapsed* PIC: *No*

Bob McCarty

License: *PT00385291* Status: *Active* PIC: *No*

Pharmacy Area

Reference Material (201 KAR 2:090) Section 1	*Compliant*
Equipment (201 KAR 2:090) Section 2	*Compliant*
Security and Control (201 KAR 2:100)	*Compliant*
Sanitation (201 KAR 2:180)	*Compliant*
Refrigeration (201 KAR 2:090) Section 2 (1)(h)	*Compliant*
Drug Storage (201 KAR 2:180) Section 5	*Compliant*
Exclusive Compounding Area (KRS 217.055(2)) 201 KAR 2:180 Section 1	*Compliant*

General

Valid R.Ph License Displayed (KRS 315.110) (2)	*Compliant*
Valid Pharmacy Permit (KRS 315.035) and KRS 315.020 (add PIC info)	*Compliant*
Valid Intern Registration Identification Card (201 KAR 2:040) Section 4	*Not Inspected*
Valid Technician Registration Displayed: KRS 315.138 (2)	*Compliant*
Records/Computer Records (201 KAR 2:170)	***Noncompliant***

Comments

Not currently signing log to document daily dispensing data reviewed and verified by each pharmacist of record.

Syringe/Needle Register (KRS 217.177)	*N/A*
Outdated Stock Removed (KRS 217.055)	*Compliant*

General *(continued)*

Prescription Labeling Requirements (KRS 217.065) *Not Inspected*

Comments

See comment on compounding inspection report (observed 2 unlabeled prescription vials- each containing capsules- left in tote on pharmacy counter)



Pseudoephedrine Log (KRS 218A.1437) KRS 218A. 1446 *N/A*

Collaborative Care Agreements (201 KAR 2:220) *N/A*

Board Authorized Protocols (201 KAR 2:380) *N/A*

Generic Substitution

Additional Prescription Recordkeeping (KRS 217.822) and 201 KAR 2:280 *Not Inspected*

Generic Drug Sign Posted (KRS 217.830) *Compliant*

Pamphlet (KRS 217.896) *Not Inspected*

Controlled Substances

CII Prescription Requirements (KRS 218A.180) and 902 KAR 55:105 *N/A*

Oral CIII-V Prescription Requirements (KRS 218A.180) and 902 KAR 55:105 *Not Inspected*

Written CIII-V Prescription Requirements (KRS 218A.180) and 902 KAR 55:105 ***Noncompliant***

Comments

Electronic prescriptions not properly received. Must get verbal authorization to dispense CIII-CV drug and maintain record of verbal prescription accordingly.

Purchase Records/DEA 222 Forms (KRS 218A.200) *Not Inspected*

KASPER (902 KAR 55:105, 110) *Compliant*

CII-V Filing Requirements - Prescription/Po: 21 (CFR 1304.04) *Compliant*

Controlled Substances *(continued)*

Exempt CV Register (KRS 218A.190) *N/A*

Biennial Inventory Complete (21 CFR 1304.11) and KRS 218A. 200 (7) *Compliant*

Comments

12/29/23 COB

Power-of-Attorney Current 21 (CFR 1305.05) *N/A*

Inform Public of Proper and Safe Disposal of Controlled Substances (KRS 218A.170(3)(4)) *N/A*

Comments

No controlled substances dispensed by pharmacy are subject to the statutory requirement.

Patient Records/Counseling

Patient Record System (201 KAR 2:210) ***Noncompliant***

Comments

Pharmacy relies on information entered by prescriber and imported from portal regarding patient drug allergies and medical conditions. Pharmacy does not independently verify or gather additional information directly from patient. Information not recorded in separate pharmacy profile. Pharmacy transitioning to new computerized record/dispensing system on 7/15/24.

Patient Recordkeeping (201 KAR 2:210) *Not Inspected*

Drug Utilization Review (201 KAR 2:210) *Not Inspected*

Comments

See previous comment r/t patient record system.

Patient Counseling (201 KAR 2:210) *Not Inspected*

Refused Offers Documented (201 KAR 2:210) *Compliant*

Inspector's Signature

I have completed this inspection in accordance with the statutes and administrative codes.

Jessa Will

Inspector: *Jessica Williams*

Pharmacist's Signature

I have read and understand the statutes and administrative codes. I acknowledge that the items noted in this report have been discussed with me. I understand that if I disagree with any of the deficiencies cited, that I have the right to refute them on this report or and other form that I choose to send to the department.

Blake McLeod

Pharmacist: *BLAKE McLEOD*

Kentucky Board of Pharmacy

125 Holmes St.
Frankfort, KY 40601

Report

Pharmacy

Name: *TMC ACQUISITION LLC* **Permit No.:** *P08150*

Address: *200 Moore Drive, Nicholasville, KY 40356*

Phone: *859-887-0013* **Fax:** *8594061242* **Email:** *leslie@tailormadecompounding.com*

Inspection

Date: *5/30/2024* **Time In:** *10:24 AM* **Time Out:** *4:36 PM*

Type: *Routine*

Notes: *Inspected to USP 797 (2008 revision)*

Pharmacist and Interns

BLAKE MCLEOD

License: *018491* **Status:** *Active* **PIC:** *Yes*

Policies and Procedures

Compounding Personnel Education and Assessment

COMPLIANT

Comments

In process of implementing updated SOP(s) that align with revised USP 797 requirements. SOP effective date 5/30/24.

Personnel Cleansing and Garbing

COMPLIANT

Cleaning and Disinfecting Compounding Area

COMPLIANT

Operation of Isolators

NOT APPLICABLE

Policies and Procedures *(continued)*

Compounding Procedures for In-Process Checks and Final Product Verification

NOT INSPECTED

Ingredient Inspection and Assessment

COMPLIANT

Checks for Compounding Accuracy and Recordkeeping of Compounding Log

NOT INSPECTED

Physical Inspection of CSPs

NOT INSPECTED

Final Check of CSPs Including Labeling

NOT INSPECTED

Maintenance and Assessment of Compounding Equipment

NOT INSPECTED

Assignment of BUDs

NOT INSPECTED

Monitoring of Storage Areas

NOT INSPECTED

Policies and Procedures *(continued)*

Packaging, Handling, Security, Storage, Disposal, Destruction, Transport and Return of CSPs and Supplies

NOT INSPECTED

Quality Assurance Program

NOT INSPECTED

Adverse Events Reporting and Monitoring

NOT INSPECTED

Hazardous and Oncology Drug Handling and Disposal

NOT INSPECTED

Comments

In process of implementing updated SOP(s) that align with revised USP 797 requirements and USP 800.

Sterilization by Steam

NOT INSPECTED

Sterilization by Dry Heat

NOT INSPECTED

Depyrogenation by Dry Heat

NOT INSPECTED

Monitoring of CSPs Dispensed Prior to Sterility Results, including Recall Procedures

NOT INSPECTED

Policies and Procedures *(continued)*

P&P reviewed and revised annually

COMPLIANT

Comments

In process of implementing updated SOP(s) that align with revised USP 797 requirements.

Training and Garbing

Documentation all compounding personnel passed initial and annual/semi-annual written exam for appropriate risk level for cleaning and disinfecting.

COMPLIANT

Comments

Tracking electronically.

Documentation all compounding personnel passed initial and annual/semi-annual written exam for hand hygiene and garbing.

COMPLIANT

Documentation all compounding personnel passed initial and annual/semi-annual written exam for aseptic technique.

COMPLIANT

Visually observed and appropriately documented competencies of cleaning and disinfecting, initially and at the completion of media fill test, and including environmental services, if applicable and when appropriate.

COMPLIANT

Comments

Compliance based on review of ongoing training records. Initial assessment of cleaning/disinfection not provided for JS.

Visually observed and appropriately documented competencies of hand hygiene and garbing, initially with initial gloved fingertip sample with zero growth.

COMPLIANT

Training and Garbing *(continued)*

Visually observed and appropriately documented competencies of hand hygiene and garbing annually/semi-annually done upon completion of aseptic media fill test performed annually/semi-annually with up to 3 total CFUs.

COMPLIANT

Visually observed and appropriately documented competencies of aseptic technique, initially and annually/semi-annually for appropriate risk level under most challenging conditions.

COMPLIANT

Training of any equipment used.

COMPLIANT

Comments

incubator, air sampler

Documentation of immediate reinstruction, reevaluation and retesting of compounding personnel who fail any testing.

NOT INSPECTED

Comments

No failures reported.

Written policy personnel cannot compound if have sunburn, illness, open sores, etc.

COMPLIANT

Personnel remove outer garments, make-up, visible jewelry (hand, wrist, ears, lips, eyebrow piercings).

COMPLIANT

Personnel keep nails short and natural.

COMPLIANT

Garbing

Garb from dirtiest to cleanest, using the line of demarcation appropriately.

COMPLIANT

Performs hand washing appropriately up to the elbows for 30 seconds and uses a nail pick.

COMPLIANT

Use waterless, alcohol based surgical scrub with persistent activity. Has chlorhexidine/emollients: Purell Surgical Scrug; Avagard; Sterillium; Surgicept; Triseptin; Alcare.

COMPLIANT

Sterile gloves donned appropriately.

COMPLIANT

Dispose of gown when leave compounding area or reuse for one shift (nonhazardous).

COMPLIANT

Non-garbed personnel are not entering compounding area.

COMPLIANT

Environment with Ante and Buffer Rooms

Floor is smooth, impervious, free from cracks and crevices, and seams are heat sealed.

COMPLIANT

Environment with Ante and Buffer Rooms *(continued)*

Ceiling tiles are sealed, free from cracks and crevices, and seams where walls and ceiling meet are sealed.

COMPLIANT

Walls are painted with epoxy based paint or other impermeable surface, are smooth, impervious, easily cleanable, and free from cracks and crevices, seams are heat sealed.

COMPLIANT

Non-shedding equipment is used.

COMPLIANT

Limited entry to necessary personnel.

COMPLIANT

Accessories: shelving, chairs, stools, carts easily cleanable and non-permeable, free from cracks and crevices, low particulate generating and limited to necessary equipment in ante and buffer rooms.

COMPLIANT

All items cleaned and disinfected before bringing into buffer room.

COMPLIANT

Ante Room has a sink with hot and cold water and hands dried with lint free non-shedding, disposable paper towels or blow dryer.

COMPLIANT

Environment with Ante and Buffer Rooms *(continued)*

Buffer Room has no sink, drain or water source.

COMPLIANT

Proper utilization of line of demarcation (LOD).

NOT APPLICABLE

HEPA Filters must be on air ducts in the ceiling of ante and buffer rooms.

COMPLIANT

Food, drinks, gum prohibited in compounding area.

COMPLIANT

If LAFW Blower turned off, must run for 30 minutes before using.

NOT INSPECTED

If no physical barrier between the buffer and ante rooms, only performing low and medium risk sterile compounding.

NOT APPLICABLE

If no physical barrier between the buffer and ante rooms, air velocity is at least 40 feet/minute continuously from buffer area across LOD into ante area.

NOT APPLICABLE

Environment with Ante and Buffer Rooms *(continued)*

If no physical barrier between the buffer and ante rooms, air velocity is recorded every shift, a minimum of daily.

NOT APPLICABLE

Pressure is recorded each shift, a minimum of daily.

COMPLIANT

Ante room is positive pressure of at least 0.02 inch water column to general pharmacy.

COMPLIANT

Buffer room is positive pressure of at least 0.02 inch water column to ante room.

COMPLIANT

Temperature is recorded daily.

COMPLIANT

Temperature of buffer room is appropriate.

COMPLIANT

Controlled storage areas for room temperature is 68 to 77 F or 20 to 25 C.

COMPLIANT

Comments

Some temp readings <68F in negative pressure buffer room. Refer to component labels/COA to verify storage conditions are appropriate.

Controlled storage area for cold temperature is 36 to 46 F or 2 to 8 C.

COMPLIANT

Environment with Ante and Buffer Rooms *(continued)*

Controlled storage area for freezer temperature is -13 to 14 F or -25 to -10 C.

NOT INSPECTED

Components store in appropriate humidity, recommended 35% to 60%.

COMPLIANT

Cleaning

Personnel appropriately garbed when cleaning.

COMPLIANT

Comments
Based on SOP and verbal description of process by technician.

Cleaning and disinfecting agent (may be one step cleaning and disinfecting) appropriate for bacteria, viruses, fungi.

COMPLIANT

Cleaning equipment is non-shedding, disposable or dedicated.

COMPLIANT

Daily cleaning of compound area takes place when no compounding is occurring and includes easily cleanable surfaces including counter tops, pass through, etc. and floors.

COMPLIANT

Monthly cleaning of compound area takes place when no compounding is occurring and includes everything in compound area – bins, equipment, ceiling, walls and floor.

COMPLIANT

Cleaning *(continued)*

Cleaning of ISO Class 5 PEC is documented each shift, a minimum of daily.

COMPLIANT

Uses low linting towels to clean ISO Class 5 PEC.

COMPLIANT

Uses germicidal detergent diluted with sterile water if not ready to use, to clean each shift or daily.

COMPLIANT

ISO Class 5 PEC is disinfected between compounding activities.

COMPLIANT

Comments

Based on SOP and verbal description of process by technician.

ISO Class 5 PEC is wiped with sterile water followed by disinfectant after spills or surface contamination.

COMPLIANT

70% sIPA allowed to remain in contact with surface for 30 seconds before compounding.

COMPLIANT

PEC cleaned in correct order of top ,back, sides, racks/poles, items on deck, deck.

COMPLIANT

Comments

Based on SOP and verbal description of process by technician.

Environmental Monitoring: Certification of Ante and Buffer Rooms

All ISO Class 5 PEC and ISO Class 7 and/or ISO Class 8 rooms have been certified as required.

COMPLIANT

Review report from certifier.

Certifier: *Air Source*

COMPLIANT

Date: *4/23/24*

Certification done to CETA guidelines, CAG-003-2006, or similar.

COMPLIANT

Certifier's equipment calibrated to manufacturer standards.

COMPLIANT

Ante room has HEPA filtered air certified to ISO Class 8 for non-hazardous compounding.

COMPLIANT

Ante room has HEPA filtered air certified to ISO Class 7 for hazardous compounding.

COMPLIANT

Buffer room has HEPA filtered air certified to ISO Class 7.

COMPLIANT

ISO Class 7 ante room, minimum of 30 ACPH.

ACPH: *34, 82*

ISO Class 7 ante room, minimum of 30 ACPH. *(continued)*

COMPLIANT

ISO Class 8 ante room, recommended 20 ACPH.

ACPH:

NOT APPLICABLE

ISO Class 7 non-hazardous buffer room, minimum of 30 ACPH with at least 15 from outside source.

ACPH: *280, 273, 150*

COMPLIANT

ISO Class 7 hazardous buffer room, minimum of 30 ACPH.

ACPH: *57*

COMPLIANT

Smoke test performed in PEC in direct compounding area to demonstrate unidirectional airflow under dynamic conditions.

COMPLIANT

Differential pressure measured to be at least positive 0.02 inch water column from ante room to general pharmacy with door closed.

COMPLIANT

Differential pressure measured to be at least positive 0.02 inch water column from buffer room to ante room with door closed.

COMPLIANT

Environmental Monitoring: Certification of Ante and Buffer Rooms *(continued)*

Differential pressure measured to be at least negative 0.01 inch water column from buffer room to positive pressure ISO 7 ante room with door closed.

COMPLIANT

If no physical separation of ante and buffer room, displacement airflow measured requiring air velocity of 40 feet/minute or more from buffer area across LOD into ante room.

NOT APPLICABLE

ISO Class 5 areas not more than 3,520 particles per cubic meter of air, taken under dynamic conditions.

COMPLIANT

ISO Class 7 areas not more than 352,000 particles per cubic meter of air, taken under dynamic conditions.

COMPLIANT

ISO Class 8 areas not more than 3,520,000 particles per cubic meter of air, taken under dynamic conditions.

COMPLIANT

Comments

Pre-ante room (work room)

Room HEPA filters leak tested and repaired if needed.

COMPLIANT

PEC HEPA filters leak tested and repaired if needed.

COMPLIANT

Environmental Monitoring: Certification of Ante and Buffer Rooms *(continued)*

PEC airflow velocity measured.

COMPLIANT

Documentation of viable air and surface sampling shall include date and time of sampling.

COMPLIANT

Documentation of viable air and surface sampling shall include sampling shall include sample locations.

COMPLIANT

Documentation of viable air and surface sampling shall include method of collection.

COMPLIANT

Documentation of viable air and surface sampling shall include frequency of sampling.

COMPLIANT

Documentation of viable air and surface sampling shall include volume of air sampled.

COMPLIANT

Documentation of surface sampling shall include size of surface sampled, 24-30 cm2.

COMPLIANT

Environmental Monitoring: Certification of Ante and Buffer Rooms *(continued)*

Documentation of viable air and surface sampling shall include time of day in relationship to compounding.

COMPLIANT

Documentation of viable air and surface sampling shall include action levels.

COMPLIANT

Viable air sampling performed using active impaction device with appropriate growth media to support bacteria and for high risk compounding fungus, at least every 6 months in all ISO classified areas using 400 – 1000 L of air per sample.

COMPLIANT

Viable air microbial action levels for ISO Class 5: 1000 liters > 1 CFU/m3 or 400 liters > 1CFU/m3.

COMPLIANT

Viable air microbial action levels for ISO Class 7: 1000 liters, > 10 CFU/m3 or 400 liters, > 4CFU/m3

COMPLIANT

Viable air microbial action levels for ISO Class 8: 1000 liters, > 100 CFU/m3 or 400 liters, > 40 CFU/m3

COMPLIANT

Environmental Monitoring: Certification of Ante and Buffer Rooms *(continued)*

Viable surface sampling performed periodically on direct compounding areas, buffer and ante rooms, pass thru and surfaces likely to be contaminated, as applicable, using media supplemented with neutralizing effects of disinfecting agents (TSA with lecithin & Polysorbate 80) and done at the conclusion of compounding.

COMPLIANT

Comments

Must sample p/t if utilized in compounding workflow.

Surface microbial action levels for ISO Class 5, less than 3 CFU/m3.

COMPLIANT

Surface microbial action levels for ISO Class 7, less than 5 CFU/m3.

COMPLIANT

Surface microbial action levels for ISO Class 8, less than 100 CFU/m3.

COMPLIANT

All CFUs analyzed down to the genus with mold, yeast, coagulase positive Staph, gram negative rods requiring immediate Investigation.

COMPLIANT

Comments

per certifier

Exceeded action levels should prompt a re-evaluation of adequacy of personnel work practices, cleaning, operational procedures and/or air efficiency and require an investigation into the source of contamination.

NOT INSPECTED

Comments

Action levels not exceeded.

Environmental Monitoring: Certification of PEC

All ISO Class 5 PECs have been certified as required.

NOT APPLICABLE

Review report from outside agency.

NOT APPLICABLE

Certification done to CETA guidelines, CAG-003-2006, or similar.

NOT APPLICABLE

Certifiers equipment calibrated to manufacturer standards.

NOT APPLICABLE

Smoke test performed in PEC in direct compounding area to demonstrate unidirectional airflow under dynamic conditions.

NOT APPLICABLE

Differential pressure measured to be at least 0.02 inches water column from ante chamber to general pharmacy area.

NOT APPLICABLE

Differential pressure measured to be at least 0.02 inches water column from main chamber to ante chamber.

NOT APPLICABLE

Environmental Monitoring: Certification of PEC *(continued)*

ISO Class 5 areas not more than 3,520 particles per cubic meter of air, taken under dynamic conditions.

NOT APPLICABLE

PEC HEPA filters leak tested and repaired if needed.

NOT APPLICABLE

PEC airflow velocity measured.

NOT APPLICABLE

Documentation of viable air and surface sampling shall include date and time of sampling.

NOT APPLICABLE

Documentation of viable air and surface sampling shall include sample locations.

NOT APPLICABLE

Documentation of viable air and surface sampling shall include method of collection.

NOT APPLICABLE

Documentation of viable air and surface sampling shall include frequency of sampling.

NOT APPLICABLE

Documentation of viable air sampling shall include volume of air sampled.

NOT APPLICABLE

Environmental Monitoring: Certification of PEC *(continued)*

Documentation of surface sampling shall include size of surface sampled, 24-30 cm2.

NOT APPLICABLE

Documentation of viable air and surface sampling shall include time of day in relationship to compounding.

NOT APPLICABLE

Documentation of viable air and surface sampling shall include action levels.

NOT APPLICABLE

Viable air sampling performed using active impaction device with appropriate growth media to support bacteria and for high risk compounding fungus, at least every 6 months in all ISO classified areas using 400 – 1000 liters of air per sample.

NOT APPLICABLE

Viable air microbial action levels for ISO Class 5: 1000 liters > 1 CFU/m3 or 400 liters > 1CFU/m3.

NOT APPLICABLE

Viable surface sampling performed periodically on direct compounding areas using media supplemented with neutralizing effects of disinfecting agents (TSA with lecithin & Polysorbate 80) and done at the conclusion of compounding.

NOT APPLICABLE

Surface microbial action levels for ISO Class 5, less than 3 CFU/m3.

NOT APPLICABLE

Environmental Monitoring: Certification of PEC *(continued)*

All CFUs analyzed down to the genus with mold, yeast, coagulase positive Staph, gram negative rods requiring immediate investigation.

NOT APPLICABLE

Exceeded action levels should prompt a re-evaluation of adequacy of personnel work practices, cleaning, operational procedures and/or air efficiency and require an investigation into the source of contamination.

NOT APPLICABLE

Compounding Procedures

Documentation of equipment maintenance and calibration logs.

NOT INSPECTED

Objects that shed prohibited from buffer room or compounding area of CAI/CACI: pencils, cardboard, paper towels, cotton gauze pads.

COMPLIANT

Essential paper products (syringe overwrap, work records in protective plastic sleeves) are wiped down with 70% sIPA in ante room before bringing into buffer room or before placing in the ante chamber of CAI/CACI.

NOT INSPECTED

Required supplies wiped down with 70% sIPA (or removing outer wrap) as item introduced into aseptic work space.

COMPLIANT

Compounding Procedures *(continued)*

Syringes, needles, tubing opened only In ISO Class 5 PEC.

COMPLIANT

Personnel use correct aseptic technique, compounding in first air.

COMPLIANT

Personnel routinely inspecting sterile gloves for wear and tear and replace as necessary.

NOT INSPECTED

Personnel routinely disinfecting sterile gloves with 70% sIPA prior to entering and when re-entering ISO Class 5 area and touching non-sterile objects.

COMPLIANT

Personnel ascertain CSP ingredients are correct by looking at label and doing unit by unit inspection of product before using.

COMPLIANT

Rubber stoppers of vials/bottles and ampules disinfected with 70% sIPA prior to introducing needle/breaking ampule, waiting 10 seconds for 70% sIPA to dry.

NOT INSPECTED

Contents thoroughly mixed and inspected for particulate matter, incompatibility or other issues.

NOT INSPECTED

Compounding Procedures *(continued)*

Before dispensing CSP, clarity is visually confirmed. Identity and amounts of ingredients, procedures to prepare, sterilize, and specific release criteria are reviewed to assure accuracy and completeness.

COMPLIANT

Comments
per compounding record

Opened single dose ampules must be discarded immediately.

NOT APPLICABLE

Single dose containers opened in worse than ISO Class 5 used within 1 hour then discarded, with time first used/discard time documented on container.

NOT APPLICABLE

Single dose containers opened in ISO Class 5 used within 6 hours then discarded, with time first used/discard time documented on container.

NOT INSPECTED

MDV used for 28 days, or as specified by manufacturer, once punctured, with date first used/discard date documented on MDV.

NOT INSPECTED

Compound record is required.

COMPLIANT

Appropriate procedures and packaging followed for each step.

COMPLIANT

Comments
per compounding record

Compounding Procedures *(continued)*

Pharmacist verification of steps performed by technicians by visual inspection.

NOT INSPECTED

Comments

Part of final verification. Discussed procedure for in-process checks by pharmacist.

Documentation of compounding accuracy by 2nd person in addition to compounder if more than one person is compounding, to ensure proper measurement, reconstitution, component usage.

NOT INSPECTED

Name and quantity of each component on batch labels.

COMPLIANT

Date and time preparation compounded (may be internal reference number) on batch labels.

COMPLIANT

Verifying pharmacist identifier on batch labels.

COMPLIANT

BUD on batch labels. Cannot use exp/expiration. May use: Use Before/Discard After/Administer By, etc.

COMPLIANT

Auxiliary labels, ie packaging and labeling of hazardous CSP, on batch lables.

COMPLIANT

Compounding Procedures *(continued)*

Standard label requirements on patient specific labels to include date of dispensing, and pharmacy name, address if CSP will leave the premises.

COMPLIANT

Verifying pharmacist identifier on patient specific labels.

COMPLIANT

BUD on patient specific labels. Cannot use exp/expiration. May use: Use Before/Discard After/Administer By, etc.

COMPLIANT

Flow rate, if applicable, on patient specific labels.

NOT APPLICABLE

Auxiliary labels, ie packaging & labeling of hazardous CSP, on patient specific labels.

COMPLIANT

Directions for use, including infusion rate, on patient specific labels.

COMPLIANT

Required controlled substances transfer warnings, where applicable, on patient specific labels.

NOT INSPECTED

Compounding Procedures *(continued)*

Identity of dispensing pharmacist on patient specific labels.

COMPLIANT

Storage requirements, when applicable, on patient specific labels.

COMPLIANT

If redispense CSPs, must ensure sterility, purity and stability of CSP and BUD cannot be changed unless retested.

NOT APPLICABLE

Check for container and closure integrity, done after compounding and if stored, before dispensing.

COMPLIANT

Comments

Verbolized process. Specify visuol verificotion procedure for CSPs dispensed from anticipatory stock in SOP (see 201 KAR 2:076 Sec 5 (4)).

Compounding accuracy documented by verification of steps.

COMPLIANT

Comments

per compounding record. See previous comment r/t in-process checks by pharmacist.

Verification of identity and quantity verified by reconciliation of components.

COMPLIANT

Labels verified as being correct.

COMPLIANT

Continuous Quality Improvement

Share data with staff.

COMPLIANT

Track and trend data.

COMPLIANT

Track complaints from patients and practitioners.

COMPLIANT

Formalized in writing.

NOT INSPECTED

Comments

In process of implementing updated SOP(s) to align with revised USP 797 requirements.

Consideration of all aspects of preparation and dispensing including environmental testing and verification of results.

NOT INSPECTED

Comments

In process of implementing updated SOP(s) to align with revised USP 797 requirements.

Description of specific monitoring and evaluation activities.

NOT INSPECTED

Comments

In process of implementing updated SOP(s) to align with revised USP 797 requirements.

Specification of how results are to be reported and evaluated.

NOT INSPECTED

Comments

In process of implementing updated SOP(s) to align with revised USP 797 requirements.

Continuous Quality Improvement *(continued)*

Identification of appropriate follow-up mechanisms when action limits or thresholds are exceeded.

NOT INSPECTED

Comments

In process of implementing updated SOP(s) to align with revised USP 797 requirements.

Delineation of the individuals responsible for each aspect of the program.

NOT INSPECTED

Comments

In process of implementing updated SOP(s) to align with revised USP 797 requirements.

Sterile Compounding of Hazardous Drugs

Personnel who handle, dispose or compound HD are trained and competency is assessed prior to handling HD and annually thereafter. Training shall be a didactic overview and verified by testing specific HD preparation techniques.

NOT INSPECTED

Personnel who compound HD shall be trained in storage, handling and disposal.

NOT INSPECTED

Personnel who compound HD shall be trained in safe aseptic manipulation practices.

NOT INSPECTED

Personnel who compound HD shall be trained in negative pressure techniques when utilizing BSC or CACI.

NOT INSPECTED

Personnel who compound HD shall be trained in correct use of Closed-System Transfer Devices (CSTD), if applicable.

NOT APPLICABLE

Sterile Compounding of Hazardous Drugs *(continued)*

Personnel who compound HD shall be trained in containment, cleanup and disposal for breakages and spills.

NOT INSPECTED

Personnel who compound HD shall be trained in treatment of personnel contact and inhalation exposure.

NOT INSPECTED

Written confirmation by all compounding personnel of reproductive capability that they understand the risks of handling HD.

COMPLIANT

HD are handled with caution at all times using chemo rated gloves during receiving, distributing, stocking, inventorying, preparing for administration, and disposal.

NOT INSPECTED

Personal compounding equipment (PPE) includes gowns with low permeability like polyethylene.

COMPLIANT

Personal compounding equipment (PPE) includes face masks.

COMPLIANT

Personal compounding equipment (PPE) includes eye protection, as appropriate.

COMPLIANT

Sterile Compounding of Hazardous Drugs *(continued)*

Personal compounding equipment (PPE) includes hair covers.

COMPLIANT

Personal compounding equipment (PPE) includes shoe covers or dedicated shoes.

COMPLIANT

Personal compounding equipment (PPE) includes double gloving with chemo rated gloves, with outer glove being sterile.

COMPLIANT

HD CSP are compounded in a BSC or CACI.

COMPLIANT

BSC or CACI is located inside an ISO Class 7 area that is physically separate from other areas and is negative pressure of 0.01 inch water column to adjacent positive pressure ISO Class 7 ante room.

COMPLIANT

Documentation from CACI manufacturer that the ISO Class 5 environment is maintained under dynamic conditions when not located in an ISO Class 7 environment but must be in a negative pressure room with at least 12 ACPH.

NOT APPLICABLE

For low volume exemption, defined by KBOP as 5 HD CSPs/2 week period, may use 2 levels of containment.

NOT APPLICABLE

Sterile Compounding of Hazardous Drugs *(continued)*

Documentation from manufacturer of recovery time to achieve ISO Class 5 air quality of CACI when turning off/on and when transferring material from ante chamber to main chamber before and during compounding.

NOT APPLICABLE

CACI located in low traffic area.

NOT APPLICABLE

For CACI, pressures recorded each shift, minimum of daily. Main chamber is at least negative 0.01 inch water column to ante chamber and ante chamber is at least positive 0.02 inch water column to general pharmacy.

NOT APPLICABLE

PEC cleaned daily/each shift in correct order of top, back, sides, racks/poles, front inside of BSC shield or CACI, gauntlets in CACI, items on deck, deck, CACI ante chamber in the same order,

COMPLIANT

Comments

Based on SOP and verbal description of process by technician.

HD shall be stored separately from other inventory.

COMPLIANT

HD disposed of in a manner that complies with all Federal and State laws.

NOT INSPECTED

12 Hour BUD

Compounded in an ISO Class 5 LAFW not located in ISO Class 7 room.

NOT APPLICABLE

Low risk, non-hazardous, patient specific CSP.

NOT APPLICABLE

BUD 12 hours or less, administration begins no later than 12 hours from beginning of compounding.

NOT APPLICABLE

Personnel gowns and garbs the same as for a clean room.

NOT APPLICABLE

Cleaning of ISO Class 5 LAWF is the same as for an ISO Class 5 LAWF in clean room.

NOT APPLICABLE

ISO Class 5 LAWF is segregated compounding area, not near garbage can, sink, window, door.

NOT APPLICABLE

Immediate use

Compounding does not take place in ISO Class 5 PEC.

NOT APPLICABLE

Immediate use *(continued)*

Low risk, non-hazardous CSP.

NOT APPLICABLE

Compounding procedure is continuous not exceeding 1 hour & administration begins no later than 1 hour from start of compounding, if not CSP is discarded.

NOT APPLICABLE

During compounding, aseptic technique is followed and if not immediately administered the CSP is under continuous supervision to minimize contact with non-sterile items.

NOT APPLICABLE

CSP is immediately and completely administered by compounder or witnessed by compounder, if not must be labeled with patient identifier, names and amounts of all components, name or initials of compounder, and exact 1-hour BUD and time.

NOT APPLICABLE

CAI not Located in ISO Class 7

Documentation from CAI manufacturer the ISO Class 5 environment is maintained under dynamic conditions when not located in an ISO Class 7 environment.

NOT APPLICABLE

Documentation from CAI manufacturer of recovery time to achieve ISO Class 5 air quality when turn off and on and when transferring material from ante chamber to main chamber before and during compounding.

NOT APPLICABLE

CAI not Located in ISO Class 7 *(continued)*

CAI located in low traffic area.

NOT APPLICABLE

Documentation from CAI manufacturer compounder is exempt from garbing.

NOT APPLICABLE

CAI Pressures documented each shift, minimum of daily. Main chamber at least positive 0.02 inch water column to ante chamber and ante chamber at least positive 0.02 inch water column to general pharmacy.

NOT APPLICABLE

Daily/shift documented cleaning of CAI, in the following order: top, back, sides, racks/poles, inside front, gauntlets, items on deck, deck, and ante chamber in same order.

NOT APPLICABLE

Personnel appropriately garbed while cleaning CAI.

NOT APPLICABLE

All items cleaned and disinfected before placing in ante chamber of CAI.

NOT APPLICABLE

Temperature is recorded daily.

NOT APPLICABLE

CAI not Located in ISO Class 7 *(continued)*

Controlled storage areas for room temperature is 68 to 77 F or 20 to 25 C.

NOT APPLICABLE

Controlled storage area for cold temperature is 36 to 46 F or 2 to 8 C.

NOT APPLICABLE

Controlled storage area for freezer temperature is -13 to 14 F or -25 to -10 C.

NOT APPLICABLE

High Risk

Active Pharmaceutical Ingredient (API): Certificate of Analysis on file.

COMPLIANT

Active Pharmaceutical Ingredient (API): Use USP or NF product and if not, safety and purity established.

COMPLIANT

Comments

per SOP

Active Pharmaceutical Ingredient (API): Label bears batch or lot number.

COMPLIANT

Active Pharmaceutical Ingredient (API): Label bears expiration date, if not, an expiration date of no more than 1 year from date of receiving is assigned.

COMPLIANT

High Risk *(continued)*

Pharmacy marks API with date received.

COMPLIANT

If pharmacy puts API in smaller container for ease of use, container bears name of API.

NOT INSPECTED

If pharmacy puts API in smaller container for ease of use, container bears date API was received.

NOT INSPECTED

If pharmacy puts API in smaller container for ease of use, container bears date API was transferred.

NOT INSPECTED

If pharmacy puts API in smaller container for ease of use, container bears batch or lot number of API.

NOT INSPECTED

If pharmacy puts API in smaller container for ease of use, container bears expiration date from manufacturer or pharmacy assigned expiration date of no more than 1 year from date of receiving.

NOT INSPECTED

APIs stored in tightly closed containers under temperature, humidity and lighting conditions per official monograph or suppliers.

COMPLIANT

Comments

See comment in previous section r/t storoge of components in negative pressure buffer room.

High Risk *(continued)*

Pre-sterilization procedures for high risk CSP, weighing and mixing, shall be completed in no worse than ISO Class 8 environment.

COMPLIANT

Appropriate sterilization methods used and documented.

COMPLIANT

Terminal sterilization of non-sterile empty vials or stoppers/closures used and documented.

COMPLIANT

Pre-filter with 1.2 micron to remove large particles, if needed.

NOT INSPECTED

Filtration performed in ISO Class 5 environment.

COMPLIANT

Documentation 0.2/ 0.22 micron sterile, non-pyrogenic microporous membrane filter is chemically/physically compatible with CSP.

COMPLIANT

Filtration is completed rapidly without filter replacement.

NOT INSPECTED

Comments

Did not observe filtration process.

Filter integrity testing is performed and documented for each filter used with each batch sterilized by filtration.

COMPLIANT

Written documentation of description of steam sterilization includes conditions and duration for specific CSP.

NOT APPLICABLE

Comments

No CSPs are steam sterilized.

Prior to sterilizing, plastic, glass and metal devices are tightly wrapped in low particle shedding paper or fabric or sealed in envelopes that prevent post-sterilization microbial penetration.

COMPLIANT

Autoclave allowed to reach 121 C before starting sterilization process.

COMPLIANT

Usual expose to 121 C at 15 psi for 20 – 60 minutes. Maintains log of temperature and exposure time for each steam sterilized CSP.

COMPLIANT

Ensures steam contacts all ingredients and surfaces to be sterilized.

NOT INSPECTED

Comments

Did not observe loading of autoclave.

Autoclave was mapped.

NOT INSPECTED

High Risk *(continued)*

Effectiveness of steam sterilization is verified each time using biological indicators (BI) and temperature-sensing devices.

COMPLIANT

For dry heat sterilization, heat filtered air is evenly distributed throughout the chamber with a blower.

COMPLIANT

Dry heat oven is equipped with system for controlling temperature and exposure period and has been mapped.

COMPLIANT

Comments

Did not review mapping documentation.

Sufficient space is left between materials to allow circulation of hot air.

NOT INSPECTED

Comment

Did not observe loading of oven.

Written documentation of description of dry heat includes conditions and duration for specific CSP.

COMPLIANT

Effectiveness of dry heat sterilization is verified each time using biological indicators (BI) and temperature-sensing devices.

COMPLIANT

For depyrogenation by heat used to render glassware, containers, vials free from pyrogens and viable microbes. Cover tightly with aluminum foil, bake at 250 C for 30 minutes, use immediately or if stored must be ISO Class 7 environment.

COMPLIANT

High Risk *(continued)*

For depyrogenation by heat written documentation of description of cycle and duration for specific load items.

COMPLIANT

For depyrogenation by heat effectiveness of cycle is verified using Endotoxin Challenge Vials (ECVs) with bacterial endotoxin testing performed on ECVs to verify the cycle is capable of achieving a 3 log reduction in endotoxins.

NOT INSPECTED

If depyrogenated glassware, containers, and/or vials are not used immediately, must be kept tightly covered with aluminum foil and stored in an ISO 7 environment.

NOT APPLICABLE

Other methods of sterilization are used with documented procedures and validation performed.

NOT APPLICABLE

Extending BUD and Sterility Testing

Sterility testing for both bacteria and fungus performed each time BUD is extended beyond USP guidelines.

COMPLIANT

Sterility testing performed on high risk CSP prepared in groups of more than 25 identical containers.

COMPLIANT

Extending BUD and Sterility Testing *(continued)*

Sterility testing performed on high risk CSP exposed longer than 12 hours at 2-8C (36-46F) or longer than 6 hours at warmer than 8C (46F) before sterilization.

NOT INSPECTED

Sterility testing is done using membrane filtration (preferred method) or direct inoculation per USP <71>.

COMPLIANT

Appropriate number of CSPs tested for sterility per UPS <71> for parenterals: less than 100 units, test 10% or 4 units, whichever is greater; for 100-500 units, test 10 units; and for greater than 500 units, test 2% or 20 units, whichever is less.

COMPLIANT

Appropriate number of CSPs tested for sterility per UPS <71> for large volume parenterals: 2% or 10 containers, whichever is less.

NOT INSPECTED

Appropriate number of CSPs tested for sterility per UPS <71> for non-parenterals (eye drops, inhalations): less than 200 units, test 5% or 2 units, whichever is greater; for 200 or more units, test 10 units; and if packaged as unit dose, use parenteral testing numbers.

NOT INSPECTED

Bacterial endotoxin testing performed on high risk CSP if prepared in groups of more than 25 identical containers.

COMPLIANT

Extending BUD and Sterility Testing *(continued)*

Bacterial endotoxin testing performed on high risk CSP if exposed longer than 12 hours at 2-8C (36-46F) or longer than 6 hours at warmer than 8C (46F) before sterilization.

NOT INSPECTED

CSP quarantined until results of sterility and endotoxin tests received or if dispensed before receiving results, written procedure requiring daily observation of incubating CSPs and immediate recall when evidence of growth. Patient and prescriber notified of potentially contaminated CSP and potential risk.

COMPLIANT

Comments

Discussed requirement for daily observation of samples by contract lab during incubation.

Positive sterility test results promptly investigated including aseptic technique, environmental control, etc. to identify source of contamination and correct the issue.

COMPLIANT

Stability data documented to support extended BUD, either from literature or testing.

NOT INSPECTED

Method suitability test performed on CSP for stability data derived from testing.

NOT INSPECTED

If potency testing is performed, strength must be within 10% of stated potency.

COMPLIANT

Transporting CSP Outside Facility

P&P for packing containers specifying which to use.

COMPLIANT

Transporting CSP Outside Facility *(continued)*

P&P for insulating and stuffing materials specifying which to use.

COMPLIANT

Written instructions to patients how to safely open containers of CSP.

COMPLIANT

Ascertain temperature of CSP during transit.

NOT INSPECTED

Specific handling and exposure instructions on the exteriors of containers packed with CSPs.

COMPLIANT

Periodic review of delivery performance of couriers to ascertain CSPs are being efficiently and properly transported.

COMPLIANT

Provide CSP labeling that includes clearly readable BUDs, storage instructions, and disposal information for out of date units.

COMPLIANT

Ascertain each patient is able to store CSP properly, including use of properly functioning refrigerator or freezer if needed.

NOT INSPECTED

Board Approved Waivers

Board has approved a waiver for non-hazardous sterile compounding.

NOT APPLICABLE

Board has approved a waiver for hazardous sterile compounding.

NOT APPLICABLE

Inspector's Signature

I have completed this inspection in accordance with the statutes and administrative codes.

Jessica Williams

Inspector: Jessica Williams

Pharmacist's Signature

I have read and understand the statutes and administrative codes. I acknowledge that the items noted in this report have been discussed with me. I understand that if I disagree with any of the deficiencies cited, that I have the right to refute them on this report or and other form that I choose to send to the department.

system issue - signature unavailable

Pharmacist: *Blake McLeod*

TAILOR MADE COMPOUNDING

TMC Acquisition, LLC
dba Tailor Made Compounding
200 Moore Drive
Nicholasville, KY 40356

6/10/2024

Kentucky Board of Pharmacy
125 Holmes Street, Suite 300
Frankfort, KY 40601
Attn:

Sent via email to : jessica.williams@ky.gov

RE: P08150 - TMC Acquisition LLC 5/30/2024 Onsite Inspection Corrective Actions

Inspector Williams,

Please see the requested information and outlined proposed corrective action in response to the 5/30/2024 onsite General Pharmacy Inspection Report noncompliant observations for Permit No.: P08150, TMC Acquisition LLC dba Tailor Made Compounding.

General:

- Records/Computer Records (201 KAR 2:170)
    - Comments: Not currently signing log to document daily dispensing data reviewed and verified by each pharmacist of record.

The Pharmacy now has a report automatically generated daily and emailed to the pharmacists each morning showing the number of records verified by each pharmacist from the previous business day. This report is printed and signed by each pharmacist who verified prescriptions the previous business day and then stored in a binder within the Dispensary.

- Prescription Labeling Requirements (KRS 217.065)
    - See comment on compounding inspection report (observed 2 unlabeled prescription vials – each containing capsules- left in tote on pharmacy counter)

Controlled Substances:

- Written CIII-V Prescription Requirements (KRS 218A.180 and 902 KAR 55:105)
    - Comments: Electronic prescriptions not properly received. Must get verbal authorization to dispense CIII-CIV drug and maintain record of verbal prescription accordingly.

TAILOR MADE COMPOUNDING

TMC Acquisition, LLC
dba Tailor Made Compounding
200 Moore Drive
Nicholasville, KY 40356

[KY BOP Outreach reference] *To address the identified deficiencies specific to the Pharmacy's validation of controlled substance prescriptions for Kentucky residents, I wanted to communicate the implementation of the Pharmacy's corrective actions.*

Effective 6/1/2024, the Pharmacy initiated a process to identify all controlled substance prescriptions for Kentucky patients submitted through the portal for pharmacist validation. All qualifying prescriptions submitted after 6/1/2024 require pharmacist validation of prescription information through the documentation of the following information on the physical prescription:

- *Authorizing clinic contact name*
- *Date of validation/call*
- *Validating Pharmacist signature*

Once validated, the documented prescription will be uploaded into the Pharmacy Processing Software and will require pharmacist credentials to indicate validation completion prior to further processing for fulfillment and dispensing. As previously implemented, all physical records will be filed in accordance with Kentucky Board of Pharmacy requirements.

The Pharmacy identified all clinics submitting qualifying prescriptions over the past 120 days to provide initial notice of the process implementation as well as an opportunity for the clinic to provide updated point of contact information. All prescriptions the pharmacy is unable to validate will be canceled 1 week after the third attempt of contact and documented as such.

The Pharmacy looks forward to continuing to work in cooperation with the Board's requests and/or additional questions. We hope that our efforts and the provided information demonstrate the pharmacy's commitment to quality assurance, compliance, and patient wellness.

Thank you,

Blake McLeod
Pharmacist-In-Charge
Chief Operating Officer
Tailor Made Compounding

859 887 0013 support@tailormadecompounding.com 859 406 1242

COMMONWEALTH OF KENTUCKY

KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601

LICENSE/PERMIT: Resident Pharmacy

EFFECTIVE DATE: 03/03/2021

NUMBER: P08150

EXPIRATION DATE: 06/30/2026

PIC: Blake Edward Mcleod

Issued to:

TMC Acquisition LLC
DBA Dba Tailor Made Compounding

200 Moore Drive
Nicholasville, KY 40356

License/Permit must be posted in public view.

The official status of this license/permit can be verified at www.pharmacy.ky.gov.

The facility above is hereby licensed or permitted at the above address, and is subject to the rules and regulations of the Kentucky Board of Pharmacy.

KENTUCKY BOARD OF PHARMACY
125 Holmes Street, Suite 300
State Office Building Annex
Frankfort, Kentucky 40601
Phone (502) 564-7910
Fax (502) 696-3806
pharmacy.ky.gov

December 31, 2025

STATE OF KENTUCKY

COUNTY OF FRANKLIN

I, Christopher Harlow, Executive Director of the Kentucky Board of Pharmacy, do hereby certify that I am an official custodian of the records of said Board and pursuant to a request, certify that as of this date the information contained herein regarding TMC Acquisition LLC is true and accurate.

Permit Type: **Pharmacy - Resident Pharmacy**
Number: **P08150**
Status: **Active**
Initiial Issue Date: **03/03/2021**
Expire Date: **06/30/2026**
Discipline Status: **Good Standing**

Witness my official hand and seal of the Board on December 31, 2025.

Christopher P. Harlow, Pharm.D.
Executive Director
Kentucky Board of Pharmacy

4VV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 02012	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: [redacted] ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: University Rx Specialists, LLC dba University Compounding Pharmacy

Physical Address: 1875 Third Avenue

City: San Diego State: CA Zip: 92101

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 619-683-2005 Toll Free # (NAC 639.708, NRS 639.23286): 800-985-8065

Fax: 888-350-5494 Contact Email: ucplicensing@fagron.com

Website: www.ucprx.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Richard Rhoads

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21369

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Richard Rhoads	NV Pharmacist Registration #: 21369
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?	✓	
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): Fagron Holding USA, LLC (Company is an LLC - there are no shares)

Corporation/Organization Name: University Rx Specialists, LLC dba University Compounding Pharmacy

Mailing Address: 201 W 5th Street, Suite 1250

City: Austin State: TX Zip: 78701

Telephone: 512-474-7400 Email: legal@fagron.us

Contact Person Name: Jay McEniry

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Vice President, LLC Manager (title) for University Compounding Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Hal Weaver

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1/6/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hal Weaver

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1/6/2026

Date

Board Use Only	Date Received: 1/9/26	Amount: $500 ck 0072005807

University Compounding Pharmacy

1875 Third Avenue, San Diego, CA 92101
Phone: 619.683.2005 Fax: 619.683.2008

November 5, 2019

Re: Self-Disclosure of University Compounding Pharmacy's Disciplinary Action by the California State Board of Pharmacy.

To Whom It May Concern:

On December 3, 2015, Joseph Grasela, RPh and University Compounding Pharmacy (UCP) entered into a stipulated settlement with the California State Board of Pharmacy wherein Pharmacy Permit PHY 45621, Sterile Compounding License 99018 and Pharmacist License RPH 40868 were placed on probation for four (4) years. A copy of the Decision and Order, Case 4347 should be on record with your board, as it has been previously submitted.

Effective July 6th 2018, Early Termination of Probation of California Pharmacy Permit No. 45621, Sterile Compounding Permit No. 99018 and Pharmacist RPH License 40868 was granted. See page 16 of the attached Decision and Order of the California Board of Pharmacy supporting Early Termination of Probation.

Following the stipulated settlement agreement from the California Board of Pharmacy, some other states responded by taking action against our respective licenses, however since being granted early termination of probation, all states have followed suit and terminated the probation orders.

License Renewal Denied Until CA License in Good Standing

- New York- ***reapplied and granted new license on 08/21/2018***

Probation for Duration of CA Probation

- Oregon- ***probation terminated as of 08/13/2018***
- Colorado- ***probation terminated as of 08/14/2018***
- Kentucky- ***probation terminated as of 06/29/2018***
- Texas- ***probation terminated on 09/13/2018***
- Georgia- ***probation terminated on 09/12/2018***
- Pennsylvania- ***probation terminated on 09/05/2018***
- Hawaii- ***probation terminated on 10/19/2018***

Current Status of Out-of-State Licenses:

Disciplinary Action

- Utah 12/15/2017

Disciplinary Action

- Virginia – Suspension of license 07/27/18, reinstated 08/14/18
  - The license was not renewed to investigate the claim that our license was "revoked" in California. In reality, the revocation did not take effect and was stayed and placed on probation. Additionally, probation in California was terminated early prior to the investigation in Virginia. The Virginia license was quickly reinstated.

Reprimand of License

- Illinois 12/05/2018

Administrative Complaint with fine

- Michigan 11/09/2019

If there are any questions, my contact information is listed below.

Thank You.

Joseph Grasela, RPh

Owner, University Compounding Pharmacy
Ph: 858-213-4688 | email: joe@ucprx.com

University Compounding Pharmacy
1875 Third Avenue, San Diego, CA 92101
Phone: 619.683.2005 Fax: 619.683.2008

To Whom It May Concern:

Re: Richard Rhoads – Disciplinary Action History

I have had no disciplinary action taken against any of my personal licenses.

Since becoming an owner of University Compounding Pharmacy on December 31, 2023, no disciplinary action has been taken against the pharmacy.

During my time as an employee of University Compounding Pharmacy, but prior to my ownership, the following disciplinary action was taken against the pharmacy. I understand that the circumstances surrounding that discipline are being disclosed in response to other questions in this application.

University Compounding Pharmacy – Disciplinary Action					
State	**Case #**	**Type**	**Fine**	**Finalized**	**Probation Terminated**
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Georgia	Dkt #2016-0225	Probation	$20,000	9/14/2016	9/12/2018
Hawaii	Case #	Probation	$1,500	10/23/2017	10/19/2018
Illinois	Case #2017-04426	Reprimand/Civil Penalty	-	12/5/2018	-
Kentucky	Case #17-0178	Probation	$6,950	4/19/2017	9/12/2018
Maine	Case #2020-PHA-16970	Reprimand/Civil Penalty	$500	4/26/2021	-
Michigan	Complaint #53-18-149968	Disciplinary	$500	10/9/2019	-
New York	License Renewal Denied	Probation	-	6/27/2016	8/21/2018
Oregon	Case #2016-0204	Probation	$10,000	7/21/2016	8/13/2018
Pennsylvania	Dkt #0004-54-17	Final Order Granting License	-	3/8/2017	9/5/2018
Texas	Order #L-17-003	Probation	$2,200	5/2/2017	09/13/0218
Utah	Case #2017-655	Reprimand/Civil Penalty	$500	12/14/2017	-
Virginia	Case #189565	License Suspension	-	7/27/2018	8/14/2018

Best Regards,

Richard Rhoads, Pharmacist
RPH-58679 (CA)

University Rx Specialists, LLC dba
University Compounding Pharmacy

Owner:
Fagron Holding USA, LLC – 100% Owner

Principal Officers and Executives	Business Address	Business Telephone
Andrew Pulido, President / Manager of University Rx Specialists, LLC	201 W 5th Street, Floor 12 Austin, TX 78701	512-474-7400
Hal Weaver, Vice President / Manager of University Rx Specialists, LLC	5401 Hangar Court Tampa, FL 33634	813-882-4500
Richard Rhoads, Secretary / Manager of University Rx Specialists, LLC	1875 Third Avenue San Diego, CA 92101	619-683-2005

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	UNIVERSITY RX SPECIALISTS
Entity No.:	1941874
Registration Date:	05/31/1995
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of October 21, 2025.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 380412023

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: University Rx Specialists, LLC dba University Compounding Pharmacy

Pharmacy/Wholesaler License # (if applicable): NV02012

Physical Address: 1875 Third Avenue

City: San Diego State: CA Zip: 92101

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 619-683-2005 Website: www.ucprx.com

Licensing Company Email: ucplicensing@fagron.com

Section 2: Personal Information

First: Richard Middle: Dale Last: Rhoads

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Arizona			0802 – 0506	
Address		City	State	Zip
1295 N. Martin PO Box 210202		Tucson	Az	85721
Diploma/Degree obtained, if any				
Doctor of Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
Cuyamaca College			0899 – 0502	
Address		City	State	Zip
900 Rancho San Diego Pky		El Cajon	CA	92019
Diploma/Degree obtained, if any				
None				
School Name			From - To (MM/YY – MM/YY)	
Southwestern College			0801 – 0502	
Address		City	State	Zip
900 Otay Lakes Rd		Chula Vista	CA	91910
Diploma/Degree obtained, if any				
None				
School Name			From - To (MM/YY – MM/YY)	
Pima Community College			0601 – 0801	
Address		City	State	Zip
1255 N Stone Ave		Tucson	Az	85709
Diploma/Degree obtained, if any				
None				
School Name			From - To (MM/YY – MM/YY)	
Valhalla High School			0895 – 0699	
Address		City	State	Zip
1725 Hillsdale Rd		El Cajon	CA	92019
Diploma/Degree obtained, if any				
High school Diploma				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
0613 – present	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
University Compounding Pharmacy			05/15 - Current
Business Address	**City**	**State**	**Zip**
1875 Third Avenue	San Diego	CA	92101
Phone	**Title**		**Number of Employed Hours**
619-683-2005	Director of Compounding, Pharmacist		> 14,000 hours
Description of Duties			
Pharmacist in Charge, Pharmacist			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.	✔	
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Richard Rhoads, **certify that as the designated representative for**

University Rx Specialists, LLC dba University Compounding Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Richard Rhoads

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/5/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Richard Rhoads

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/5/26

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of San Diego

I, Richard Rhoads, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/5/26

Date

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

Subscribed and Sworn to before me this 5 day of January 2026

S.T

Notary Public Signature

SEAN THOMAS
COMM. #2442916
Notary Public - California
San Diego County
My Comm. Expires Apr. 27, 2027

(Seal)

University Compounding Pharmacy
1875 Third Avenue, San Diego, CA 92101
Phone: 619.683.2005 Fax: 619.683.2008

To Whom It May Concern:

Re: Richard Rhoads – Disciplinary Action History

I have had no disciplinary action taken against any of my personal licenses.

Since becoming an owner of University Compounding Pharmacy on December 31, 2023, no disciplinary action has been taken against the pharmacy.

During my time as an employee of University Compounding Pharmacy, but prior to my ownership, the following disciplinary action was taken against the pharmacy. I understand that the circumstances surrounding that discipline are being disclosed in response to other questions in this application.

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Hawaii	Case #	Probation	$1,500	10/23/2017	10/19/2018
Illinois	Case #2017-04426	Reprimand/Civil Penalty	-	12/5/2018	-
Kentucky	Case #17-0178	Probation	$6,950	4/19/2017	9/12/2018
Maine	Case #2020-PHA-16970	Reprimand/Civil Penalty	$500	4/26/2021	-
Michigan	Complaint #53-18-149968	Disciplinary	$500	10/9/2019	-
New York	License Renewal Denied	Probation	-	6/27/2016	8/21/2018
Oregon	Case #2016-0204	Probation	$10,000	7/21/2016	8/13/2018
Pennsylvania	Dkt #0004-54-17	Final Order Granting License	-	3/8/2017	9/5/2018
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Utah	Case #2017-655	Reprimand/Civil Penalty	$500	12/14/2017	-
Virginia	Case #189565	License Suspension	-	7/27/2018	8/14/2018

Best Regards,

Richard Rhoads, Pharmacist
RPH-58679 (CA)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: University Rx Specialists, LLC dba University Compounding Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): NV02012

Physical Address: 1875 Third Avenue

City: San Diego State: CA Zip: 92101

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 619-683-2005 Toll Free # (NAC 639.708, NRS 639.23286): 800-985-8065

Fax: 888-350-5494 Contact Email: ucplicensing@fagron.com

Website: www.ucprx.com

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220): Richard Rhoads

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21369

Name of Designated Person(s) as defined by revised USP-797 guidelines: Richard Rhoads

Email of Designated Person(s): ucplicensing@fagron.com

Telephone of Designated Person(s): 619-683-2005

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ■ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☒ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☒ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 10/16/2025

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ☒ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☒ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Every week

10. Will you be performing sterile hazardous drug compounding? Yes ☒ No

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

See attached list

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL Bio Pharma

Address: 840 Research Parkway

City: Oklahoma City State: OK Zip: 73104

Telephone: 800-393-1595

13. What is your procedure for visual inspection of compounded sterile products?

Each article is inspected by qualified personnel in a visual inspection booth with adequate lighting against a white and black background, assessing for any particulates, defects, fill volume, and container closure integrity. P-9.210

14. How often do you perform glove fingertip and medial fill testing?

Every 3 months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Didactic training annually (Critical point or similar)
Gowning and gloving - successful assessment and fingertip, garbing sampling 3 consecutive successful initially, once every 3 months thereafter
Aseptic compounding assessment - visual assessment, media fill with 250 vials, surface sample, post compounding fingertip sample -- every 3 months
Knowledge assessments for each task performed, competency assessment for each task performed - annually

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Cleaning frequencies: LAFW, all horizontal surfaces, equipment, floors - daily
Walls, ceilings, storage bins - monthly

Cleaning/disinfecting agents: TBI-3300 (contec) sterile solution disinfectant
Peridox (contec) sterile solution sporicide

17. Who performs the sterile compounding process at your facility?

Qualified technicians - Mara Olmos, Christine Winn, Alvin Elevado, Abukar Abukar, Carl Vinzon

18. Who is responsible and accountable for the sterile compounding process at your facility?

Qualified pharmacists - Robert Jackson Rick Rhoads
Cindy Shen
Annie Le

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Shipping containers and ice packaging with shipping verifications twice yearly

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? ~~6ft Ductless LAFWs~~ N/A or		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device: N A		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

we do not compound sterile hazardous

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

N/A

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

See attached list.

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

Every 3 months

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ■ Yes No

4. What is the frequency for completing volumetric active air sampling?

Monthly

5. What is the frequency for completing surface sampling? Weekly AND with every batch		
6. What is the frequency for using sporicidal agents? Weekly		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	X Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	X Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Richard Rhoads

Name of Person who Completed the Form

Pharmacist in Charge

Title

Signature (copies or stamps not accepted)

1/5/26

Date

Board Use Only	Date Received: 1/9/26	Date Approved: _____	Approved By: _____

STERILE PREPS COMPOUNDED

DRUG PRODUCT
BI-MIX(PHENTOLAMINE/PAPAVERINE) 0.5MG-30MG/ML INJECTABLE
BI-MIX(PHENTOLAMINE/PAPAVERINE) 1MG-30MG/ML INJECTABLE
BI-MIX(PHENTOLAMINE/PAPAVERINE) 2MG-30MG/ML INJECTABLE
BI-MIX(PHENTOLAMINE/PAPAVERINE) 3MG-30MG/ML INJECTABLE
PGE1/PHENTOLAMINE 10MCG-0.5MG/ML INJECTABLE
PGE1/PHENTOLAMINE 20MCG-0.5MG/ML INJECTABLE
PGE1/PHENTOLAMINE 40MCG-0.5MG/ML INJECTABLE
QUAD-MIX(PGE1/PHENTOLAMINE/PAPAVERINE/ATROPINE) 10MCG-1-30-0.15MG/ML INJECTABLE
QUAD-MIX(PGE1/PHENTOLAMINE/PAPAVERINE/ATROPINE) 20MCG-2-30-0.15MG/ML INJECTABLE
QUAD-MIX(PGE1/PHENTOLAMINE/PAPAVERINE/ATROPINE) 60MCG-2-30-0.15MG/ML INJECTABLE
TRI-MIX (TEST DOSE) PGE1/ PHENTOLAMINE/ PAPAVERINE 10MCG-1MG-30MG/ML INJECTABLE
TRI-MIX (TEST DOSE) PGE1/ PHENTOLAMINE/ PAPAVERINE 8.3MCG-0.83MG-22.5MG/ML INJECTABLE
TRI-MIX PGE-1/PHENTOLAMINE/PAPAVERINE 20MCG-1MG-30MG/ML INJECTABLE
TRI-MIX-PGE1/PHENTOLAMINE/PAPAVERINE 10MCG-1MG-30MG/ML INJECTABLE
TRI-MIX-PGE1/PHENTOLAMINE/PAPAVERINE 20MCG-2MG-30MG/ML INJECTABLE
TRI-MIX-PGE1/PHENTOLAMINE/PAPAVERINE 40MCG-2MG-30MG/ML INJECTABLE
TRI-MIX-PGE1/PHENTOLAMINE/PAPAVERINE 5MCG-0.5MG-15MG/ML INJECTABLE
TRI-MIX-PGE1/PHENTOLAMINE/PAPAVERINE 60MCG-3MG-26MG/ML INJECTABLE
TRI-MIX-PGE1/PHENTOLAMINE/PAPAVERINE 8.3MCG-0.83MG-22.5MG/ML INJECTABLE
TRI-MIX-PGE1/PHENTOLAMINE/PAPAVERINE 80MCG-3MG-25MG/ML INJECTABLE
PHENYLEPHRINE 1MG/ML INJECTABLE
VANCOMYCIN FORTIFIED OPHTHALMIC * 25MG/ML SOLUTION
TOBRAMYCIN FORTIFIED OPHTHALMIC * 14MG/ML SOLUTION
EDTA DISODIUM OPHTHALMIC (PRESERVATIVE FREE) 3% SOLUTION
ACETYLCYSTEINE OPHTHALMIC 10% SOLUTION
VANCOMYCIN FORTIFIED OPHTHALMIC 50MG/ML SOLUTION
TOBRAMYCIN FORTIFIED OPHTHALMIC 13.6MG/ML SOLUTION
HEPARIN/BUFFERED LIDOCAINE (ALENTURA TM) 66,000 UNITS-325/20NL SOLUTION

PRODUCT	CATEGORY
BI-MIX(PHENTOLAMINE/PAPAVERINE) 0.5MG-30MG/ML INJECTABLE	3
BI-MIX(PHENTOLAMINE/PAPAVERINE) 1MG-30MG/ML INJECTABLE	3
BI-MIX(PHENTOLAMINE/PAPAVERINE) 2MG-30MG/ML INJECTABLE	3
BI-MIX(PHENTOLAMINE/PAPAVERINE) 3MG-30MG/ML INJECTABLE	3
PGE1/PHENTOLAMINE 10MCG-0.5MG/ML INJECTABLE	3
PGE1/PHENTOLAMINE 20MCG-0.5MG/ML INJECTABLE	3
PGE1/PHENTOLAMINE 40MCG-0.5MG/ML INJECTABLE	3
QUAD-MIX(PGE1/PHENTOLAMINE/PAPAVERINE/ATROPINE) 10MCG-1-30-0.15MG/ML INJECTABLE	3
QUAD-MIX(PGE1/PHENTOLAMINE/PAPAVERINE/ATROPINE) 20MCG-2-30-0.15MG/ML INJECTABLE	3
QUAD-MIX(PGE1/PHENTOLAMINE/PAPAVERINE/ATROPINE) 60MCG-2-30-0.15MG/ML INJECTABLE	3
TRI-MIX (TEST DOSE) PGE1/ PHENTOLAMINE/ PAPAVERINE 10MCG-1MG-30MG/ML INJECTABLE	3
TRI-MIX (TEST DOSE) PGE1/ PHENTOLAMINE/ PAPAVERINE 8.3MCG-0.83MG-22.5MG/ML INJECTABLE	3
TRI-MIX PGE-1/PHENTOLAMINE/PAPAVERINE 20MCG-1MG-30MG/ML INJECTABLE	3
TRI-MIX-PGE1/PHENTOLAMINE/PAPAVERINE 10MCG-1MG-30MG/ML INJECTABLE	3
TRI-MIX-PGE1/PHENTOLAMINE/PAPAVERINE 20MCG-2MG-30MG/ML INJECTABLE	3
TRI-MIX-PGE1/PHENTOLAMINE/PAPAVERINE 40MCG-2MG-30MG/ML INJECTABLE	3
TRI-MIX-PGE1/PHENTOLAMINE/PAPAVERINE 5MCG-0.5MG-15MG/ML INJECTABLE	3
TRI-MIX-PGE1/PHENTOLAMINE/PAPAVERINE 60MCG-3MG-26MG/ML INJECTABLE	3
TRI-MIX-PGE1/PHENTOLAMINE/PAPAVERINE 8.3MCG-0.83MG-22.5MG/ML INJECTABLE	3
TRI-MIX-PGE1/PHENTOLAMINE/PAPAVERINE 80MCG-3MG-25MG/ML INJECTABLE	3
PHENYLEPHRINE 1MG/ML INJECATBLE	3
EDTA DISODIUM OPHTHALMIC (PRESERVATIVE FREE) 3% SOLUTION	3
HEPARIN/BUFFERED LIDOCAINE (ALENTURA-TM) 66,0000 UNITS-325MG/20ML SOLUTION	3

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INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 5/29/2025 Inspector: Marc Gasca

Firm: UNIVERSITY COMPOUNDING PHARMACY Phone: (619) 683-2005

Address: 1875 THIRD AVE City: SAN DIEGO Zip: 92101

Ownership: CORPORATION

Permit #: LSC99018 PHY45621 Permit Exp: 8/1/2025 DEA#: [redacted] DEA Exp: 5/31/2026

Date of Self Assessment Form: 2/14/2025 Other Permit #: N/A Date of DEA Inventory: 7/31/2024

Hours M-F: 8:30AM-5PM Hours Saturday: CLOSED Hours Sunday: CLOSED

PIC JOSEPH GRASELA RPH40868 Administrator

RPH Consultant

Staff RPH Name:	License #:
MASON M MCDOWELL	RPH79887
MY-ANH T DINH	RPH49170
SALLIE H YANG	RPH53959
RICHARD D RHOADS	RPH58679
MELISSA M MACKEWICZ	RPH62761
ANNIE H LE	RPH71541
ASHLEY LAURENCE	RPH74347
ROBERT P JACKSON	RPH69796
MICHAEL P GOBLE	RPH61699
JOHN E DONLON JR	RPH45064
CINDY M SHEU	RPH56825

Staff Name:	License #:
ABIGAIL UDAVE	TCH195021
ABUKAR A ABUKAR	TCH166334
ALAN R PEREIDA	TCH180988
ALEXANDRA V MENDEZ MI	TCH196851
ALVIN L ELEVADO	TCH86619
ANGEL M GUTIERREZ	TCH173521
ANITTA MORTERA	TCH191598
ANNELISE E JIMENEZ	TCH108359
BETHANNIE J CASTILLO RU	TCH197414
CANDY J ACEVEDO MOJAR	TCH183150
CARL S YINZON	TCH165085
CHRISTINE G WINN	TCH103141
GIULIANA A CHAVEZ	TCH192955
HALIM A ABDALA	TCH163343
HALLIE G PETERSON	TCH189740
HEATHER Y GALLARDO	TCH121443
JAKE O BARRERA	TCH121904
JANET LEON-QUIROS	TCH168235
JEZZABEL CACHUA	TCH137902
MARIA A ORAZI	TCH17781
MARIA V OLMOS	TCH129079
MARISSA A MACIAS	TCH196951
MIA V RENINGER	TCH173864
MONICA S COSTELLO	TCH24162

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INSPECTION REPORT

SERGIO E TORRES CAMARG. TCH193132
VALERY I ANDRADE TCH184416

Inspector Remarks:

Hybrid sterile compounding license renewal inspection

- ***Request of several documents was sent on 5/5/2025***
- ***Documents received from 5/8/2025 - 5/19/2025, reviewed remotely***
- ***Inspection conducted in person at the facility on 5/29/2025, assisted remotely by RPH Rick Rhoads (contact email: rick@ucprx.com; contact phone number: 619-683-2005), onsite by PIC Grasela (contact email: joe@ucprx.com; contact phone number: 619-683-2005), TCH Monica Costello (Quality Manager), Maria Orazi (Operations Manager) and RPH Rick Rhoads (Director of Compounding)***
- ***Designated Person(s): PIC Grasela, RPH Robert Jackson, RPH Rhoads***

General Information

University Compounding Pharmacy is an independent retail pharmacy, providing patient-specific compounded sterile and nonsterile preparations to patients. The pharmacy is a PCAB-accredited facility, licensed in 45 states. Prescriptions are available for patient pick up and shipment via common carrier (primarily FedEx, USPS). Hours of operation are Monday-Friday 8:30am-5pm, closed on weekends (pharmacist available for consultation 7 days per week).

- Compounding Self-Assessment: completed on 2/14/2025
- Outpatient Self-Assessment: completed on 2/14/2025
- Pharmacy Law Waivers: None used at this time, RPH Rhoads
- FDA, DEA, and/or accreditation inspections w/ applicable reports issued within past 12 months: Reviewed NABP VPP inspection report (site visit: 6/24/2024-6/26/2024)
- Adverse drug reactions in the past 12 months: Reported to BOP, per RPH Rhoads
- Previous CA Board of Pharmacy Inspection Report
    - Reviewed previous inspection report issued on 4/3/2024 for previous corrections or written notice of noncompliance, previous noncompliance issues: No corrections, nor written notices issued

Sterile Compounding Area

No changes to the physical layout of the sterile compounding area, nor any changes to compounding equipment in the past 12 months, per RPH Rhoads

ISO 8 Ante Room (+ pressure) -> (LEADING TO 2 ISO-CLASSIFIED ROOMS)
ISO 8 Weigh Room (+ pressure) AND
ISO 7 Buffer Room (+ pressure)

- *ISO 8 Ante Room*
    - Line of demarcation, separating dirty and clean side
    - Sink (hand hygiene station) on clean side of LOD
    - Storage carts/racks
    - Stainless steel workstations
    - Pass-thru x 1 (leading to ISO-8 weigh room)
    - Gowning supplies
- *ISO 8 Weigh Room*
    - Dry heat oven x 1

INSPECTION REPORT

- Powder hood x 2
- Stir plate x 6
- Stainless steel workstations

- *ISO 7 Buffer Room*
  - ISO 5 LAFW x 4
  - Stainless steel workstation
  - Pass-thru x 1 (leading to ISO-8 ante room)

Certification performed by Technical Safety Services (TSS) on 4/24/2025
- Dynamic testing, non-viable air sampling, HEPA filter leak testing, air changes, smoke study: Reviewed
- In-house viable air sampling performed monthly, reviewed April 2025 results (within specification)
- In-house viable surface sampling performed weekly, reviewed 5/19/2025 results (within specification)
  - NOTE: Ante room pass-thru (leading to ISO-8 weigh room) not sampled, education provided regarding surface sampling location requirements

- **Types of Compounding/Risk Levels**
  - No changes in types of CSPs compounded at the facility in past 12 months, per RPH Rhoads
  - Category 2 (tobramycin, vancomycin ophthalmics) and Category 3 CSPs (bi/tri/quad mix injections, hep-lido bladder irrigation)
  - Non-HD CSPs only

Standard Operating Procedures (SOPs)
- Documentation of annual review of SOPs by PIC, documented on 12/19/2024
- Reviewed the following SOPs:
  - Required Garb for Cleanroom Facility Access
  - Beyond Use Dating (BUD) of Compounded Preparations
  - Environmental Monitoring of the Clean Room Facility
  - Daily Monthly Cleaning of the Clean Room Facility

Recordkeeping
- Master formula/compounding record
  - Reviewed for CSP name/strength, manufacturer/lot number/expiration date of each component, equipment, necessary quality review, instructions for storage and handling of CSP, lot number, BUD
- Refrigerator/freezer/incubator/room temperature: Reviewed logs for March, April 2025
- Pressure differential: Reviewed logs for March, April 2025
- Cleaning: Reviewed logs for March, April 2025
  - Cleaning agents used: PREempt, TB1-3300, Peridox, sIPA
  - Pharmacy staff responsible for daily and monthly cleaning of all ISO-classified areas

Labeling Requirements
- Assigned internal identification number: Reviewed
- Beyond use date: Reviewed
- Name and strength of each active ingredient: Reviewed
- Instructions for storage, handling, and administration: Reviewed

Sterile Compounding Attire

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- Sterile low-lint outer garb, head cover, beard cover, sterile face mask, shoe covers: Available
- Sterile gloves and alcohol-based hand rub: Available

Training/Competency

- Pharmaceutical calculations, gloved fingertip sampling, media fill testing, observational skills assessments (hand hygiene/garbing, cleaning/disinfection, aseptic technique): Reviewed

Quality Assurance

- End-product testing of potency and sterility performed at least monthly by 3rd party laboratory
  - USP <71> Sterility, USP <85> Bacterial Endotoxins testing performed on all batched injectable CSPs
  - All batched CSPs quarantined until sterility/endotoxin results complete (no at-risk batch releases)

Education

- Education provided regarding BPC 4127.1(f) as it pertains to adverse effects reported or potentially attributable to a pharmacy's sterile compounded drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration (reports to the CA Board of Pharmacy should be emailed to compoundingreport@dca.ca.gov)
- Education provided regarding USP Chapter <797> as it pertains to:
  - For entities compounding any Category 3 CSPs, surface sampling of all classified areas, and pass-through chambers connecting to classified areas, must be completed prior to assigning a BUD longer than the limits established in Table 13, and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs
  - When a compounded single-dose CSP or CSP stock solution is used as a component to compound additional CSPs, the original compounded single-dose CSP or CSP stock solution must be entered or punctured in ISO Class 5 or cleaner air and must be stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). The component CSP may be used for sterile compounding for up to 12 h or its assigned BUD, whichever is shorter, and any remainder must be discarded.
  - Garbing competency evaluation consists of a visual observation and gloved fingertip and thumb sampling (GFT) of both hands
  - Aseptic manipulation competency evaluation consists of a visual observation, media-fill testing, followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area to assess aseptic technique and related practices

Discussion

- The following links and resources stated below were provided to PIC Grasela via email during the inspection:

November 1, 2023, is the compendial date for several USP General Chapters, including General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations, <797> Pharmaceutical Compounding—Sterile Preparations, <800> Hazardous Drugs—Handling in Healthcare Settings, and <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging. Consistent with the policy statement the Board released on September 12, 2023, it is the Board's expectation that licensees are moving forward with all necessary implementation activities to comply with the updated USP compounding standards.
The Board has undertaken a review of its compounding regulations and identified changes necessary to clarify or make more specific requirements of federal law and USP General Chapters.

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During this transition period, licensees are encouraged to monitor the regulation process for updates, including signing up for the Board's subscriber alert system and by checking the Board's website.

Licensees are reminded to also ensure continuing compliance with other laws, regulations, and requirements that may apply to their activities, including, without limitation: the Federal Food, Drug, and Cosmetic Act (21 USC §§ 321–399i), including Section 503A thereof (21 USC § 353a); provisions of California's Sherman Food, Drug, and Cosmetic Law (Health and Safety Code §§ 109875–111929.4); and laws, regulations, and requirements related to radiopharmaceuticals and/or the handling of hazardous drugs, including requirements established by Cal/OSHA.

Educational Links and References:

1. Revisions to USP Compounding General Chapters <795> and <797> https://go.usp.org/2022_Revisions_795_797
   - BUD Scientific Rationale for the 2021 Proposed Revisions to <795>
   - BUD Reference for the 2021 Proposed Revisions to <795>
   - BUD Scientific Rationale for the 2021 Proposed Revisions to <797>
   - BUD Reference for the 2021 Proposed Revisions to <797>
2. 9/29/23, Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act.
   https://www.fda.gov/media/94155/download
3. FDA Drug Establishments Current Registration Site:
   https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm
4. FDA to Compounders: Know Your Bulks and Excipients Suppliers:
   https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipients-suppliers

DISCLAIMER:

Any issues referenced/discussed in this report are not intended to be an all-inclusive list of issues that may exist at your facility. Your facility is responsible for investigating and determining the causes of any issues and items to be corrected and for preventing their recurrence. Further review of items provided at inspection, may result in further communication after this report.

To complete this inspection, please provide the following to Inspector Marc Gasca via email (marc.gasca@dca.ca.gov) **no later than 6/12/2025:**

1. Updated surface sampling diagram

Licensee Remarks:

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INSPECTION REPORT

I have reviewed, discussed, understand and received a copy of this form.

Pharmacist (sign) Joseph Gasek

Pharmacist (print) Joe Ginsek

Inspector (sign) _____

Inspector (print) _____

Owner(sign) Joseph Gasek

Owner(print) Joe Ginsek

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

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INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 5/29/2025 Inspector: Marc Gasca

Firm: UNIVERSITY COMPOUNDING PHARMACY Phone: (619) 683-2005

Address: 1875 3RD AVE City: SAN DIEGO Zip: 92101

Ownership: CORPORATION

Permit #: PHY45621 LSC99018 Permit Exp: 8/1/2025 DEA#: [redacted] DEA Exp: 5/31/2026

Date of Self Assessment Form: 2/14/2025 Other Permit #: N/A Date of DEA Inventory: 7/31/2024

Hours M-F: 8:30AM-5PM Hours Saturday: CLOSED Hours Sunday: CLOSED

PIC JOSEPH GRASELA RPH40868 Administrator ___

RPH Consultant ___

Staff RPH Name:	License #:
MASON M MCDOWELL	RPH79887
MY-ANH T DINH	RPH49170
SALLIE H YANG	RPH53959
RICHARD D RHOADS	RPH58679
MELISSA M MACKEWICZ	RPH62761
ANNIE H LE	RPH71541
ASHLEY LAURENCE	RPH74347
ROBERT P JACKSON	RPH69796
MICHAEL P GOBLE	RPH61699
JOHN E DONLON JR	RPH45064
CINDY M SHEU	RPH56825

Staff Name:	License #:
ABIGAIL UDAVE	TCH195021
ABUKAR A ABUKAR	TCH166334
ALAN R PEREIDA	TCH180988
ALEXANDRA V MENDEZ MI	TCH196851
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JANET LEON-QUIROS	TCH168235
JEZZABEL CACHUA	TCH137902
MARIA A ORAZI	TCH17781
MARIA V OLMOS	TCH129079
MARISSA A MACIAS	TCH196951
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INSPECTION REPORT

SERGIO E TORRES CAMARG TCH193132
VALERY I ANDRADE TCH184416

Inspector Remarks:

Here today for a routine inspection. University Compounding Pharmacy is an independent retail pharmacy, providing compounded (both sterile and nonsterile) preparations and retail pharmacy services to its patients. The front end of the pharmacy offers a variety of OTC items and nutritional supplements for purchase. The pharmacy is open for business Monday through Friday 8:30am-5pm. The pharmacy is a PCAB-accredited facility and licensed in 45 states. Prescriptions are available for patient pick up and shipment via common carrier (primarily FedEx, USPS). PIC Joe Grasela, TCH Monica Costello (Quality Manager), Maria Orazi (Operations Manager) and RPH Rick Rhoads (Director of Compounding) were present during the inspection and available to respond to inspection inquiries.

Avcrage Number of Prescriptions **per day:** 600 Rx's (~ 400 compounded prescriptions, 50% CSPs/50% CNSPs)
Staffing Ratio: 10 RPH, 19 TCH (observed)
Designated Person(s): PIC Grasela, RPH Michael Goble, RPH Rhoads

Reviewed:

Notices to the public displayed in public view

- Original license and renewal
  - NOTE: Original facility licenses not available, pharmacy contacted BOP for replacements during inspection
- Notice to Consumer poster
- Language notice/interpretive services

Facility

- Security: only RPHs possess key (manual locking of pharmacy, security/camera system)
- Sink with hot and cold running water
- Readily accessible bathroom
- Licensed staff, name tag
- Pharmacy Software: LifeFile
- Pharmacy and licensees on Board's email notification list
  - Pharmacy email: joe@ucprx.com

Reports:

- Community Pharmacy Self-Assessment
  - Completed 2/14/2025
- Compounding Self-Assessment
  - Completed on 2/14/2025

INSPECTION REPORT

- Biennial Controlled Substance Inventory
  - Completed on 7/31/2024 (end of day), pharmacy stocks Schedule III-V medications only

Policies and Procedures: Reviewed

- Quality Assurance
- Impaired Employee/Theft and Diversion (chemically, mentally, or physically)
- Pharmacy technician job description
- Interpretive Services
- Temporary Absence of Pharmacist (NOT AVAILABLE)

Drug Stock

- Drug Acquisition Procedures:
  - Wholesalers: Cardinal, Nucare, PCCA, Letco, Medisca, Spectrum, Kalchem, Darmerica
- Current Active Stock:
  - Randomly selected drugs reviewed for expiration dates (check monthly for expired medications conducted by pharmacy personnel)
- Disposition Procedures:
  - Recalls, outdates quarantined
  - Reverse Distributor: PharmaLink, Reliable Pharmaceutical Returns

Prescription Process

- Reviewed dispensing process, prescription label
- Consultation: not observed during inspection
  - NOTE: written notice of availability of consultation available, revision requested to include all days/hours of availability

Nonsterile Compounding Area

Within the pharmacy, there contains an enclosed negative-pressure HD compounding room as well as an enclosed non-HD compounding room. Externally-vented HD room contains 9 powder hoods (mainly compounding HRT CNSPs, per RPH Rhoads). Non-HD room contains 6 powder hoods and tablet press. Room and PEC certification performed annually by 3rd-party certifier.

Recordkeeping

- Master formulation/compounding record
  - Reviewed for CNSP name/strength/dosage form, manufacturer/lot/expiration date of

INSPECTION REPORT

each component, equipment, quality control procedures, storage requirements, BUD

- Refrigerator/freezer/room temperature: reviewed log for April 2025
- Cleaning: Reviewed log for April 2025

Personal Protective Equipment

- Head cover
- Face mask
- Shoe covers
- Gown (disposable, long-sleeved)

Quality Assurance

- End-product potency testing performed at least monthly by 3rd-party laboratory, reviewed May 2025 results (within specification)

Training/Competency

- Ongoing training and competency records: reviewed for TCH Andrade

Education

- Education provided regarding BPC 4058, which states "Every person holding a license issued under this chapter to operate a premises shall display the original license and current renewal license upon the licensed premises in a place where it may be clearly read by the public"
- Education provided regarding CCR 1714.1(f), which states "The pharmacy shall have written policies and procedures regarding the operations of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of ancillary staff, the pharmacist's responsibilities for checking all work performed by ancillary staff and the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the board or its designee at all times during business hours"
- Education provided regarding CCR 1707.2(b)(1)(A) as it pertains to patient receipt of written notice of right to request consultation
- Education provided regarding CCR 1707.2(b)(1)(B) as it pertains to patient receipt of written notice of availability of consultation (including hours of availability and telephone number)
- Education provided regarding CCR 1707.2(b)(1)(C) as it pertains to availability of pharmacist for consultation (must be no less than 6 days per week and a minimum of 40 hours per week)
- The Board is no longer mailing out renewal applications for individuals. Please refer to the information on the Board's website to learn more

Discussion

- The following links and resources stated below were provided to PIC Grasela via email during the inspection:

November 1, 2023, is the compendial date for several USP General Chapters, including General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations, <797> Pharmaceutical Compounding—Sterile Preparations, <800> Hazardous Drugs—Handling in Healthcare Settings, and <825> Radiopharmaceuticals—Preparation, Compounding,

INSPECTION REPORT

Dispensing, and Repackaging. Consistent with the policy statement the Board released on September 12, 2023, it is the Board's expectation that licensees are moving forward with all necessary implementation activities to comply with the updated USP compounding standards.

The Board has undertaken a review of its compounding regulations and identified changes necessary to clarify or make more specific requirements of federal law and USP General Chapters.

During this transition period, licensees are encouraged to monitor the regulation process for updates, including signing up for the Board's subscriber alert system and by checking the Board's website.

Licensees are reminded to also ensure continuing compliance with other laws, regulations, and requirements that may apply to their activities, including, without limitation: the Federal Food, Drug, and Cosmetic Act (21 USC §§ 321–399i), including Section 503A thereof (21 USC § 353a); provisions of California's Sherman Food, Drug, and Cosmetic Law (Health and Safety Code §§ 109875–111929.4); and laws, regulations, and requirements related to radiopharmaceuticals and/or the handling of hazardous drugs, including requirements established by Cal/OSHA.

Educational Links and References:

1. Revisions to USP Compounding General Chapters <795> and <797>
https://go.usp.org/2022_Revisions_795_797

BUD Scientific Rationale for the 2021 Proposed Revisions to <795>
BUD Reference for the 2021 Proposed Revisions to <795>
BUD Scientific Rationale for the 2021 Proposed Revisions to <797>
BUD Reference for the 2021 Proposed Revisions to <797>

2. 9/29/23, Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act.
https://www.fda.gov/media/94155/download

3. FDA Drug Establishments Current Registration Site:
https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm

4. FDA to Compounders: Know Your Bulks and Excipients Suppliers:
https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipients-suppliers

DISCLAIMER:

Any issues referenced/discussed in this report are not intended to be an all-inclusive list of issues that may exist at your facility. Your facility is responsible for investigating and determining the causes of any issues and items to be corrected and for preventing their recurrence. Further review of items provided at inspection may result in further communication after this report.

To complete this inspection, please provide the following to Inspector Marc Gasca via email (marc.gasca@dca.ca.gov) **no later than 6/12/2025:**

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

1. Revised notice of availability of patient consultation
2. Policy and procedure regarding temporary absence of a pharmacist

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) Joseph Grasek

Pharmacist (print) Joseph Grasek

Owner(sign) Joseph Grasek

Owner(print) Joseph Grasek

Inspector (sign) _____

Inspector (print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

CALIFORNIA STATE BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

License No. PHY 45621
Receipt No. 00198746

Valid Until: 8/1/2026

UNIVERSITY COMPOUNDING PHARMACY
1875 3RD AVE
SAN DIEGO, CA 92101

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.

The official status of this license can be verified at www.pharmacy.ca.gov

This permit is valid only at the address shown.

---- NON-TRANSFERABLE ----- POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19) PHY

CALIC100.RENWALR.080722025.10478.SEQID5547

UNIVERSITY COMPOUNDING PHARMACY
1875 3RD AVE
SAN DIEGO, CA 92101 5547

BOARD OF PHARMACY
2720 GATEWAY OAKS DR, SUITE 100
SACRAMENTO, CA 95833

BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal Certificate

Sterile Compounding License

License No. LSC 99018
Receipt No. 00198751

Valid Until: 8/1/2026

UNIVERSITY COMPOUNDING PHARMACY
1875 THIRD AVE
SAN DIEGO, CA 92101

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.

This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

---- NON-TRANSFERABLE ----- POST IN PUBLIC VIEW -----

WPHLSC 09/30/19

CALIC100.RENWALR.08092025.11055.SEQID12356

UNIVERSITY COMPOUNDING PHARMACY
1875 THIRD AVE
SAN DIEGO, CA 92101 12356

BOARD OF PHARMACY
2720 GATEWAY OAKS DR, SUITE 100
SACRAMENTO, CA 95833

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 45621

NAME: UNIVERSITY COMPOUNDING PHARMACY

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR ◆ PRIOR DISCIPLINARY ACTION

SECONDARY STATUS: PROBATION TERMINATED/COMPLETED

ADDRESS

1875 3RD AVE
SAN DIEGO CA 92101
SAN DIEGO COUNTY

ISSUANCE DATE

AUGUST 23, 2002

EXPIRATION DATE

AUGUST 1, 2026

CURRENT DATE / TIME

JANUARY 7, 2026
7:2:39 AM

PUBLIC RECORDS

› DISCIPLINARY ACTIONS (1)

DISCLAIMER: DISCIPLINARY ACTIONS

DESCRIPTION: CURRENT WEB SITE INFORMATION ON BOARD OF PHARMACY DISCIPLINARY ACTIONS ONLY GOES AS FAR BACK AS *JANUARY 1998* FOLLOWING THE EFFECTIVE DATE OF THE DISCIPLINARY PENALTY.
DISCIPLINARY ACTIONS RENDERED BY THE BOARD AND PENALTIES IMPOSED BECOME OPERATIVE ON THE EFFECTIVE DATE OF THE ACTION EXCEPT IN SITUATIONS WHERE THE LICENSEE OBTAINS A COURT-ORDERED STAY THROUGH THE APPEAL PROCESS. THIS MAY OCCUR AFTER THE PUBLICATION OF THE INFORMATION ON THIS WEBSITE.

TO OBTAIN INFORMATION PRIOR TO JANUARY 1998 OR FOR INFORMATION ON SPECIFIC DISCIPLINE LISTED SUBMIT A WRITTEN REQUEST TO THE *STATE BOARD OF PHARMACY, 2720 GATEWAY OAKS DRIVE, SUITE 100, SACRAMENTO, CA 95833, ATTENTION PUBLIC RECORDS DESK.*

PUBLIC DISCLOSURES:

- **CASE NUMBER:** AC201100434700
- **EFFECTIVE DATE OF ACTION:** APRIL 1, 2016
- **DESCRIPTION OF ACTION:** BY STIPULATION: THE LICENSE IS REVOKED, REVOCATION STAYED, AND PLACED ON PROBATION FOR 4 YEARS SUBJECT TO THE TERMS AND CONDITIONS IN THE DECISION.

PUBLIC DOCUMENTS

› DOCUMENTS (1)

CASE NUMBER: AC201100434700 **DOCUMENT:** LINK

LICENSE RELATIONSHIPS

NAME: UNIVERSITY COMPOUNDING PHARMACY
LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY
LICENSE NUMBER: 99018 **PRIMARY STATUS:** CLEAR ◆ PRIOR DISCIPLINARY ACTION ◆ PROBATION TERMINATED/COMPLETED

ADDRESS :
1875 THIRD AVE
SAN DIEGO CA 92101
SAN DIEGO COUNTY

NAME: GRASELA, JOSEPH
LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST
LICENSE NUMBER: 40868 **PRIMARY STATUS:** CLEAR ◆ PRIOR DISCIPLINARY ACTION ◆ PROBATION TERMINATED/COMPLETED

ADDRESS NOT DISCLOSED

BOARD OF PHARMACY

LICENSING DETAILS FOR: LSC 99018

NAME: UNIVERSITY COMPOUNDING PHARMACY

LICENSE TYPE: STERILE COMPOUNDING PHARMACY

LICENSE STATUS: CLEAR ❖ PRIOR DISCIPLINARY ACTION

SECONDARY STATUS: PROBATION TERMINATED/COMPLETED

ADDRESS

1875 THIRD AVE
SAN DIEGO CA 92101
SAN DIEGO COUNTY

ISSUANCE DATE

JULY 1, 2003

EXPIRATION DATE

AUGUST 1, 2026

CURRENT DATE / TIME

JANUARY 7, 2026
7:2:54 AM

PUBLIC RECORDS

› DISCIPLINARY ACTIONS (1)

DISCLAIMER: DISCIPLINARY ACTIONS

DESCRIPTION: CURRENT WEB SITE INFORMATION ON BOARD OF PHARMACY DISCIPLINARY ACTIONS ONLY GOES AS FAR BACK AS *JANUARY 1998* FOLLOWING THE EFFECTIVE DATE OF THE DISCIPLINARY PENALTY.
DISCIPLINARY ACTIONS RENDERED BY THE BOARD AND PENALTIES IMPOSED BECOME OPERATIVE ON THE EFFECTIVE DATE OF THE ACTION EXCEPT IN SITUATIONS WHERE THE LICENSEE OBTAINS A COURT-ORDERED STAY THROUGH THE APPEAL PROCESS. THIS MAY OCCUR AFTER THE PUBLICATION OF THE INFORMATION ON THIS WEBSITE.

TO OBTAIN INFORMATION PRIOR TO JANUARY 1998 OR FOR INFORMATION ON SPECIFIC DISCIPLINE LISTED SUBMIT A WRITTEN REQUEST TO THE *STATE BOARD OF PHARMACY, 2720 GATEWAY OAKS DRIVE, SUITE 100, SACRAMENTO, CA 95833, ATTENTION PUBLIC RECORDS DESK.*

PUBLIC DISCLOSURES:

- ❖ **CASE NUMBER:** AC201100434700
- ❖ **EFFECTIVE DATE OF ACTION:** APRIL 1, 2016
- ❖ **DESCRIPTION OF ACTION:** BY STIPULATION: THE LICENSE IS REVOKED, REVOCATION STAYED, AND PLACED ON PROBATION FOR 4 YEARS SUBJECT TO THE TERMS AND CONDITIONS IN THE DECISION.

PUBLIC DOCUMENTS

› DOCUMENTS (1)

CASE NUMBER: AC201100434700 **DOCUMENT:** LINK

LICENSE RELATIONSHIPS

NAME: UNIVERSITY COMPOUNDING PHARMACY
LICENSE/REGISTRATION TYPE: PHARMACY (COMMUNITY)
LICENSE NUMBER: 45621 **PRIMARY STATUS:** CLEAR ❖ PRIOR DISCIPLINARY ACTION ❖ PROBATION TERMINATED/COMPLETED

ADDRESS :
1875 3RD AVE
SAN DIEGO CA 92101
SAN DIEGO COUNTY

BOARD OF PHARMACY

LICENSING DETAILS FOR: RPH 58679

NAME: RHOADS, RICHARD DALE

LICENSE TYPE: REGISTERED PHARMACIST

LICENSE STATUS: CLEAR

ADDRESS NOT DISCLOSED

ISSUANCE DATE

AUGUST 22, 2006

EXPIRATION DATE

FEBRUARY 29, 2028

CURRENT DATE / TIME

JANUARY 7, 2026
7:3:18 AM

4WW

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	☐ Retail/Community	☐ Retail/Community
☑ Out-of-Nevada	☑ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☑ Other: Specialty Pharmacy	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
The applicant remains owned by AnovoRx Group, LLC. This is not a change at the Grandparent level.		the applicant level. This is a change	☐ Long Term Care
	* Current license #: PH 04500		☐ Hospital
			☑ Other: Specialty Pharmacy

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: AnovoRx Group, LLC

Physical Address: 17500 South 40th Street, Bldg B, Suite B600A

City: Chandler State: AZ Zip: 85226

Mailing Address (if different from physical address): 1710 N Shelby Oaks Dr, Suite 2

City: Memphis State: TN Zip: 38134

Telephone: 901-201-5470 Toll Free # (NAC 639.708, NRS 639.23286): 844-288-5007

Fax: 901-201-5465 Contact Email: officialcontact@anovorx.com

Website: www.anovorx.com

Nevada Business License # (if applicable) NV20131161181

Supervising/Managing Pharmacist Name (NRS 639.220): Samuel E. Webster

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22436

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Samuel E. Webster	NV Pharmacist Registration #: 22436
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Tennessee

Parent Company (if any): AnovoRx Holdings, LLC

Corporation/Organization Name: AnovoRx Group, LLC

Mailing Address: 1710 N Shelby Oaks Dr, Suite 2

City: Memphis State: TN Zip: 38134

Telephone: 901-201-5470 Email: Officialcontact@anovorx.com

Contact Person Name: Cathy Bellehumeur, VP Regulatory Compliance and Licensing

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CFO and Secretary (title) for AnovoRx Group, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Jason T. Shackelford, CFO and Secretary

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

09.04.2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Jason T. Shackelford hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CFO and Secretary (title) for AnovoRx Group, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 4th day of September, 2025

Notary Public

DORA GARCIA
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jason T. Shackelford, CFO and Secretary

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

09.04-2025

Date

Board Use Only	Date Received: 10/15/25	Amount: $500 ck 9177

anovo

Dedicated.
Exclusive.
Unique.

September 4, 2025 VIA EMAIL

Re: Information Update for Grandparent of Non-Resident Pharmacy Licensee
Licensee: AnovoRx Group, LLC NCPDP 036-5432 NPI 1750028130
Home State Pharmacy License: AZ License Number: Y009511
Location: 17500 S. 40 St. Bldg. B Suite B600A Chandler AZ 85226

INFORMATION UPDATE FOR GRANDPARENT OF LICENSEE

AnovoRx Growth, LLC (the "Licensee") is pleased to inform you that today the TPG family of companies increased its investment in the Licensee's parent company. Today an affiliate of the current 40% owner of our parent company became the 100% owner of our parent company. This makes a member of the TPG family of companies the sole grandparent of the Licensee. Having our existing investor increase its ownership percentage of our parent company will help Anovo maintain its healthy financial condition.

This update will not result in any change to the Licensee itself. The Licensee's FEIN, home state pharmacy permit number, DEA registration number, management, day-to-day operations, parent company and pharmacist-in-charge remain intact. The chart below shows the Licensee's details before and after this update.

Key: Updated information is **bolded**. All other information remains the same.		
ITEM	**Before**	**From 09/04/2025**
Name of Licensee	AnovoRx Group, LLC	AnovoRx Group, LLC
FEIN of Licensee	45-5299748	45-5299748
Address of Licensee	17500 S. 40 St. Bldg. B Suite B600A Chandler AZ 85226	17500 S. 40 St. Bldg. B Suite B600A Chandler AZ 85226
Home State Pharmacist in Charge	Samuel Webster	Samuel Webster
Officers of Licensee	• Joel Kimbrough, President/ CEO • Kyle Truitt, COO • Jason Shackelford, CFO and Secretary	• Joel Kimbrough, President/CEO • Kyle Truitt, COO • Jason Shackelford, CFO and Secretary
Board of Directors of Licensee	Joel Kimbrough	Joel Kimbrough
Parent of Licensee (owns 100% of the Licensee)	AnovoRx Holdings, Inc. FEIN of Parent: 46-1775496 Address: 1710 N Shelby Oaks Dr. STE 2 Memphis TN 38134	AnovoRx Holdings, **LLC** FEIN of Parent: 46-1775496 Address: 1710 N Shelby Oaks Dr. STE 2 Memphis TN 38134
Grandparent(s) of Licensee and % ownership of Licensee's parent company, AnovoRx Holdings, LLC	• Estate of Jon B. Peters 13.5% • Joel Ray Kimbrough 13.5% • Diane J. Callahan 6% • TPG Growth V Amplifier, L.P. 40%	**Atlas Borrower, LLC** (an affiliate of TPG Growth V Amplifier, L.P.) **100% owner of parent** See Attached Business Organization Chart as of 9/04/25

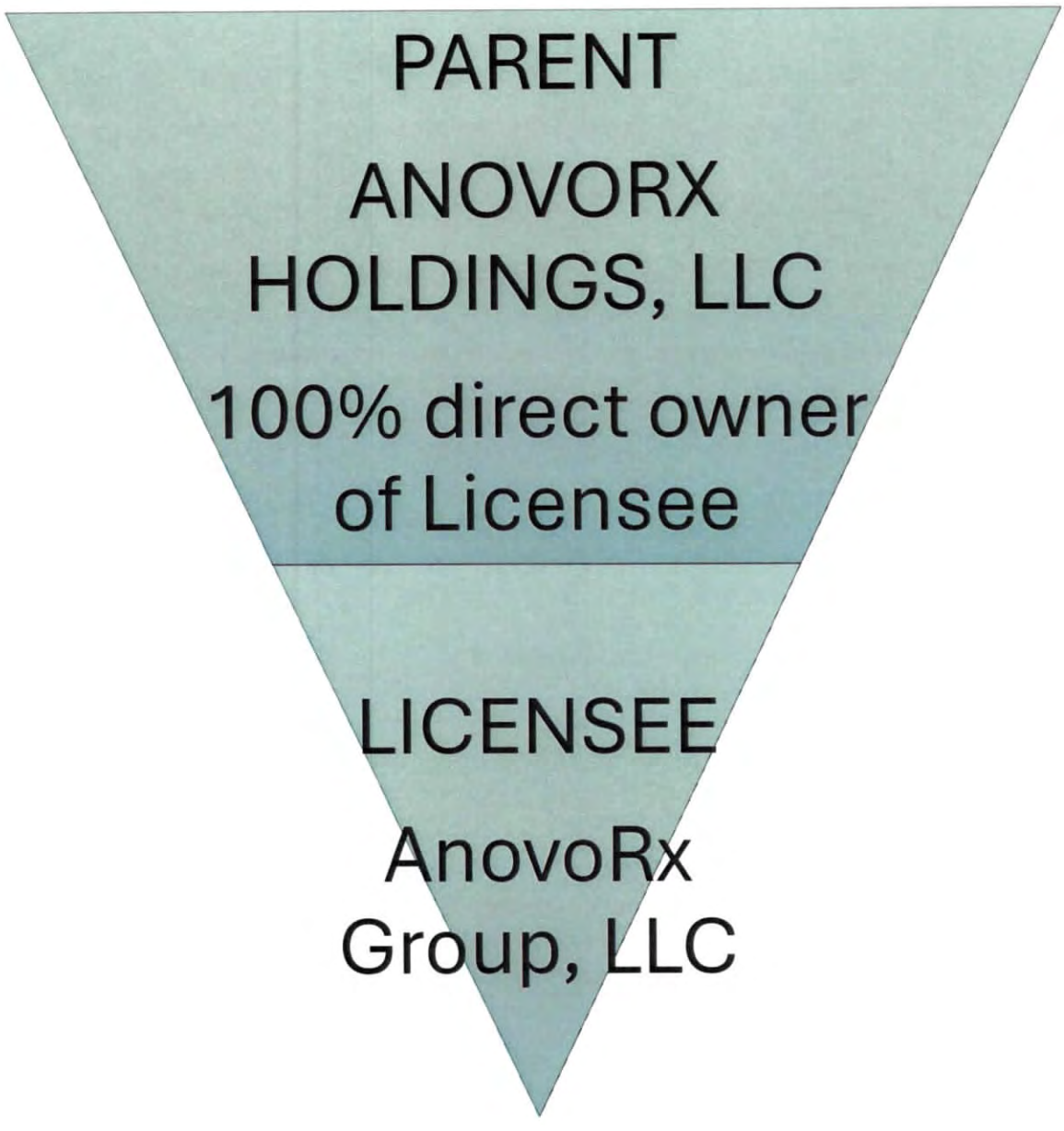
	• Equity Partners XX(20), LLC 13.5% • 13.5% held by various individuals and trusts, none of whom own 5% or more	

Please send us an email at officialcontact@anovorx.com if you need any further information.

AnovoRx Group, LLC

Jason T. Shackelford
Chief Financial Officer and Secretary

Web AnovoRx.com Phone 901-201-5470 Toll free 1-844-288-5007
Address AnovoRx | 1710 N. Shelby Oaks Drive, Suite 2 | Memphis, TN 38134


PARENT
ANOVORX HOLDINGS, LLC
100% direct owner of Licensee
LICENSEE
AnovoRx Group, LLC

Division of Business and Charitable Organizations
Department of State
State of Tennessee
312 Rosa L. Parks Avenue, 6th Floor
Nashville, Tennessee 37243
Phone: 615-741-2286
sos.tn.gov/

Tre Hargett
Secretary of State

CATHY BELLEHUMEUR
1710 N SHELBY OAKS DRIVE, STE 2
MEMPHIS, TN 38134, USA

05/13/2025

Request Type: Certificate of Existence/Authorization

Issuance Date: 05/13/2025

Request #: C2025032899

Document Receipt

Order Number: C2025032899

Verification #: 0516CFF0

Receipt #: 2025-349483

Filing Fee: $20.00

Payment: Credit Card - 3898383889 $20.00

Entity Name:	ANOVORX GROUP, LLC		
SOS Control #:	000685324	Initial Filing Date:	05/02/2012
Entity Type:	Limited Liability Company (LLC)	Formation Locale:	TENNESSEE
Status:	Active	Duration Term:	Perpetual
Fiscal Year Close:	December	Annual Report Due:	04/01/2026
Business County:	SHELBY		
Managed By:	Member Managed		
Obligated Member Entity:	No		

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

ANOVORX GROUP, LLC

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;
* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;
* has filed the most recent annual report required with this office;
* has appointed a registered agent and registered office in this State;
* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Verification #: 0516CFF0

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler AnovoRx Group, LLC

Pharmacy/Wholesaler License # (if applicable) PH04500

Physical Address 17500 South 40th Street, Bldg B, Suite B600A

City Chandler State AZ Zip 85226

Mailing Address (if different from physical address) 1710 N. Shelby Oaks Dr, Ste 2

City Memphis State TN Zip 38134

Telephone 901-201-5470 Website https://www.anovorx.com

Licensing Company Email Officialcontact@anovorx.com

Section 2: Personal Information

First Samuel Middle Elliott Last Webster

Aliases, nickpames, name changes, etc.) Sam

[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: GILBERT HIGH SCHOOL			From - To (MM/YY – MM/YY): 08/86 05/90	
Address: 1101 E ELLIOT ROAD	City: GILBERT		State: AZ	Zip: 85234
Diploma/Degree obtained, if any: HIGH SCHOOL DIPLOMA				
School Name: ARIZONA STATE UNIVERSITY			From - To (MM/YY – MM/YY): 08/90 – 12/99	
Address: 1151 S FOREST AVE	City: TEMPE		State: AZ	Zip: 85281
Diploma/Degree obtained, if any: B.S. MICROBIOLOGY				
School Name: UNIVERSITY OF ARIZONA			From - To (MM/YY – MM/YY): 08/05 – 05/09	
Address: 1703 E MABEL ST	City: TUCSON		State: AZ	Zip: 85721
Diploma/Degree obtained, if any: PHARM D				
School Name:			From - To (MM/YY – MM/YY):	
Address:	City:		State:	Zip:
Diploma/Degree obtained, if any:				
School Name:			From - To (MM/YY – MM/YY):	
Address:	City:		State:	Zip:
Diploma/Degree obtained, if any:				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2000 – PRESENT	[redacted]			
09/1997 05/2000				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: ANOVA Rx GROUP LLC			From - To (MM/YY – MM/YY): 09/22 - PRESENT	
Business Address: 17500 S 40TH ST BUILDING B, SUITE 600A	City: CHANDLER		State: AZ	Zip: 85226
Phone: 844-288-5007	Title: PHARMACIST IN CHARGE (PIC)		Number of Employed Hours: ≈ 6300 HOURS	
Description of Duties: OVERSEE DAY TO DAY OPERATIONS OF ANOVA Rx IN AZ. FILL & SHIP PRESCRIPTIONS. ORDERING & RECEIVING MEDICATIONS. INVENTORY				
Business Name: ADHERE Rx PHARMACY			From - To (MM/YY – MM/YY): 11/20 – 09/22	
Business Address: 1343 N COLORADO ST #109	City: GILBERT		State: AZ	Zip: 85233
Phone: 919 463 5555	Title: PHARMACIST IN CHARGE (PIC)		Number of Employed Hours: ≈ 900 HOURS	
Description of Duties: OVERSAW DAY TO DAY OPERATIONS OF PHARMACY.				
Business Name: TC SCRIPT			From - To (MM/YY – MM/YY): 5/19 - 11/20	
Business Address: 17255 N 82ND ST #130	City: SCOTTSDALE		State: AZ	Zip: 85255
Phone: 855 544 6189	Title: PHARMACIST		Number of Employed Hours: 720	
Description of Duties: CHECK PRESCRIPTIONS / COUNSEL PATIENTS / INVENTORY				
Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				
Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	—	—
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I, Samuel E Webster, certify that as the designated representative for

Arrow Rx LLC Grow

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SW I am at least 21 years of age;
3. SW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sam Webster

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-10-2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sam Webster

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-10-2026

Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Shelby

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2-10-2026

Date

Subscribed and Sworn to before me this 10th day of February, 2026

Dora Garcia

Notary Public Signature

DORA GARCIA
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY

(Seal)

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

DEMOGRAPHICS

AZ permit# : Y009511	AZ Permit Exp.Date : 10/31/2026	Business Name : AnovoRx Group, LLC
Address : 17500 South 40 Street Building B		
Zip : 85226	City : Chandler	State : AZ
Phone : (901) 201-5470	Fax : (901) 201-5465	Email : officialcontact@anovorx.com
Inspection Date : 03/19/2025	PIC : Samuel E. Webster	Pic License Exp Date : 10/31/2025
DEA # : [redacted]	DEA # Exp. date : 06/30/2026	Inspection Reviewed With : PIC
Reviewers License# : S017587	Inspection type : Routine	

Inspection Conducted By : Steve Haiber

Facility Data

# Rxs/Week	RPh Hours/Week	# Rxs/Hours
150	80	1.875

PERMITS

1	Arizona Posted	☑ S ☐ N/I ☐ V ☐ N/A ARS § 32-1933(A); R4-23-606(A)	

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2 DEA — ☑ S ☐ N/I ☐ V ☐ N/A
ARS § 36-2522(A)(2); 21 CFR 1301.35(c)

FA2624422

3 Suppliers — ☑ S ☐ N/I ☐ V ☐ N/A
ARS § 32-1929; R4-23-601(A); R4-23-604(A); R4-23-605(A); R4-23-607(A)

AnovoRx Distribution (W003768) / McKesson - non-drug supplies

LICENSES

1 Pharmacists — ☑ S ☐ N/I ☐ V ☐ N/A
ARS § 32-1925(A); R4-23-201(A)

(2)

2 Interns / Graduate interns — ☐ S ☐ N/I ☐ V ☑ N/A
ARS § 32-1923(B); R4-23-301(G)

None

3 Technicians / Trainees — ☑ S ☐ N/I ☐ V ☐ N/A
ARS § 32-1925(A); R4-23-1101(A); R4-23-1102(D); R4-23-1103(B)(2)

(1)

4 Current renewal licenses maintained — ☑ S ☐ N/I ☐ V ☐ N/A
ARS § 32-1933(B)

PHARMACY

1 Drug storage and security — ☑ S ☐ N/I ☐ V ☐ N/A
R4-23-609(G)(H)

Keyed hardlocks on entry doors. Badge readers for authorized employee access after pharmacist unlocks entry doors.

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2	Personnel and security procedures	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-610
3	Facilities	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-611(A)
4	Drug supply Orphan drug products delivered from the product's drug manufacturer and stored within AnovoRx Distribution 3PL (L000429) when Anov oRx Group pharmacy (Y009511) requires the product it is sold by the manufacturer and distributed to AnovoRx Distribution (W003768) an d then sold / delivered to AnovoRx Group pharmacy (Y009511). AnovoRx Distribution 3PL and FSW facility is located adjacent to AnovoRx Group pharmacy.	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-611(B)
5	Quarantine expired drugs Secure locked cabinet to hold pending return for destruction	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-611(B)(4)
6	Equipment Manual fill functions only performed at this pharmacy. Front end processing functions performed by AnovoRx Group (Y008359) 1710 SHE LBY OAKS DR N Suite 5 MEMPHIS, TN.	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-612
7	Policies and procedures On line	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-610(A); R4-23-611(B)

TECHNICIANS

1	Training program	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-1105(B)(D)

2	Training program - compounds Pharmacy does not perform compounding activity.	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-1105(C)
3	Activities - trainees None on staff	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-1104(A)
4	Activities - technicians	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-1104(A)(B)
5	Policies and procedures On line	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-1104(F)(G)

COUNSELING

1	Documentation No face to face patient dispensing activity performed. Pharmacist available at AnovoRx Group pharmacy in Memphis TN to receive patie nt / caregiver / practitioner calls. Documentation of any contacts recorded within patient profile record.	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(G)(H)
2	Oral consultation Pharmacist available at AnovoRx Group pharmacy in Memphis TN to receive patient / caregiver / practitioner calls. Documentation of an y contacts recorded within patient profile record.	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(C)(D)(E)
3	Written information CPR plus system generated	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(C)(I)

PRESCRIPTION AUDIT

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1	Prescription files Legend only / no CS drug filled at this facility	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1964; ARS § 36-2525(C)(1)(2)
2	Prescription label	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1968(D); ARS § 36-2525(L)
3	CII prescriptions	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1968; 36-2525(A) to (G); R4-23-407(A)
4	CIII - CV prescriptions	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1968; 36-2525(A)(C)(2)(H)(I); R4-23-407(A)
5	Non-controlled prescriptions	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1968; R4-23-407(A)
6	Transfers None observed	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-407(D)
7	Telephone No calls received at this pharmacy location. All verbal prescription orders received , transcribed, imaged by a pharmacist at AnovoRx Gr oup pharmacy in Memphis TN.	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1968(A)(5); R4-23-402(A)(1)(2)
8	Refill authorizations New prescription obtained	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1968(A)(6); R4-23-402(A)(13); R4-23-407(E)(5)
9	Facsimile None observed.	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-407(E)

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10	Electronically transmitted	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-407(F); R4-23-408(H)
11	Patient information No calls received at this pharmacy location. Patient profile activity performed by a technician or pharmacist at AnovoRx Group pharmac y in Memphis TN.	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(A)(3)(4)
12	Allergies / medical conditions No calls received at this pharmacy location. Patient profile activity performed by a technician or pharmacist at AnovoRx Group pharmac y in Memphis TN.	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(A)(3)(b)
13	Brand / generic Orphan single source brand products only.	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1963.01
14	Foreign prescriptions None received or filled	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1969
15	Prescription blank advertising prohibited Not utilized	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-404(B); ARS § 32-1901.01(B)(25)
16	Prescription audit numbers 3/19/2025 - reviewed imaged order within CRP plus system.		

COMPUTER REQUIREMENTS

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1	Security Individual user ID assigned to each licensee	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-408(F)
2	Log books / printout Log maintained. Reviewed Jan 2024 to date.	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-408(C)(4)
3	Reports	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-408(B)(5)(6)
4	Policies and procedures On line.	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-408(A)

IMMUNIZATIONS

1	Certification Pharmacy does not perform immunization activity.	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1974(D)(K); R4-23-411(A)
2	Recordkeeping	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1974(F)(3); R4-23-411(F)(I)
3	Reporting requirements	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1974(F); R4-23-411(F)(2)
4	Current certificate maintained	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-411(C)(2)
5	Administration without a prescription	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1974(A)(B); R4-23-411(A)

6	Prescription only administration	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1974(C)(I); R4-23-411(A)(4); (B); (I)

MECHANICAL STORAGE / COUNTING DEVICES

1	Cell identification Pharmacy does not utilize this technology.	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(A)(1)
2	Paper / electronic log	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(A)(2)(3)
3	Training	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(C)(1)(D)
4	Maintenance	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(C)(2)(D)
5	Accuracy validation testing	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(C)(3)(D)
6	Return by approval only	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(B)(G)
7	Policies and procedures	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(E)

MECHANICAL COUNTING DEVICES

1	Training Pharmacy does not utilize this technology.	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-616(A)(1)(B)

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2	Maintenance	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-616(A)(2)(B)
3	Accuracy validation testing	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-616(A)(3)(B)
4	Policies and procedures	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-616(C)

CONTROLLED SUBSTANCE RECORDS

1	CIIs purchase / sale / disposal	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 36-2523(A); ARS § 36-2524; R4-23-601(D);R4-23-1003(A)(4)(B)
	Pharmacy has not purchased, received or stored any C2 drug.		
2	CIII - CVs purchase / sale / disposal	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 36-2523(A); R4-23-601(D); R4-23-612(11); R4-23-1003(A)(4)
	Pharmacy has not purchased, received or stored any C2 drug.		
3	Inventory	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 36-2523(B); R4-23-1003
	Pharmacy holds DEA registration FA2624422 | Annual CSI documentation maintained for zero inventory of C2 and C3-5 drug.		
4	Audit	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 36-2523
	Not performed		
5	DEA 106 Theft/Loss reporting	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-1003(A)(2); 21 CFR 1301.76(b)
	None reported		

MISCELLANEOUS

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1	Badges - name / title Worn by each employee	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(K); R4-23-671(B)(4); R4-23-1104(E)
2	Sales of drugs to practitioners None	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1981(7)(d); R4-23-601(D); R4-23-1003(A)(4)
3	Schedule V register No CS drug	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 36-2525(J)
4	Delivery Fed-Ex, UPS / overnight priority / receipt signature required	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1901.01(B)(23); R4-23-402(I)
5	CQA training / Policies and procedures DT exception reporting program / monthly quality meeting	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1973; R4-23-620
6	Non-controlled substances purchase / sale / disposal Secure locker to store product pending final disposition	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-601(D)
7	Dextromethorphan sales restrictions No OTC sales	☐ S ☐ N/I ☐ V ☑ N/A	ARS 32-1978

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8	Federal medication guides CPR plus generated	☑ S ☐ N/I ☐ V ☐ N/A	21 CFR part 208
9	Pharmacy to pharmacy transfer of drugs (intracompany) None	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-601(D); R4-23-1003(A)(4)

METHAMPHETAMINE PRECURSORS

1	Storage No PSE stocked, dispensed or sold	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1977(B)
2	Documentation	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1977(C); 21 CFR 1314
3	Self-certification	☐ S ☐ N/I ☐ V ☑ N/A	21 CFR 1314.35; 21 CFR 1314.40

SHARED SERVICES

1	Current resident / nonresident permit Shared prescription processing utilizing AnovoRx Group pharmacy (Y008359) in Memphis TN	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-621(A)
2	Same owner / written contract / common electronic file AnovoRx Group / shared common file CPR plus	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-621(B)

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3	Notification to patients Witten notice included with each dispensed order	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-621(C)
4	Maintain manual / electronic records CPR plus system	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-621(D)
5	Work outside pharmacy No remote staff tethered to this permit	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-621(F)
6	Policies and procedures On line	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-621(E)

COMPOUNDING PRACTICES (GENERAL)

1	Documentation product compounded Pharmacy does not perform this activity	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-410(C)(1)(e); R4-23-410(I)(K)
2	Patient label	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-410(I)(4)
3	Beyond-use dates	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-410(I)(4)(b); R4-23-410(B)(3)(d)
4	Equipment	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-410(F)(G)

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

5	Product produced in excess	☐ S ☐ N/I ☐ V ☑ N/A R4-23-410(B)(2); R4-23-410(J)
6	Component removed from original container	☐ S ☐ N/I ☐ V ☑ N/A R4-23-410(I)(6)
7	Compounds for medical practitioners	☐ S ☐ N/I ☐ V ☑ N/A R4-23-410(B)(3); R4-23-601(D); R4-23-1003(A)(4)
8	Patient written list	☐ S ☐ N/I ☐ V ☑ N/A R4-23-410(I)(5)
9	Protective apparel	☐ S ☐ N/I ☐ V ☑ N/A R4-23-410(C)(2)(c)
10	Facility	☐ S ☐ N/I ☐ V ☑ N/A R4-23-410(E)
11	Components for compounding/storage	☐ S ☐ N/I ☐ V ☑ N/A R4-23-410(B)(H)
12	Policies and procedures	☐ S ☐ N/I ☐ V ☑ N/A R4-23-410(D)(G)(H)(I)(K)

STERILE COMPOUNDING

1	Compounding area Pharmacy does not perform this activity	☐ S ☐ N/I ☐ V ☑ N/A R4-23-670(A)(E)(F)
2	Equipment	☐ S ☐ N/I ☐ V ☑ N/A R4-23-670(B)

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

3	Sterile product reference	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(B)(6)
4	Certification hood / environment	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(D)(14)(g)
5	Documentation routine cleaning / maintenance	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(D)(14)(g)
6	Personnel protective clothing	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(E)(3)(F)(2)
7	Annual / semi-annual media fill tests	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(E)(4)(F)(3)
8	Documentation of product compounded	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-410(C)(1)(e); R4-23-410(I)(K)
9	Beyond-use dates	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(D)(14)(d); R4-23-410(B)(3)(d)
10	Process / product validation testing	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(D)(14)(f)
11	Policies and procedures	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(C)(D)

AUDIT

Date Of Inventory : 05/01/2025

Inventory Taken : Open

Date Of Audit : 03/19/2025

Name & Strength of Drug	Initial Inventory	Total Purchased	Total Accounted For	Closing Inventory	Sales (Rx & log)	Total Can Account for	Difference	Percentage
No CS Drug received, stocked or dispensed at this pharmacy - audit not performed								

NOTES

Routine inspection performed 03/19/2025 - AnovoRx Group, LLC (Y009511)
Overall inspection - satisfactory

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 09/03/2024
Receipt Number: 2024177224
Receipt Amount $: 480.00

Pharmacy - Independent

	PERMIT NO	EXPIRES
	Y009511	**10/31/2026**
Issued to :	AnovoRx Group, LLC AnovoRx Group, LLC 1710 N SHELBY OAKS DR SUITE 2 MEMPHIS, TN 38134	AnovoRx Group, LLC 17500 SOUTH 40 STREET BUILDING B SUITE B-600A CHANDLER, AZ 85226

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF
PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : AnovoRx Group, LLC
LICENSE NUMBER : Y009511
EXPIRES : 10/31/2026

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.

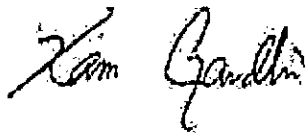
Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260,
Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	AnovoRx Group, LLC
Address :	17500 South 40 Street Building B Suite B-600A Chandler AZ 85226
Registration No :	Y009511
Permit Type :	Pharmacy
Sub Type :	Independent
Date Issued :	03/24/2023
Expiration Date :	10/31/2026
Status :	OPEN
Discipline :	No



Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 02/12/2026

4XX

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada The applicant remains owned by AnovoRx Group, LLC. This is not a change at the applicant level. This is a change at the Grandparent level.	☐ New Pharmacy ☑ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 02963	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: Specialty Pharmacy	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☑ Other: Specialty Pharmacy

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: AnovoRx Group, LLC

Physical Address: 1710 N. Shelby Oaks Drive Suite 1

City: Memphis State: TN Zip: 38134-7403

Mailing Address (if different from physical address): 1710 N. Shelby Oaks Drive Suite 2

City: Memphis State: TN Zip: 38134-7403

Telephone: 901-201-5470 Toll Free # (NAC 639.708, NRS 639.23286): 1-844-288-5007

Fax: 901-201-5465 Contact Email: officialcontact@anovorx.com

Website: www.anovorx.com

Nevada Business License # (if applicable) NV20131161181

Supervising/Managing Pharmacist Name (NRS 639.220): E. Nelson Burford, home state managing pharmacist

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 9384 TN

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Angela Jonakin	NV Pharmacist Registration #: 24579
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Tennessee

Parent Company (if any): AnovoRx Holdings, LLC

Corporation/Organization Name: AnovoRx Group, LLC

Mailing Address: 1710 N. Shelby Oaks Drive Suite 2

City: Memphis State: TN Zip: 38134-7403

Telephone: 901-201-5470 Email: officialcontact@anovorx.com

Contact Person Name: Cathy Bellehumeur, VP Regulatory Compliance and Licensing

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CFO and Secretary (title) for AnovoRx Group, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Jason T. Shackelford, CFO and Secretary

Print Name of Authorized Person

Jason Shackelford

Original signature of Authorized Person (copies or stamps not accepted)

09.04.2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Jason T. Shackelford hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CFO and Secretary (title) for AnovoRx Group, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 4th day of September, 2025

Notary Public

DORA GARCIA
STATE OF TENNESSEE
NOTARY PUBLIC
SHELBY COUNTY

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jason T. Shackelford, CFO and Secretary

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

09-04-2025
Date

Board Use Only	Date Received: 10/15/25	Amount: $500 CK 9178

anovo

Dedicated.
Exclusive.
Unique.

September 4, 2025 VIA EMAIL

Re: Information Update for Grandparent of Non-Resident Pharmacy Licensee
Licensee: AnovoRx Group, LLC NCPDP 444-5640 NPI 1619213212
Home State Pharmacy License: TN License Number: 5129
Location: 1710 N Shelby Oaks Dr Suite 1 Memphis TN 38134

INFORMATION UPDATE FOR GRANDPARENT OF LICENSEE

AnovoRx Growth, LLC (the "Licensee") is pleased to inform you that today the TPG family of companies increased its investment in the Licensee's parent company. Today an affiliate of the current 40% owner of our parent company became the 100% owner of our parent company. This makes a member of the TPG family of companies the sole grandparent of the Licensee. Having our existing investor increase its ownership percentage of our parent company will help Anovo maintain its healthy financial condition.

This update will not result in any change to the Licensee itself. The Licensee's FEIN, home state pharmacy permit number, DEA registration number, management, day-to-day operations, parent company and pharmacist-in-charge remain intact. The chart below shows the Licensee's details before and after this update.

Key: Updated information is **bolded**. All other information remains the same.		
ITEM	**Before**	**From 09/04/2025**
Name of Licensee	AnovoRx Group, LLC	AnovoRx Group, LLC
FEIN of Licensee	45-5299748	45-5299748
Address of Licensee	1710 N. Shelby Oaks DR Suite 1 Memphis TN 38134	1710 N. Shelby Oaks DR Suite 1 Memphis TN 38134
Home State Pharmacist in Charge	E. Nelson Burford (aka Nelson Burford)	E. Nelson Burford (aka Nelson Burford)
Officers of Licensee	• Joel Kimbrough, President/ CEO • Kyle Truitt, COO • Jason Shackelford, CFO and Secretary	• Joel Kimbrough, President/CEO • Kyle Truitt, COO • Jason Shackelford, CFO and Secretary
Board of Directors of Licensee	Joel Kimbrough	Joel Kimbrough
Parent of Licensee (owns 100% of the Licensee)	AnovoRx Holdings, Inc. FEIN of Parent: 46-1775496 Address: 1710 N Shelby Oaks Dr. STE 2 Memphis TN 38134	AnovoRx Holdings, **LLC** FEIN of Parent: 46-1775496 Address: 1710 N Shelby Oaks Dr. STE 2 Memphis TN 38134
Grandparent(s) of Licensee and % ownership of Licensee's parent company, AnovoRx Holdings, LLC	• Estate of Jon B. Peters 13.5% • Joel Ray Kimbrough 13.5% • Diane J. Callahan 6% • TPG Growth V Amplifier, L.P. 40%	**Atlas Borrower, LLC** (an affiliate of TPG Growth V Amplifier, L.P.) **100% owner of our parent** See Attached Business Organization Chart as of 9/04/25

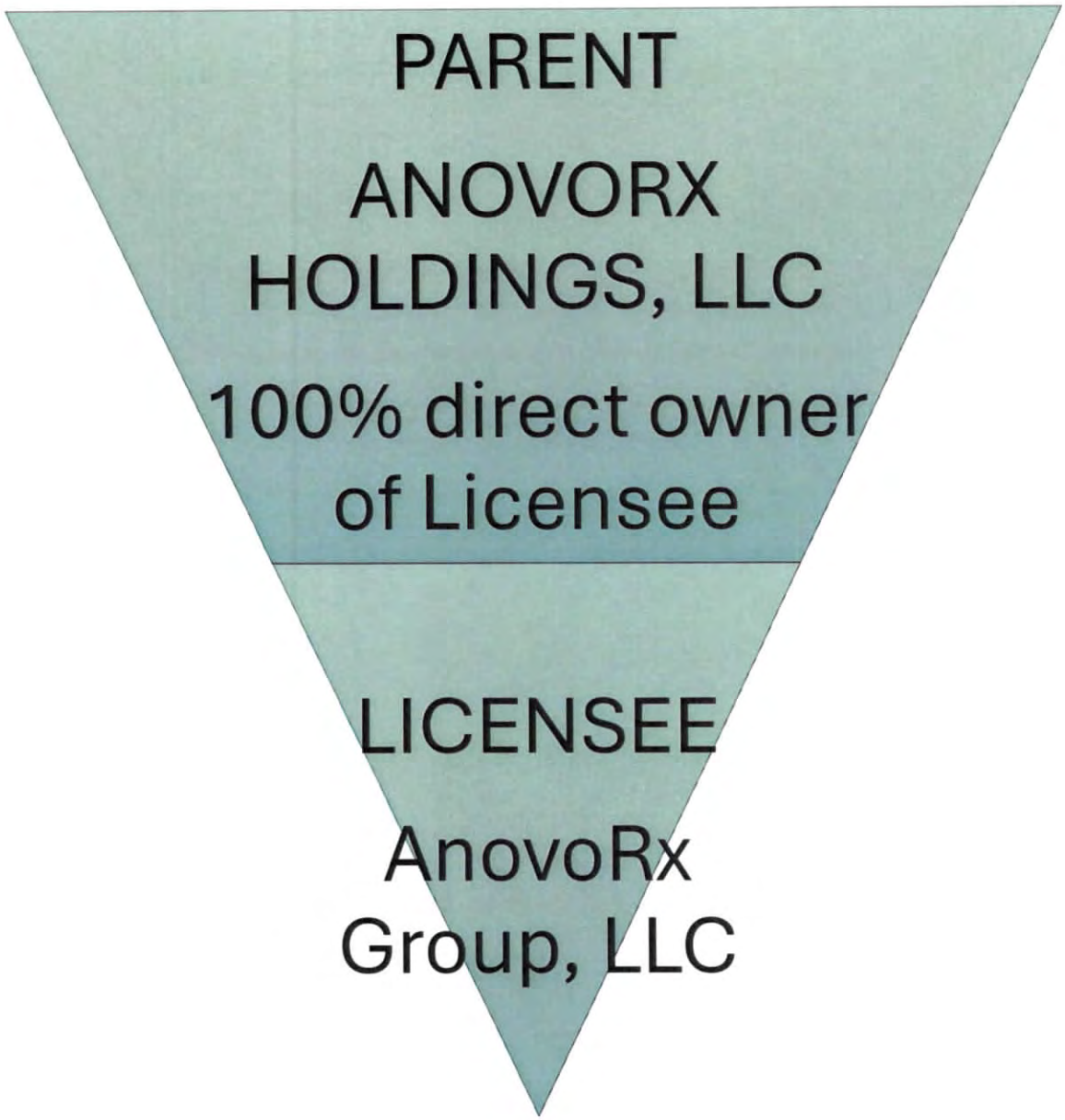
	• Equity Partners XX(20), LLC 13.5% • 13.5% held by various individuals and trusts, none of whom own 5% or more	

Please send us an email at officialcontact@anovorx.com if you need any further information.

AnovoRx Group, LLC

Jason T. Shackelford
Chief Financial Officer and Secretary

Web AnovoRx.com Phone 901-201-5470 Toll free 1-844-288-5007
Address AnovoRx | 1710 N. Shelby Oaks Drive, Suite 2 | Memphis, TN 38134


PARENT
ANOVORX HOLDINGS, LLC
100% direct owner of Licensee
LICENSEE
AnovoRx Group, LLC

Division of Business and Charitable Organizations
Department of State
State of Tennessee
312 Rosa L. Parks Avenue, 6th Floor
Nashville, Tennessee 37243
Phone: 615-741-2286
sos.tn.gov/

Tre Hargett
Secretary of State

CATHY BELLEHUMEUR
1710 N SHELBY OAKS DRIVE, STE 2
MEMPHIS, TN 38134, USA

05/13/2025

Request Type: Certificate of Existence/Authorization

Issuance Date: 05/13/2025

Request #: C2025032899

Document Receipt

Order Number: C2025032899

Verification #: 0516CFF0

Receipt #: 2025-349483

Filing Fee: $20.00

Payment: Credit Card - 3898383889 $20.00

Entity Name:	ANOVORX GROUP, LLC		
SOS Control #:	000685324	Initial Filing Date:	05/02/2012
Entity Type:	Limited Liability Company (LLC)	Formation Locale:	TENNESSEE
Status:	Active	Duration Term:	Perpetual
Fiscal Year Close:	December	Annual Report Due:	04/01/2026
Business County:	SHELBY		
Managed By:	Member Managed		
Obligated Member Entity:	No		

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

ANOVORX GROUP, LLC

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;
* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;
* has filed the most recent annual report required with this office;
* has appointed a registered agent and registered office in this State;
* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Verification #: 0516CFF0

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler AnovoRx Group, LLC

Pharmacy/Wholesaler License # (if applicable) PH02963

Physical Address 1710 N. Shelby Oaks Dr, Ste 1

City Memphis State TN Zip 38134

Mailing Address (if different from physical address) 1710 N. Shelby Oaks Dr, Ste 2

City Memphis State TN Zip 38134

Telephone 901-201-5470 Website https://www.anovorx.com

Licensing Company Email Officialcontact@anovorx.com

Section 2: Personal Information

First Angela Middle Metz Last Jonakin

Alias(es, nicknames, name changes, etc.) Angela Metz

[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of TN Health Science Center College of Pharmacy		08/08-05/12	
Address	**City**	**State**	**Zip**
881 Madison Ave	Memphis	TN	38163
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Christian Brothers University		08/04-05/08	
Address	**City**	**State**	**Zip**
650 E Pkwy S	Memphis	TN	38104
Diploma/Degree obtained, if any			
Bachelor's of Science, Biology			

School Name		From - To (MM/YY – MM/YY)	
Bartlett High School		08/00-05/04	
Address	**City**	**State**	**Zip**
5688 Woodlawn St	Bartlett	TN	38134
Diploma/Degree obtained, if any			
High school diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/19-current	[redacted]			
08/18-01/19				
09/12-08/18				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
AnovoRx			11/21-current
Business Address	**City**	**State**	**Zip**
1710 N Shelby Oaks Dr Ste 1	Memphis	TN	38134
Phone	**Title**		**Number of Employed Hours**
901-201-5470	Pharmacy supervisor, staff pharmacist		4120

Description of Duties
Receipt and interpretation of prescriber orders for accuracy and appropriateness. Verification of prescriptions entered for accuracy. Supervision of multiple staff pharmacists and technicians performing daily duties. Counseling of patients on proper dosing, administration, side effects, and clinical pearls of medication use. Counseling on disease state management. Completion of DURs. Reporting of adverse events to pharmacovigilance groups. Collaboration with drug manufacturers to ensure positive patient outcomes through initiation of programs regarding side effects, efficacy, and compliance.

Business Name			From - To (MM/YY – MM/YY)
Walmart Pharmacy			09/17-11/21
Business Address	**City**	**State**	**Zip**
6727 Raleigh LaGrange Rd	Memphis	TN	38134
Phone	**Title**		**Number of Employed Hours**
(901)498-5327	Pharmacy Manager, staff pharmacist		4480

Description of Duties
Receipt and interpretation of prescriber orders for accuracy and appropriateness. Verification of prescriptions entered for accuracy. Supervision of multiple staff pharmacists and technicians performing daily duties. Counseling of patients on proper dosing, administration, side effects, and clinical pearls of medication use. Completion of DURs and MTM. Supervision of inventory maintenance through efficient ordering and return of expiring/unused drugs. Performance of health testing and administration of immunizations.

Business Name			From - To (MM/YY – MM/YY)
Walgreens			07/12-09/17
Business Address	**City**	**State**	**Zip**
1359 Poplar Ave	Memphis	TN	38104
Phone	**Title**		**Number of Employed Hours**
(901)276-5491	Pharmacy Manager, staff pharmacist		5520

Description of Duties
Receipt and interpretation of prescriber orders for accuracy and appropriateness. Verification of prescriptions entered for accuracy. Supervision of multiple staff pharmacists and technicians performing daily duties. Counseling of patients on proper dosing, administration, side effects, and clinical pearls of medication use. Completion of DURs and MTM. Supervision of inventory maintenance through efficient ordering and return of expiring/unused drugs. Performance of health testing and administration of immunizations.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N / A	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I, Angela Jonakin, certify that as the designated representative for

AnovoRx Group, LLC

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Angela Jonakin

Print Name (First, Last)

Angela Jonakin

Original Signature (electronic, copies or stamps not accepted)

2-10-2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Angela Jonakin

Print Name (First, Last)

Angela Jonakin

Original Signature (electronic, copies or stamps not accepted)

2-10-2026

Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Shelby

I, Angela Jonakin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Angela Jonakin

Original Signature

2-10-2026

Date

Subscribed and Sworn to before me this 10th day of February .2026

Dora Garcia

Notary Public Signature

DORA GARCIA
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY
(Seal)

DEPARTMENT OF HEALTH
TENNESSEE BOARD OF PHARMACY
COMMUNITY INSPECTION
COMPLIANCE INSPECTION

PHARMACY: Uptown Rx Group	
STREET: 1710 N Shelby Oaks Dr Ste 1	
CITY: Memphis	ZIP: 38134
DATE OPENED:	TELEPHONE NO.: (901) 201-5470
LICENSE NO.: 5124	EXPIRY DATE: 1/6/27
DEA NO.: [redacted]	EXPIRY DATE: 6/30/26
PHARMACIST IN CHARGE/Duty: Nelson Bunsen	LIC NO.: 9384 / EXPIRY DATE: 1/2/27

Inspected by: Dean Johnson — Date: 12/5/25

This Inspection Satisfactory: Yes ☐ No ☐

☐ Opening ☐ Relocation ☐ New Ownership ☐ Follow-up ☐ Counseling Compliance ☑ Periodic ☐ Remodeling

Compliance Yes	Compliance No	PERSONNEL
✓		1. Appropriate identification/Name Tags
✓		2. D. Ph./Tech ration
✓		3. Personnel/apparel clean
✓		4. Tech registry & Affidavit

Compliance Yes	Compliance No	PHYSICAL REQUIREMENTS
✓		5. Certificates Displayed
✓		6. RX Dept. - Sufficient Space/Counseling
✓		7. Fully enclosed when applicable
✓		8. Key Lockable/Key Control

Compliance Yes	Compliance No	DRUGS AND EQUIPMENT
✓		9. Dispensing area clean, orderly, well lighted
✓		10. Sink, hot and cold water
✓		11. Refrigeration
✓		12. References, periodicals
✓		13. Vials and closures (child-proof)
✓		14. Shelves and drug stock clean
✓		15. Drugs in-date
N/A		16. Labels correct on repackaging
✓		17. Legend drugs stored in RX Dept.
✓		18. Syringes/insulin, restricted products non-accessible

Pharmacy Hours: 7-7 M-F 8-9 S&S

Compliance Yes	Compliance No	
✓		19. RXs numerically filed ☐ All C's together ☐ C-11's separate ☐ Multiple file method
N/A		
✓		20. Patients identifiable
✓		21. Prescribers identifiable
N/A		22. New verbal RXs initialed by appropriate personnel
✓		23. Date of original dispensing
✓		24. Initials of dispensing D. Ph.
✓		25. Quantity dispensed indicated
N/A		26. Appropriate Emergency C-11 RXs
✓		27. Computer labels applied appropriately to RXs
✓		28. Pharmacist Signature Log
N/A		29. Daily Print Out

Compliance Yes	Compliance No	DRUG PRODUCT SUBSTITUTION
✓		30. Authorization documented on Rx
✓		31. Manufacturer indicated on Rx or System
✓		32. Approved products used

Compliance Yes	Compliance No	PATIENT COUNSELING
✓		33. Patient profiles
✓		34. Drug Utilization Review
✓		35. Patient Counseling Consistently done 84

Compliance Yes	Compliance No	CONTROLLED SUBSTANCE RECORDS
✓		36. Readily retrievable
✓		37. All C-11 records separate
✓		38. DEA Form 222 Copy 3 on hand & completed
✓		39. Drug Receipt date on invoices
✓		40. Record of drug transfers
✓		41. ☐ Schedule V sales record book ☐ Methamphetamine Sales Log
✓		42. Last DEA Inventory (date) 5/29/25
✓		42. Last Theft/loss report (date) none
N/A		43. Access to Control Substance Monitoring Database

ITEMS TO BE CORRECTED: **RESPONSE REQUIRED** YES ☐ NO ☑

Immediately

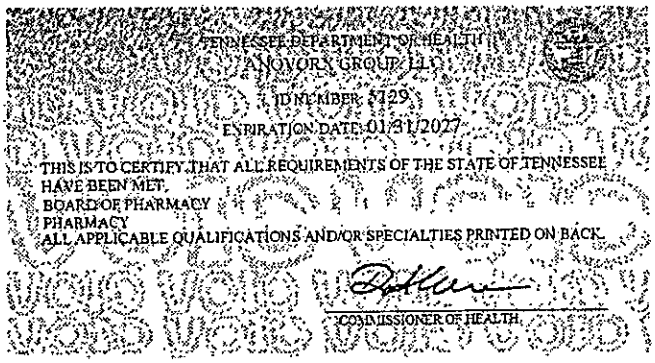
Needs Improvement

Within 30 Days

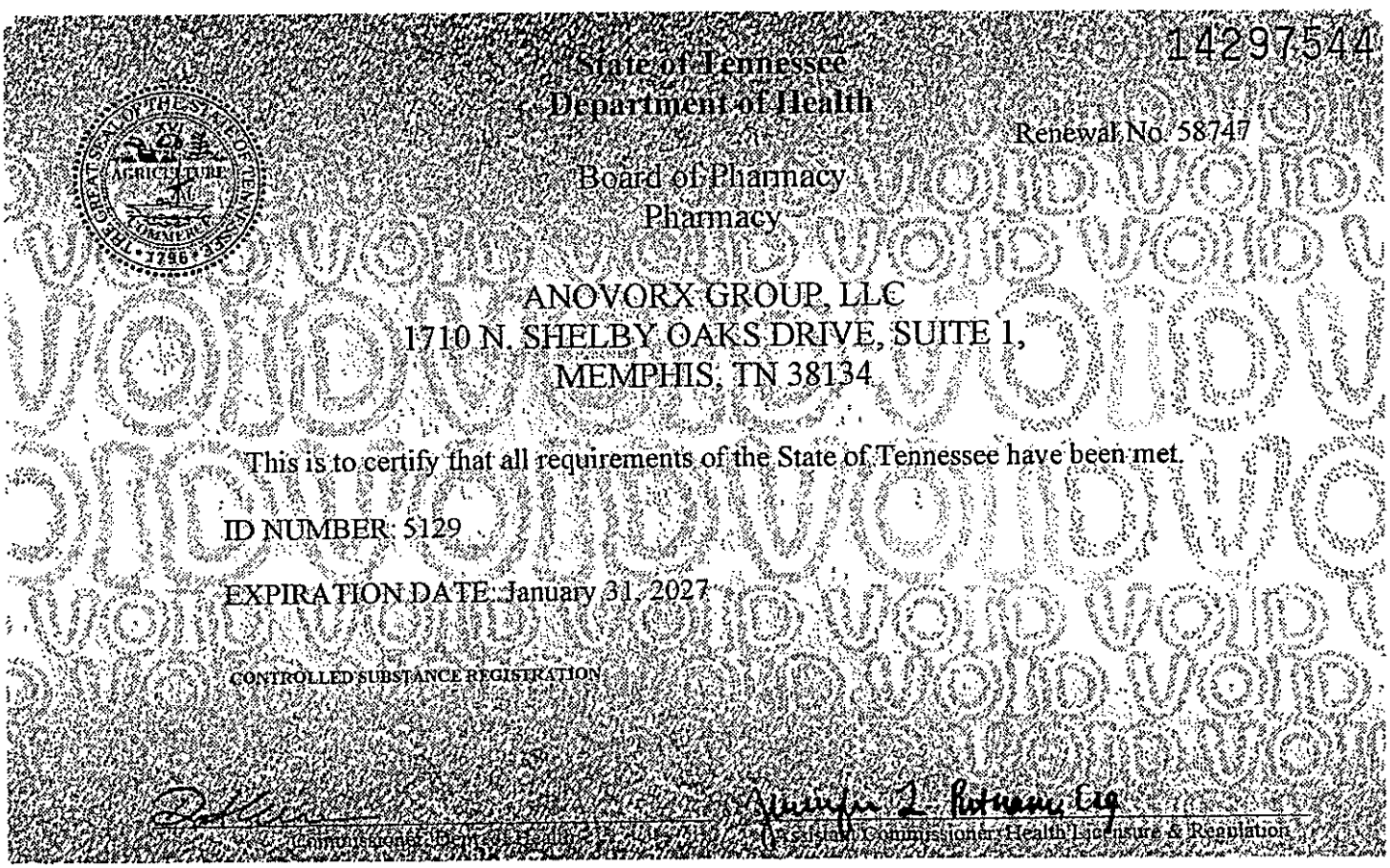
Remarks or Recommendations:

I [signature] hereby acknowledge and understand all notations made on this report, and confirm that I will notify the Board of Pharmacy within 30 days, in writing, of the correction of all deficiencies. (If noted.)

/Pharmacist Signature


TENNESSEE DEPARTMENT OF HEALTH
ANOVORX GROUP, LLC
ID NUMBER: 5129
EXPIRATION DATE: 01/31/2027
THIS IS TO CERTIFY THAT ALL REQUIREMENTS OF THE STATE OF TENNESSEE HAVE BEEN MET.
BOARD OF PHARMACY
PHARMACY
ALL APPLICABLE QUALIFICATIONS AND/OR SPECIALTIES PRINTED ON BACK.
COMMISSIONER OF HEALTH

ANOVORX GROUP, LLC
1710 N. SHELBY OAKS DRIVE, SUITE 2
MEMPHIS, TN 38134


14297544

State of Tennessee

Department of Health

Renewal No. 58747

Board of Pharmacy

Pharmacy

ANOVORX GROUP, LLC
1710 N. SHELBY OAKS DRIVE, SUITE 1,
MEMPHIS, TN 38134

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 5129

EXPIRATION DATE: January 31, 2027

CONTROLLED SUBSTANCE REGISTRATION

Commissioner, Department of Health

Assistant Commissioner, Health Licensure & Regulation

Last Updated: 2/12/2026

For more information, please contact
Health Care Facilites
(615)741-7221 or 800-310-4650

Health Care Facilities

Licensed Facilities

Current Listings

Type = Pharmacy
County = All
Results = 3

Click here to return to the search page

1

ANOVORX GROUP, LLC
1710 N. SHELBY OAKS DRIVE, SUITE 1
Memphis, TN 38134
901-201-5470

Qualifications
Controlled Subs

Rank: Pharmacy
Pharmacist: BURFORD, E NELSON

Facility License Number: 00005129
Status: Licensed
Date of Original Licensure: 01/07/2013
Date of Expiration: 01/31/2027
No Disciplinary Actions

2

AnovoRx Group, LLC
1710 N. Shelby Oaks Dr. Suite 5
Memphis, TN 38134
901-201-5470

Qualifications
Controlled Subs

Rank: Pharmacy
Pharmacist: MCLEAN, KATIE M

Facility License Number: 00005905
Status: Licensed
Date of Original Licensure: 11/23/2016
Date of Expiration: 09/30/2026
No Disciplinary Actions

3

AnovoRx Group, LLC
17500 South 40th St., Building B, Suite B600A
Chandler, AZ 85226
844-288-5007

Qualifications
Controlled Subs

Rank: Pharmacy
Pharmacist: WEBSTER, SAM E

Facility License Number: 00007594
Status: Licensed
Date of Original Licensure: 05/05/2023
Date of Expiration: 05/31/2027
No Disciplinary Actions

4YY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	☐ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	■ Other: Closed Door Mail Order	■ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: ClearMedix Pharmacy, LLC

Physical Address: 510 E Wilson Bridge Rd Suite D

City: Worthington State: Ohio Zip: 43085

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 855-314-0136 Toll Free # (NAC 639.708, NRS 639.23286): 855-314-0136

Fax: 855-314-0136 Contact Email: info@clearmedixpharmacy.com

Website: www.clearmedixpharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Ian Duncan Hill

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23900

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Ian Hill	NV Pharmacist Registration #: 23900
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): ZenithSphere, LLC

Corporation/Organization Name: ZenithSphere, LLC

Mailing Address: 510 E Wilson Bridge Rd Suite D

City: Worthington State: Ohio Zip: 43085

Telephone: 855-314-0136 Email: info@clearmedixpharmacy.com

Contact Person Name: Ian Hill

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist in Charge (title) for ClearMedix Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Ian Hill

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2/11/26

Date

JOHATHAN NABIL HADDAD NOTARY PUBLIC

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Ian Hill hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for ClearMedix Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 11th day of February, 20 26

Jonathan Haddad
Notary Public

JONATHAN NABIL HADDAD - NOTARY PUBLIC
COMM EXP: OCT 16, 2030
STATE OF OHIO

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ian Hill

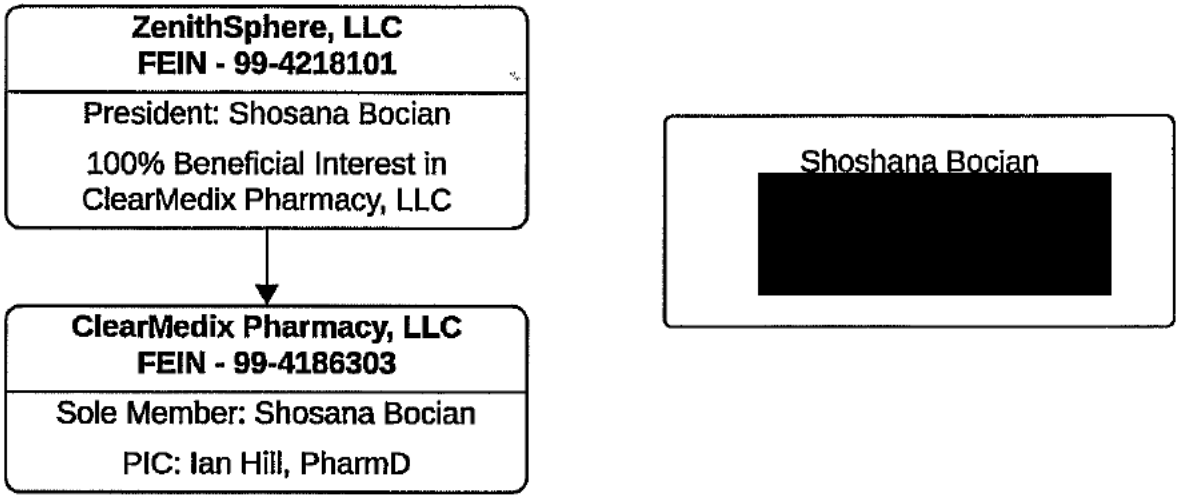
Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

2/11/26

Date

Board Use Only	Date Received: 2/13/26	Amount: $300


ZenithSphere, LLC
FEIN - 99-4218101
President: Shosana Bocian
100% Beneficial Interest in
ClearMedix Pharmacy, LLC
ClearMedix Pharmacy, LLC
FEIN - 99-4186303
Sole Member: Shosana Bocian
PIC: Ian Hill, PharmD
Shoshana Bocian
[redacted]

UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show CLEARMEDIX PHARMACY, LLC, a Delaware Limited Liability Company, Registration Number 5333478, was registered in the State of Ohio on December 27, 2024, is currently authorized to transact business in this state.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 19th day of December, A.D. 2025.

Ohio Secretary of State

Validation Number: 202535303454

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler ClearMedix Pharmacy, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 510 E Wilson Bridge Rd Suite D

City Worthington State Ohio Zip 43085

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855 314 0136 Website www.clearmedixpharmacy.com

Licensing Company Email _____

Section 2: Personal Information

First Ian Middle Duncan Last Hill

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
ClearMedix Pharmacy			09/24 - Present	
Business Address		**City**	**State**	**Zip**
510 E Wilson Bridge Rd Suite D		Worthington	Ohio	43085
Phone	**Title**		**Number of Employed Hours**	
855 314 0136	Pharmacist In Charge		640	
Description of Duties				
At ClearMedix Pharmacy I am responsible for the establishment and successful opening of a brand new non-sterile compounding pharmacy including facility design, equipment procurement, and staff hiring.				

Business Name			From - To (MM/YY – MM/YY)	
Hims and Hers			11/21 - 09/24	
Business Address		**City**	**State**	**Zip**
9750		New Albany	OH	43054
Phone	**Title**		**Number of Employed Hours**	
855 918 4467	Lead Pharmacist		6080	
Description of Duties				
Maintained product dispensing, robot cell validation, and prescription verification operations of the pharmacy and work with the pharmacy leadership team to ensure the success of the fulfillment service level agreement				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Toledo		08/09-05/15	
Address	City	State	Zip
2801 Bancroft St	Toledo	OH	43606
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Franklin Regional High School		08/05-06/09	
Address	City	State	Zip
3200 School Rd	Murrysville	PA	15668
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07-23-Present	[redacted]			
07/18-06/23				
06/16-07/18				
07/15-06/16				
06/13-06/15				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Ian Duncan HILL, **certify that as the designated representative for**

ClearMedix Pharmacy, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. IH I am at least 21 years of age;
3. IH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. IH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. IH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. IH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. IH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ian Hill

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/11/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ian Hill

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/11/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin

I, Ian Hill, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/11/2026

Date

Subscribed and Sworn to before me this 11 day of February 2026

Jonathon Haddad

Notary Public Signature

JONATHAN NABIL HADDAD - NOTARY PUBLIC STATE OF OHIO COMM EXP: OCT 16, 2030 (Seal)

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License 0230000027

Clearmedix Pharmacy Llc

510 E Wilson Bridge Rd Ste D
Worthington, OH 43085-2373
Franklin County

Terminal - Pharmacy - Category 2

USP Inspection Guide (Updated 11/7/2024)

December 16, 2024

License 0230000027 - Clearmedix Pharmacy Llc

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by Alex Seminara
Start 12/16/2024 1:55 PM
End 12/16/2024 3:11 PM

Organization

Name
Clearmedix Pharmacy Llc

License Type
Terminal - Pharmacy - Category 2

Category

License Number
0230000027

Business Type
MO - Mail Order Pharmacy

DEA Number

Responsible Person
Ian Hill, R.Ph.

Hours of Operation

Contact

Address
510 E Wilson Bridge Rd Ste D
Worthington, OH 43085-2373
Franklin County

Primary Number
(855) 314-0136

Fax Number

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Daniel DiStefano, R.Ph.			03439312		
Ian Hill, R.Ph.		Responsible Person	03334995		ian.hill@clearmedixpharmacy.com

1) *Initial Inspection Information

1) Personnel conducting inspection

Observation
Compliance Specialist Alex Seminara

6) Does the TDDD distribute dangerous drugs outside of Ohio?

Yes

Observation
Discussed plans to apply all 49 remaining states

28.1) Definitions – pharmacy compounding (OAC 4729:7-2-01)

1) Does the pharmacy compound?

Yes: Non-sterile Compounding

28.6.1) Introduction and Scope

1) Informational: USP Definition of Compounding and Scope

Observation
USP 795 | Effective 11/1/20203
This chapter describes the minimum standards to be followed for the preparation of compounded nonsterile preparations (CNSPs) for humans and animals. For purposes of this chapter, nonsterile compounding is defined as combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.
The requirements in this chapter must be followed to minimize harm, including death, to human and animal patients that could result from 1) excessive microbial contamination, 2) variability from the intended strength of correct ingredients (e.g., ±10% of the labeled strength), 3) physical and chemical incompatibilities, 4) chemical and physical contaminants, and/or 5) use of ingredients of inappropriate quality.
Handling of nonsterile hazardous drugs (HDs) must additionally comply with Hazardous Drugs—Handling in Healthcare Settings □800□.

3) Does the facility compound CNSPs (compounded nonsterile products)?

Yes: Nasal and sinus preparations intended for local application (i.e., nasal sprays and nasal irrigations)

4) Does the facility perform any practies that are not considered compounding, and are therefore not subject to the requirements of USP 795?

No: The facility does not perform any practices not subject to the requirements of USP 795.

5) Are compounding leadership and all personnel involved in preparing, storing, transporting, packaging, and dispensing CNSPs responsible for compliance with USP 795?

Yes: Compounding personnel are responsible for ensuring that the applicable practices and quality standards in USP 795 are continually and consistently applied to their operations.

Yes: Compounding personnel proactively identify and remedy potential problems within their operations.

Yes: Personnel engaged in compounding and dispensing of CNSPs comply withy laws and regulations of the applicable regulatory jurisdiction.

6) Has the facility appointed a designated person?

Yes

Observation
Discussed Ian Hill, RPh has been identified as the Designated Person

7) What activities is the designated person responsible for?

Oversees a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs

Selecting components

Monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed

Ensuring that standard operating procedures (SOPs) are fully implemented.

Ensuring that follow-up is carried out if problems, deviations, or errors are identified

Establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs

28.6.2) Personnel Training and Evaluation

1) Do all personnel who compound or have direct oversight of compounding receive initial training before being allowed to perform their job functions independently?

Yes

Observation
Discussed that training program indicates that all competencies must be completed to a satisfactory degree before performing job functions independently

2) Has the designated person created and implemented a training program that equips personnel with knowledge and training in the required skills necessary to perform their assigned tasks?

Yes: Frequency of training is described

Yes: Process for evaluating the competency of personnel is described

Yes: Equips personnel with the skills to perform their assigned tasks.

3) Do personnel who compound or have direct oversight with compounding personnel complete training initially and at least every 12 months?

Yes

4) Do SOPs describe training requirements for personnel who do not compound and only perform functions such as in-process checks, final verification, or dispensing?

Yes

5) Does facility training demonstrate knowledge and competency initially and at least annually in the core competencies?

Yes: Hand hygiene

Yes: Garbing

Yes: Cleaning and sanitizing

Yes: Handling and transporting components and CNSPs

Yes: Mixing and measuring

Yes: Proper use of equipment and devices selected to compound CNSPs

Yes: Documentation of the compounding process

6) Do training procedures include a review of appropriate written materials?

Yes: USP 795

Yes: Staff understand and interpret safety data sheets (SDSs)

Yes: Staff understandi certificates of analysis (CofA)

Yes: Staff read and understand procedures related to their compounding duties

7) Does the training process document personnel have been trained and successfully completed competency assessments?

Yes: Personnel are observed and guided throughout the training process.

Yes: Personnel are expected to repeat procedures independently under direct supervision.

Yes: Personnel are permitted to perform the procedure without direct supervision only after independently demonstrating understanding and competency.

Yes: Upon completion of the training program the designated person or assigned trainer documents personnel have been successfully trained and completed competency assessments.

8) Does the designated person monitor and observe compounding activities?

Yes: Routinely monitors and observes compounding activities

Yes: Takes immediate corrective action if deficient practices are observed.

9) Does the facility have SOPs that describe the procedures for monitoring and observing compounding activities and personnel?

Yes

Observation
Observed policy which demonstrates procedures for monitoring and observing compounding activities and personnel

28.6.3) Personal Hygiene and Garbing

1) Does the facility require that individuals entering the compounding area maintain appropriate personal hygiene?

Yes: Individuals are trained to report conditions that present a personal risk of potential contamination to the compounding environment and CNSP to the designated person.

Yes: The designated person evaluates whether individuals should be excluded from working in the compounding area until personal conditions resolve.

Observation
Observed policy which demonstrates management of individuals entering the compounding area maintain appropriate personal hygiene

3) Does the designated person permit accommodations for personal items provided that the quality of the environment and CNSP are not affected?

Other

Observation
Discussed that currently there are no accommodations for personal items but will be evaluated on a case by case basis with appropriate documentation

4) Do compounding staff perform appropriate hand hygiene procedures when entering the compounding area?

Yes: Personnel wash hands with soap and water for at least 30 seconds

Yes: Personnel dry hands completely with disposable towels or wipers

Yes: Personnel don gloves

5) Does the facility wipe or replace other items before beginning to compound a CNSP that has different components?

Yes

6) Do compounding personnel inspect gloves for holes, punctures or tears?

Yes

Yes: Gloves are replaced immediately if defects are detected.

7) Are gloves worn for all compounding activities?

Yes

8) Is other garb appropriate for the type of compounding performed?

Yes: Garb protects personnel from chemical exposures

Yes: Garb prevents CNSP contamination

Yes: Garbing requirements are determined by the facility and documented in the SOPs.

Yes: Frequency of changing garbing is determined by the facility and documented in the facility's SOPs.

9) Is garbing replaced immediately if it becomes visibly soiled or if its integrity is compromised?

Yes

10) Is garb stored in a manner that minimizes contamination?

Yes

11) Is garb removed and discarded when leaving the compounding area?

Yes

Yes: All garb, except gowns (as applicable), are removed and discarded when leaving the compounding area.

Yes: Unsoiled/undamaged gowns remain in the compounding area for reuse during the same shift.

12) Do facility SOPs describe cleaning and sanitization procedures for reusing goggles, respirators, and other reusable equipment?

Not Applicable

Observation
Discussed all PPE is single use / disposable

28.6.4) Buildings and Facilities

1) COMPOUNDING AREA: Is there a designated area for nonsterile compounding?

Yes

Yes: The method of designation is described in the facility's SOPs.

Yes: Other activities are not occurring in the compounding area at the same time as compounding.

2) Is the compounding area suitable?

Yes: The compounding area is well lit, clean, orderly, and sanitary condition

Yes: The compounding area is in a good state of repair.

Yes: The compounding area is not carpeted.

3) Does the compounding area provide for the orderly placement of equipment and materials?

Yes

4) STORAGE AREA: Are temperatures monitored and recorded in the compounding area?

Yes: Temperatures are monitored with a continuous recording device.

Yes: Temperatures are stored in the continuous temperature device and are retrievable.

Observation

Discussed Sonicu is utilized for continuous monitoring

5) Is temperature monitoring equipment calibrated or verified for accuracy?

Yes: As recommended by the manufacturer

Yes: Every 12 months if not specified by the manufacturer.

6) Does the facility have a process to evaluate CNSPs exposed to temperature excursions?

Yes

Observation

Observed SOP which outlines the process to evaluate CNSPs exposed to temperature excursions

7) Are all CNSPS, components, equipment and containers stored off the floor?

Yes

8) WATER SOURCES: Does the facility have an easily accessible sink with hot and cold water?

Yes

9) Is the sink empty of all items unrelated to compounding?

Yes

10) Is the sink cleaned when visibly soiled before being used to clean compounding equipment?

Yes

11) Are plumbing systems free of defects that may contribute to CNSP contamination?

Yes

12) Is purified water used for rinsing equipment and utensils?

Yes

28.6.5) Cleaning and Sanitizing

1) Are work surfaces cleaned at appropriate intervals?

Yes: Beginning and end of each shift

Yes: After spill/splash contamination is known or suspected

Yes: Between compounding CNSPs with different components

2) Are floors cleaned at appropriate intervals?

Yes: On days compounding occurs

Yes: After spills

Yes: When surface contamination is known or suspected

3) Are walls cleaned at appropriate intervals?

Yes: When visibly soiled

Yes: After spills

Yes: When surface contamination is known or suspected

Observation

Observed SOP which states once monthly in addition to as documented above

4) Are ceilings cleaned at appropriate intervals?

Yes: When visibly soiled

Yes: When surface contamination is known or suspected

Observation

Observed SOP which states once monthly in addition to as documented above

5) Is storage shelving cleaned at appropriate intervals?

Yes: at least every 3 months

Yes: After spills

Yes: When surface contamination is known or suspected

Observation

Observed SOP which states once monthly in addition to as documented above

6) Are surfaces resistant to damage caused by cleaning and sanitizing agents?

Yes

7) Are floors in the compounding area easily cleanable?

Yes: Floors are non-porous.

Yes: Floors are not particle generating.

8) Are appropriate cleaning and sanitizing agents used?

Yes

Observation

Observed SOP utilizes EPA-registered disinfectant detergent as the preferred agent

28.6.6.1) Equipment

1) Is the equipment used in the compounding process suitable?

Yes: Equipment surfaces are not reactive, additive or sorptive.

Yes: Equipment surfaces do not alter the quality of the CNSP.

Yes: Disposable or dedicated equipment is used to reduce the chance of bioburden and cross contamination.

2) Is the equipment used in compounding stored in a manner that minimizes the risk of contamination?

Yes. Equipment is stored in a manner that minimizes contamination risk.

Yes: Equipment is located to facilitate use, maintenance and cleaning.

3) Is equipment used in compounding or testing of compounded preparations properly inspected and maintained?

Yes: Inspected prior to use

Yes: Equipment is verified for accuracy as recommended by the manufacturer or at least every 12-months.

Yes: Equipment is cleaned after compounding

8) Are other devices and equipment used in compounding cleaned according to USP minimum frequencies?

Yes: Before their first use

Yes: According to manufacturer recommendations

Yes: Cleaned between compounding CNSPs with different components, if no manufacturer recommendation is available

28.6.6.2) Components

1) Does the facility have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP?

Yes

2) Are SDSs readily accessible to all personnel working with components?

Yes

Observation
Discussed SDS retrieval is included in onboarding as well as annual training

3) Is the designated person responsible for component selection?

Yes

4) API COMPONENT SELECTION: Do APIs used in compounding comply with USP 795?

Yes: Components comply with USP monographs, if one exists.

Yes: Components have a COA that includes specifications and test results showing the API meets expected quality.

Yes: Components are manufactured at an FDA-registered facility.

5) COMPONENTS OTHER THAN APIs: Do other components used in compounding comply with USP 795?

Yes: Components are accompanied by a COA that verifies the component meets the criteria in the USP/NF, if one exists.

Yes: Components are manufactured in an FDA-registered facility.

Yes: If a component cannot be obtained form an FDA-registered facility, the designated person selects a component for suitable for the intended use.

6) WATER: Is purified water or better quality used for compounding nonsterile drug preparations?

Yes

7) COMPONENT RECEIPT: Is the COA of non-conventionally manufactured products reviewed?

Yes: Review documents the receipt date, quantity received, and supplier name.

Yes: Review documents the lot number and expiration date.

Yes: Review documents the results of any in-house or third-party testing performed.

8) COMPONENT RECEIPT: Does the facility has a process to identify and label components that lack a vendor expiration date?

Other

Observation
Discussed no components are utilized where the vendor does not assign an expiration date

9) COMPONENT RECEIPT: Are components found to of unacceptable quality are promptly rejected?

Yes: labeled as rejected and segregated from active stock

Yes: Other lots of rejected components from the same vendor are examined

10) COMPONENT EVALUATION: Are components visually inspected prior to use?

Yes

11) COMPONENT EVALUATION: Is a process in place to ensure components are of the correct identity and were properly stored prior to each use?

Yes

12) COMPONENT HANDLING: Are components handled in accordance with manufacturer instructions and/or pre applicable laws and regulations?

Yes

13) COMPONENT HANDLING: Are components removed from the original container discarded if not used?

Yes

14) COMPONENT SPILL AND DISPOSAL: Does the facility maintain current chemical hazard and disposal information?

Yes

15) COMPONENT SPILL AND DISPOSAL: Is the facility prepared to handle a nonhazardous component spill?

Yes: The management and documentation of nonhazardous component spills and disposal is described in the facility SOPs.

Yes: Spill kit is readily accessible in the compounding area.

Yes: Personnel required to remediate spills receive training in spill management of chemicals used and stored in the compounding facility.

Yes: Spill training is conducted and documented at least every 12 months for all personnel required to clean up spills.

Observation
Observed SOP regarding spill management

16) COMPONENT SPILL AND DISPOSAL: Is component waste disposed of in accordance with laws and regulations?

Yes

28.6.7) Master Formulation and Compounding Records

1) MASTER FORMULAS: Does the facility have a master formula for each unique formulation of a CNSP?

Yes: Changes and alterations are approved and documented

Yes: SOPs describe how master formulas are created, altered and approved

2) MASTER FORMULAS: Do master formulas contain all required elements?

Yes: Contain the name, strength or activity, and dosage form

Yes: Contain the identities and amounts of all components

Yes: Contain the relevant characteristics of components (e.g., particle size, salt form, purity grade, solubility, etc.), if appliable

Yes: Contain the container closure system

Yes: Contain complete instructions for preparing the CNSP

Yes: Contain the equipment and supplies needed

Yes: Contain a description of the compounding process

Yes: Contain a physical description of the final CNSP

Yes: Contain beyond-use date and storage requirements

Yes: Contain a reference source for assigned BUD

Yes: Contain calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s), where appliable

Yes: Contain labeling requirements (e.g. shake well)

Yes: Contain quality control (QC) procedures (e.g., pH testing, visual inspection, etc.) and expected results

Yes: Contain other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature, etc.)

3) COMPOUNDING RECORDS: Does the facility create a compounding record for each CNSP?

Yes

4) COMPOUNDING RECORDS: Do compounding records contain all the required elements?

Yes: Contain the name, strength or activity, and dosage form

Yes: Contain the date (or date and time) of preparation

Yes: Contain an assigned internal identification number (Rx number or lot number)

Yes: Contain a method to identify individuals involved in the compounding process

Yes: Contain a method to identify the individual(s) verifying the final CNSP

Yes: Include the name, vendor or manufacturer, lot number, and expiration date of each component

Yes: Include the weight or measurement of each component

Yes: Include the total quantity of CNSP compounded

Yes: Contain the assigned beyond-use date

Yes: Contain the storage requirements of the CNSP

Yes: Contain calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s), where applicable

Yes: Contain a physical description of the final CNSP

Yes: Contain the results of quality control procedures (e.g., pH testing, visual inspection, etc.)

Yes: Contain a reference to the master formula record for the CNSP

28.6.8) Release Inspections and Testing

1) Are all release inspections included in the facility's documentation?

Yes

2) Do visual inspections confirm the CNSP is ready for releasing and dispensing?

Yes

3) Are CNSPs not dispensed or released on day of preparation visually inspected before being dispensed?

Yes

28.6.9) Labeling

2) Do prepared CNSP contain a label with the minimum required information in USP 795?

Yes: Contain the assigned internal identification number

Yes: Contain the active ingredients and their amounts, activities, or concentrations

Yes: Contain the storage conditions, if other than controlled room temperature

Yes: Contain the beyond use date

Yes: Contain the dosage form

Yes: Contain the total amount or volume, if it is not obvious from the container

Observation
(Lot number, Rx number, etc.)

3) Do labels on dispensed CNSPs contain all information required by USP 795?

Yes: Contain the route of administration

Yes: Indicate the preparation was compounded

Yes: Include any applicable special handling instructions

Yes: Iclude any applicable warning statements

Yes: Contain the compounding facility name and contact information if the CNSP is sent outside the facility or healthcare system in which it was compounded

4) Do facility SOPs describe labeling procedures?

Yes: Labeling procedures are defined in facility SOPs.

Yes: Procedures include processes to prevent labeling errors.

Yes: CNSP label verification includes confirmation of the prescription or medication order.

Yes: CNSP label verification includes confirmation of the master formula record and compounding record.

28.6.10.1) Terminology and Parameters

1) Does the CNSP label state the beyond use date?

Yes

2) Does the facility consider parameters which may affect CNSP quality when assigning a BUD?

Yes: Includes a review of chemical and physical stability properties of the API and added substances

Yes: Includes a review of the compatibility of the container closure system with the finished preparation

Yes: Includes a review of the degradation of the container closure system

Yes: Includes a review of the potential for microbial proliferation in the CNSP

Yes: Includes a review for significant deviations from essential compounding steps

28.6.10.2) Establishing a BUD

1) INFORMATION: General BUD description.

Observation
USP 795 | Effective 11/01/2023
The BUDs in Table 4 are based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply.

The aqueous and nonaqueous dosage forms in Table 4 are defined based on the water activity (aw) of the most similar drug preparations described in Table 3 or Application of Water Activity Determination to Nonsterile Pharmaceutical Products ☐1112☐. In general, the use of aw aids in assessing the susceptibility of CNSPs to microbial contamination and the potential for API degradation due to hydrolysis. The aw is different from the water content and may be considered as the available water to support microbial growth and hydrolytic reactions. Nonaqueous dosage forms will not support spore germination or microbial growth due to their low aw. Reduced aw greatly assists in the prevention of microbial proliferation in conventionally manufactured products and is expected to convey the same benefit to CNSPs.

Compounders are not required to measure aw for CNSPs. While the manufactured products in ☐1112☐, Table 2 and compounded preparations in Table 3 below are not exhaustive, they provide examples of dosage forms that have an aw < 0.6 and those that have an aw ≥ 0.6 and can assist personnel in determining the BUD by dosage form using Table 4.

When preparing CNSPs, raw materials and equipment contribute a bioburden to the final preparation. CNSPs with an aw ≥ 0.6, and a BUD within the limits of Table 4, should contain suitable antimicrobial agents to protect against the proliferation of bacteria, yeast, and mold contamination that may be inadvertently introduced anytime during the compounding process or throughout the BUD under appropriate handling and storage conditions. All CNSPs with an extended BUD must follow 10.5 Extending BUDs for CNSPs. Careful consideration should be taken when selecting a preservative to ensure microbiological effectiveness and stability. When antimicrobial preservatives are contraindicated in a CNSP, storage of the preparation in a refrigerator is required if such storage does not change the physical or chemical properties of the CNSP (i.e., precipitation).

4) Does the facility assign BUDs in accordance with USP 795?

Yes: Non-preserved aqueous dosage forms: 14 days refrigerated.

Yes: Preserved aqueous dosage forms: 35 days refrigerated or room temperature

Yes: Non-aqueous oral liquids: 90 days refrigerated or room temperature

Yes: Other non-aqueous dosage forms: 180 days refrigerated or room temperature

Yes: CNSPs are protected from moisture, freezing, and excessive heat, and where necessary, from light.

28.6.10.3) CNSPs Requiring a Shorter BUD

1) Does the facility have a process to determine if data shows a CNSP requires a shorter BUD?

Yes

2) Do assigned BUDs take into account the shortest expiration date of any starting components?

Yes

3) Are BUDs longer than the shortest BUD of any of the individual components?

Yes

28.6.10.4) Extending BUDs for CNSPs

1) Are all CNSPs with a USP-NF monograph assigned a BUD that does not exceed the BUD specified in the monograph?

Yes:

28.6.11) SOPs

1) Does the facility have SOPs on all aspects of the compounding operation?

Yes

2) Are all personnel who conduct or oversee compounding activities trained in the facility SOPs?

Yes

3) Is an employee designated to ensure facility SOPs are fully implemented?

Yes

28.6.12) Quality Assurance and Quality Control

1) DEFINITIONS: Quality Assurance and Quality Control

Observation
USP 795 | Effective 11/01/2023
Quality assurance (QA) is a system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

Quality control (QC) is the sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CNSP. See Quality Assurance in Pharmaceutical

2) Are QA and QC programs formally established?

Yes

3) Are QA and QC programs complete?

Yes: Programs ensures adherence to procedures.
Yes: Programs prevents and detects errors and other quality problems.
Yes: Programs evaluates complaints and adverse events.
Yes: Programs completes investigations and corrective actions.

4) Do facility SOPs describe each aspect of the QA program?

Yes

5) Is the QA and QC program reviewed annually by the designated person?

Yes

6) RECALL PROCEDURES: Does the facility have recall procedures in place?

Yes

7) RECALL PROCEDURES: Do SOPs for recalls of dispensed CNSPs contain all elements required by USP 795?

Yes: Contains procedures to determine the severity of the problem and the urgency for implementation
Yes: Contains procedures to determine the distribution on any affected CNSP
Yes: Contains procedures to identify patients who have received the CNSP.
Yes: Contains procedures for disposal and documentation of the recalled CNSP.
Yes: Contains procedures for investigation and documentation of the recall.

8) RECALL PROCEDURES: Do SOPs for recalls require documentation and notification to the appropriate regulatory bodies?

Yes: The facility has documentation of implemented recall procedures.
Yes: The facility has a policy to document a recall if implemented, but no recalls have occurred.
Yes: The facility has reported recalls to the appropriate regulatory bodies.
Yes: The facility has a policy to report recalls to the appropriate regulatory body, but no recalls have occurred.

9) COMPLAINT HANDLING: Does the facility have a SOP for handling complaints?

Yes

10) COMPLAINT HANDLING: Are complaints reviewed to identify potential quality problems and actions taken?

Yes

11) COMPLAINT HANDLING: Are records of complaints readily retrievable and complete?

Yes: Records contain name of the complainant or other unique identifier.
Yes: Records contain date the complaint was received.
Yes: Records identify the nature of the complaint.
Yes: Records contain the response to the complaint.
Yes: Records include the name and strength of the CNSP involved in the complaint.
Yes: Records include the CNSP internal identification number (Rx number or lot number), if known.

12) COMPLAINT HANDLING: Do complaint records include the findings of investigation?

Yes

13) COMPLAINT HANDLING: Are CNSPs returned in connection with a complaint quarantined and destroyed?

Yes

14) ADVERSE EVENT REPORTING: Are adverse events properly reported?

Yes
Present staff unaware of any reported ADE

28.6.13) CNSP Packaging and Transporting

1) Do facility SOPs include CNSP packaging requirements?

Yes

2) Do SOPs describe CNSP transport?

Yes: Includes the mode of CNSP transportation.

Yes: Describes CNSP special handling instructions.

Yes: Instructs when temperature monitoring devices are needed.

28.6.14) Documentation

1) Does the facility maintain written or electronic documentation demonstrating compliance with USP 795?

Yes: Includes documentation of personnel training, competency assessments, and qualification records including corrective actions for any failures.

Yes: Includes equipment records (e.g., calibration, verification, maintenance reports).

Yes: Includes COAs and all documentation required for components not conventionally manufactured.

Yes: Includes records of receipt for all components.

Yes: Includes SOPs, master formula records, and compounding records.

Yes: Includes release inspection and testing records.

Yes: Includes information related to complaints and adverse events including corrective actions taken.

Yes: Includes results of all investigations and corrective actions.

Yes: Includes records of cleaning and sanitizing the designated compounding area.

Yes: Includes temperature logs.

Yes: Includes accommodations to personnel compounding CNSPs.

Yes: Includes required routine reviews (e.g., yearly review of QA and QC programs, yearly review of chemical hazard and disposal information, etc.)

2) Does the facility maintain required documentation in a readily retrievable manner for at least 3 years?

Yes

40) Substance Abuse and Mental Health Resources for Healthcare Professionals

1) Substance Abuse and Mental Health Resources for Healthcare Professionals

Observation

The healthcare profession is not immune to substance use disorder and mental health conditions. Such medical conditions impair a healthcare professional's competency, ability, and judgment. Substance use disorder and/or mental health conditions that are left untreated may not only cause a healthcare professional to risk their career, but may also endanger the life of a patient. These medical conditions can be effectively treated, and it is possible for healthcare professionals that are in treatment or recovery to return to practice.

The State of Ohio Board of Pharmacy encourages all healthcare professionals who may be struggling with substance use disorder or mental health condition to seek help. The following are resources that can assist healthcare professionals in getting help: (The resources listed here are for informational purposes only and do not constitute an endorsement by the State of Ohio Board of Pharmacy. They do not represent a complete list of the resources available)

Ohio Careline 1-800-720-9616, emotional support, with referral to other resources if needed.
Crisis text line, text "4hope" to 741 741 to speak with a crisis counselor.
Treatment Bridge 1-877-275-6364, for addiction and mental health services.
National Suicide prevention dial 988, or call 1-800-273-8255.
Ohio Domestic Violence Network 1-800-934-9840
Pharmacist Rehabilitation Organization (www.ohiopro.org) for pharmacists and pharmacy interns.
Ohio Physicians Health Program (www.ophp.org)

41) Inspection Affirmation

1) Inspection Affirmation

Observation
As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content.

If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection:
(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or
(2) An explanation disputing the observed violations.

I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner.

I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action.

Responses must be either emailed (with a copy of the inspection report) to WRITTENRESPONSE@PHARMACY.OHIO.GOV or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

No Issue Found

Reviewed by Ian Hill, R.Ph.

(signature)

Ohio Board of Pharmacy

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until March 31, 2027.

ClearMedix Pharmacy LLC

ClearMedix Pharmacy

510 E Wilson Bridge Rd Ste D

Worthington, OH 43085-2373

License Number: 0230000027

License Type: Terminal - Pharmacy - Category 2

Sub-Category: MO – Mail Order Pharmacy

Expiration Date: March 31, 2027

Responsible Person – Print, sign, and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
Ian Hill	

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request in eLicense Ohio - elicense.ohio.gov.

Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

eLicense Ohio
Professional Licensure

License Look Up

2/11/2026 1:17 PM

ClearMedix Pharmacy LLC

License Number	0230000027
Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Terminal - Pharmacy - Category 2
License Issue Date	11/12/24
License Expiration Date	3/31/27
License Effective Date	4/1/25
Street Address	510 E Wilson Bridge Rd Ste D
City	Worthington
State	OH
Zipcode	43085-2373
Country	United States
Board Action	No

Supervised By:

Supervisor Name	Supervisor License	Status	Start Date	End Date
IAN HILL	03334995	Active	Thu Aug 08 00:00:00 GMT 2024	

Current date & time: **2/11/2026 1:17 PM**

Disclaimer: The Joint Commission and NCQA consider on-line status information as fulfilling the primary source verification requirement for verification of licensure in compliance with their respective credentialing standards.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Clearmedix Pharmacy LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License #:(if applicable) _____

Physical Address 510 E Wilson Bridge Rd, Suite D

City Worthington State OH Zip 43085

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855-314-0136 Website www.clearmedixpharmacy.com

Licensing Company Email _____

Section 2: Personal Information

First Shoshana Middle Miriam Last Bocian

Alias(es, nicknames, name changes, etc.) Shani

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Brown University		06/16 - 06/17	
Address	City	State	Zip
1 Prospect Street	Providence	RI	02912
Diploma/Degree obtained, if any			
Masters of Arts			

School Name		From - To (MM/YY – MM/YY)	
Yeshiva University - Stern College		08/11 - 06/15	
Address	City	State	Zip
245 Lexington Ave	New York	NY	10016
Diploma/Degree obtained, if any			
Bachelors of Arts			

School Name		From - To (MM/YY – MM/YY)	
Kehillah Jewish High School		08/06 - 06/10	
Address	City	State	Zip
3900 Fabian Way	Palo Alto	CA	94303
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/20 - Present	[redacted]			
06/10 - 11/20				
08/92 - 06/10				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Allermi, Inc.			01/20 - Present	
Business Address		**City**	**State**	**Zip**
3739 Balboa Street, #1152		San Francisco	CA	94121
Phone	**Title**			
650-332-4535	CEO			
Description of Duties				
Lead technological development, marketing and business operations				

Business Name			From - To (MM/YY – MM/YY)	
American Hebrew Academy			11/17 - 06/18	
Business Address		**City**	**State**	**Zip**
4334 Hobbs Road		Greensboro	NC	27410
Phone	**Title**			
N/A	Teacher			
Description of Duties				
Taught social studies and Judaic studies				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		√
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		√
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		√
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		√
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		√
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		√
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		√
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		√
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		√

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shoshana Bocian
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/9/2026
Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Shoshana Bocian, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/9/2026
Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles
Subscribed and sworn to (or affirmed) before me on this 9th day of February, 2026 by Shoshana Bocian
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.
Signature _____ (Seal)

ENC1 KRYSTAL N. LANGFORD COMM. # 2411068 NOTARY PUBLIC • CALIFORNIA LOS ANGELES COUNTY My Comm. Expires July 18, 2026 ENC1

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site ClearMedix Pharmacy, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 510 E Wilson Bridge Rd Suite D

City Worthington State Ohio Zip 43085

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855 314 0136 Website www.clearmedixpharmacy.com

Licensing Company Email _____

Section 2: Personal Information

First Ian Middle Duncan Last Hill

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Toledo		08/09-05/15	
Address	City	State	Zip
2801 Bancroft St	Toledo	OH	43606
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Franklin Regional High School		08/05-06/09	
Address	City	State	Zip
3200 School Rd	Murrysville	PA	15668
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/23-Present	[redacted]			
07/18-06/23				
06/16-07/18				
07/15-06/16				
06/13-06/15				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ian Hill

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/11/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin

I, Ian Hill, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/11/2026

Date

Subscribed and Sworn to before me this 11th day of February 2026

Jonathan Haddad

Notary Public Signature

JONATHAN NABIL HADDAD - NOTARY PUBLIC
STATE OF OHIO
COMM EXP: OCT 16, 2030
Seal

4ZZ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: [redacted]
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☒ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Scottsdale Professional Pharmacy, LTD dba. Customedico Pharmacy + Wellness

Physical Address: 10900 N. Scottsdale Rd, Ste 403

City: Scottsdale State: AZ Zip: 85254

Mailing Address (if different from physical address): SAME

City: _____ State: _____ Zip: _____

Telephone: (480)946-9477 Toll Free # (NAC 639.708, NRS 639.23286): 877-846-9477

Fax: (480)946-1345 Contact Email: sarah@customedico.com

Website: www.customedico.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Lee Ori, PharmD

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): Jennifer Siefert, Rph | 19522

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Jennifer Siefert, Rph	NV Pharmacist Registration #: 19522
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Arizona

Parent Company (if any): Cuco Group

Corporation/Organization Name: Scottsdale Professional Pharmacy, LTD dba. Customedico Pharmacy + Wellness

Mailing Address: 10900 N. Scottsdale Rd Suite 403

City: Scottsdale State: AZ Zip: 85254

Telephone: 480-946-9477 Email: info@customedico.com

Contact Person Name: Sarah Simmers, PharmD

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Scottsdale Professional Pharmacy / Customedico Pharmacy + Wellness (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Sarah Simmers, PharmD

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

January 12, 2026

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Sarah Simmers hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for Scottsdale Professional Pharmacy dba. Customedico Pharmacy + Wellness (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

LUIS ASTORGA
Notary Public - Arizona
Maricopa County
Commission # 684831
My Comm. Expires May 7, 2029

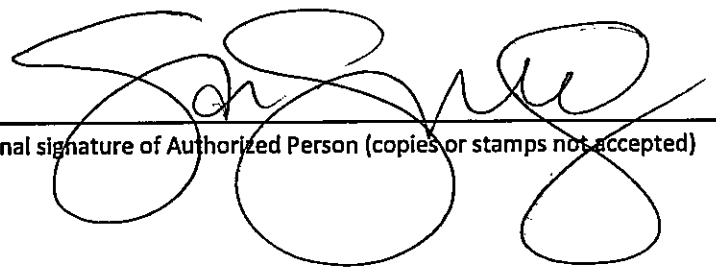
SUBSCRIBED AND SWORN TO
Before me, a notary public this 12th day of January, 2026

Notary Public

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SARAH SIMMERS

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

January 12, 2026

Date

Board Use Only	Date Received: 1 23 26	Amount: 500.00	V#5329

customedico

pharmacy + wellness

January 12, 2026

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

Re: Request to list all officer, directors, stockholders and percent of ownership

I, Sarah Simmers, PharmD, am the President of Scottsdale Professional Pharmacy, LTD registered with the AZ Corporations Commission.

The shares of Scottsdale Professional Pharmacy, LTD are 100% held by CuCo Group, LLC, a Delaware, Limited Liability Company.

I, Sarah Simmers, PharmD, hold 100% of CuCo Group, LLC, and thus 100% of the shares of Scottsdale Professional Pharmacy, LTD.

Sarah Simmers, PharmD
President
Scottsdale Professional Pharmacy
dba Customedico Pharmacy + Wellness

STATE OF ARIZONA

Office of the
CORPORATION COMMISSION

CERTIFICATE OF GOOD STANDING

I, the undersigned Executive Director of the Arizona Corporation Commission, do hereby certify that:

SCOTTSDALE PROFESSIONAL PHARMACY, LTD.

ACC file number: 02384377

was incorporated under the laws of the State of Arizona on 01/07/1992;

That all annual reports owed to date by said corporation have been filed or delivered for filing, and all annual filing fees owed to date have been paid; and

That, according to the records of the Arizona Corporation Commission, said corporation is in good standing in the State of Arizona as of the date this Certificate is issued.

This Certificate relates only to the legal existence of the above named entity as of the date this Certificate is issued, and is not an endorsement, recommendation, or approval of the entity's condition, business activities, affairs, or practices.

IN WITNESS WHEREOF, I have hereunto set my hand, affixed the official seal of the Arizona Corporation Commission, and issued this Certificate on this date: 03/10/2020

Matthew Neubert, Executive Director

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Scottsdale Professional Pharmacy dba Customedico Pharmacy + Wellness

Pharmacy/Wholesaler License # (if applicable): Y007156

Physical Address: 10900 N. Scottsdale Rd Ste 403

City: Scottsdale State: AZ Zip: 85254

Mailing Address (if different from physical address): – Same –

City: State: Zip:

Telephone: 480-946-9477 Website: www.customedico.com

Licensing Company Email: sarah@customedico.com

Section 2: Personal Information

First: Sarah Middle: K. Last: Simmers

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
NORTH DAKOTA STATE UNIVERSITY			08/1994 - 05/2000	
Address		City	State	Zip
1340 ADMINISTRATION AVE		FARGO	ND	58105
Diploma/Degree obtained, if any				
PHARMD				
School Name			From - To (MM/YY – MM/YY)	
PARSHALL HIGH SCHOOL			08/1989 - 05/1994	
Address		City	State	Zip
601 MAIN ST		PARSHALL	ND	58770
Diploma/Degree obtained, if any				
HIGH SCHOOL GRADUATE				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/24 - CURRENT	[redacted]			
03/20 - 03/24				
12/15 - 03/20				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

SARAH SIMMERS, PHARMD WORK HISTORY

North Memorial Hospital Pharmacy 3300 Oakdale Ave N Robbinsdale, MN 55422	Staff Pharmacist Decentralized June 2000 – June 2001
Allina Home Infusion (now Option Care) 2750 Arthur St Roseville, MN 55113	Clinical Pharmacist August 2000 – January 2004
Cardinal Health Nuclear Pharmacy Svs 1610 30th Ave S. Moorhead, MN 56560	Certified Authorized Nuclear Pharmacist March 2005 – December 2008
Essentia Health Clinic 1027 Washington Ave Detroit Lakes, MN 56501	Clinic Program Pharmacist October 2006 – November 2009
Customceutical Compounding 5611 E Shea Blvd, Bldg 3 Phoenix, AZ 85013	Owner | Pharmacist-In-Charge October 2010 – November 2020
Customedico Pharmacy + Wellness 10900 N Scottsdale Rd, Ste 403 Scottsdale, AZ 85254	Owner | Compliance Officer Pharmacist January 2017 - Present
First Choice Pharmacy 1850 N. Central Ave, Ste 1020 Phoenix, AZ 85004	Pharmacist-In-Charge December 2021 - Present

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name SEE ATTACHED			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2/16/2021		MO		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
4:21-cv-00249-SEP		US District Court, Eastern District of Missouri		
Reason/Charge				
Breach of contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Voyant / Epicure Medical / Foxhole				
Name of Business/Industry/Entity				

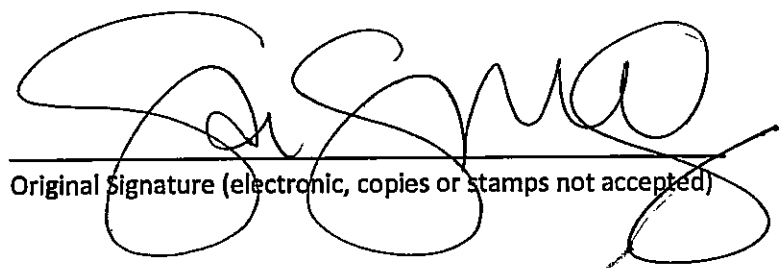
Provide explanation below:

United States District Court, Eastern District of Missouri (Case: 4:21-cv-00249-SEP), Voyant (Aware Products LLC, doing business as Voyant) filed a complaint on February 16, 2021, against Epicure Medical LLC, Foxhole, and Ori.

Claims were for breach of contract, account stated, promissory estoppel, and unjust enrichment.

The dispute originated from a March 26, 2020, letter of intent (LOI) submitted on Foxhole letterhead by Ori, committing to purchase 1 million units of 2-ounce hand sanitizer at 93 cents per unit for a total of $930,000. The actual purchase order was executed by Epicure Medical. I, Sarah Simmers, was a managing member of Foxhole Medical.
The agreement was made during the early days of the COVID-19 pandemic, with the letter stating it was intended for the immediate procurement of bottles and caps prior to a formal purchase order.

The legal dispute centered on whether a binding contract was formed and breached regarding the procurement and payment for hand sanitizer production. The lawsuit was settled out of court in 2025.



Original Signature (electronic, copies or stamps not accepted)

1/12/2026
Date

I, Sarah Simmers, **certify that as the designated representative for**

Scottsdale Professional Pharmacy, dba Customedico Pharmacy + Wellness,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SK I am at least 21 years of age;
3. SK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sarah Simmers, PharmD
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

January 12, 2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sarah Simmers

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/17/2026

Date

Please have this section completed in the presence of a Notary Public.

State of ARIZONA, ss. County of MARICOPA

I, SARAH SIMMERS, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/17/2026

Date

Subscribed and Sworn to before me this 17 day of January 2026

Notary Public Signature

MICHAEL AMENTLER
Notary Public - State of Arizona
MARICOPA COUNTY
Commission # 689224
Expires September 24, 2029

(Seal)

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
http://www.azpharmacy.gov

602-771-ASBP (2727)
FAX: 602-771-2749

Pharmacist

Reciprocity
S017695

EXPIRES
10/31/2027

Receipt Date: 10/23/2025
Receipt Number: 2025213875
Receipt Amount $: 180.00

Issued to : Sarah Kathryn Simmers
9204 E ASTER DR
SCOTTSDALE, AZ 85260

Kam Gaddis
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF
PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Sarah Kathryn Simmers
Reciprocity : S017695
EXPIRES : 10/31/2027

http://www.azpharmacy.gov

- **Your Reciprocity number must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/registration/permit current.**

Important Information

LICENSE/REGISTRATION HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license/registration number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license/registration, the licensee/registrant agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

DEMOGRAPHICS

AZ permit# : Y007156	AZ Permit Exp.Date : 10/31/2024	Business Name : Customedico Pharmacy & Wellness
Address : 10900 N. Scottsdale Rd., #403		
Zip : 85254	City : Scottsdale	State : AZ
Phone : (480) 946-9477	Fax : (480) 946-1345	Email : lee@customedico.com
Inspection Date : 09/25/2024	PIC : Lee Ori	Pic License Exp Date : 10/31/2025
DEA # : [redacted]	DEA # Exp. date : 08/31/2025	Inspection Reviewed With : Sarah Simmers
Reviewers License# : S017695	Inspection type : Routine	
Inspection Conducted By : Dennis Waggoner		

Facility Data

# Rxs/Week	RPh Hours/Week	# Rxs/Hours
350	50	7

PERMITS

1	Arizona	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1933(A); R4-23-606(A)
2	DEA	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 36-2522(A)(2); 21 CFR 1301.35(c)

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

3	Suppliers	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1929; R4-23-601(A); R4-23-604(A); R4-23-605(A); R4-23-607(A)

LICENSES

1	Pharmacists	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1925(A); R4-23-201(A)
2	Interns / Graduate interns	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1923(B); R4-23-301(G)
3	Technicians / Trainees	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1925(A); R4-23-1101(A); R4-23-1102(D); R4-23-1103(B)(2)
4	Current renewal licenses maintained	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1933(B)

PHARMACY

1	Drug storage and security	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-609(G)(H)
2	Personnel and security procedures	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-610
3	Facilities	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-611(A)
4	Drug supply	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-611(B)
5	Quarantine expired drugs	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-611(B)(4)

6	Equipment	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-612
7	Policies and procedures	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-610(A); R4-23-611(B)

TECHNICIANS

1	Training program	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-1105(B)(D)
2	Training program - compounds	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-1105(C)
3	Activities - trainees	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-1104(A)
4	Activities - technicians	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-1104(A)(B)
5	Policies and procedures	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-1104(F)(G)

COUNSELING

1	Documentation	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(G)(H)
2	Oral consultation	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(C)(D)(E)
3	Written information	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(C)(I)

PRESCRIPTION AUDIT

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

1	Prescription files	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1964; ARS § 36-2525(C)(1)(2)
2	Prescription label	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1968(D); ARS § 36-2525(L)
3	CII prescriptions No C2 prescriptions dispensed.	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1968; 36-2525(A) to (G); R4-23-407(A)
4	CIII - CV prescriptions	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1968; 36-2525(A)(C)(2)(H)(I); R4-23-407(A)
5	Non-controlled prescriptions	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1968; R4-23-407(A)
6	Transfers	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-407(D)
7	Telephone	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1968(A)(5); R4-23-402(A)(1)(2)
8	Refill authorizations	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1968(A)(6); R4-23-402(A)(13); R4-23-407(E)(5)
9	Facsimile	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-407(E)
10	Electronically transmitted	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-407(F); R4-23-408(H)
11	Patient information	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(A)(3)(4)

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

12	Allergies / medical conditions	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(A)(3)(b)
13	Brand / generic	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1963.01
14	Foreign prescriptions	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1969
15	Prescription blank advertising prohibited	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-404(B); ARS § 32-1901.01(B)(25)
16	Prescription audit numbers C3-5: 70019300-170019399, Rx: 211700-211799		

COMPUTER REQUIREMENTS

1	Security	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-408(F)
2	Log books / printout	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-408(C)(4)
3	Reports	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-408(B)(5)(6)
4	Policies and procedures	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-408(A)

IMMUNIZATIONS

1	Certification	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1974(D)(K); R4-23-411(A)

2	Recordkeeping	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1974(F)(3); R4-23-411(F)(I)
3	Reporting requirements	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1974(F); R4-23-411(F)(2)
4	Current certificate maintained	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-411(C)(2)
5	Administration without a prescription	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1974(A)(B); R4-23-411(A)
6	Prescription only administration	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1974(C)(I); R4-23-411(A)(4); (B); (I)

MECHANICAL STORAGE / COUNTING DEVICES

1	Cell identification	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(A)(1)
2	Paper / electronic log	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(A)(2)(3)
3	Training	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(C)(1)(D)
4	Maintenance	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(C)(2)(D)
5	Accuracy validation testing	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(C)(3)(D)
6	Return by approval only	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(B)(G)

7	Policies and procedures	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-615(E)

MECHANICAL COUNTING DEVICES

1	Training	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-616(A)(1)(B)
2	Maintenance	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-616(A)(2)(B)
3	Accuracy validation testing	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-616(A)(3)(B)
4	Policies and procedures	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-616(C)

CONTROLLED SUBSTANCE RECORDS

1	CIIs purchase / sale / disposal	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 36-2523(A); ARS § 36-2524; R4-23-601(D);R4-23-1003(A)(4)(B)
2	CIII - CVs purchase / sale / disposal	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 36-2523(A); R4-23-601(D); R4-23-612(11); R4-23-1003(A)(4)
3	Inventory	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 36-2523(B); R4-23-1003
4	Audit	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 36-2523
5	DEA 106 Theft/Loss reporting	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-1003(A)(2); 21 CFR 1301.76(b)

MISCELLANEOUS

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1	Badges - name / title	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-402(K); R4-23-671(B)(4); R4-23-1104(E)
2	Sales of drugs to practitioners	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1981(7)(d); R4-23-601(D); R4-23-1003(A)(4)
3	Schedule V register	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 36-2525(J)
4	Delivery	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1901.01(B)(23); R4-23-402(I)
5	CQA training / Policies and procedures	☑ S ☐ N/I ☐ V ☐ N/A	ARS § 32-1973; R4-23-620
6	Non-controlled substances purchase / sale / disposal	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-601(D)
7	Dextromethorphan sales restrictions Reminder to verify age of purchaser is at least 18 y/o or older.	☑ S ☐ N/I ☐ V ☐ N/A	ARS 32-1978
8	Federal medication guides	☑ S ☐ N/I ☐ V ☐ N/A	21 CFR part 208
9	Pharmacy to pharmacy transfer of drugs (intracompany)	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-601(D); R4-23-1003(A)(4)

METHAMPHETAMINE PRECURSORS

1	Storage	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1977(B)

2	Documentation	☐ S ☐ N/I ☐ V ☑ N/A	ARS § 32-1977(C); 21 CFR 1314
3	Self-certification	☐ S ☐ N/I ☐ V ☑ N/A	21 CFR 1314.35; 21 CFR 1314.40

SHARED SERVICES

1	Current resident / nonresident permit	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-621(A)
2	Same owner / written contract / common electronic file	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-621(B)
3	Notification to patients	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-621(C)
4	Maintain manual / electronic records	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-621(D)
5	Work outside pharmacy	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-621(F)
6	Policies and procedures	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-621(E)

COMPOUNDING PRACTICES (GENERAL)

1	Documentation product compounded	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(C)(1)(e); R4-23-410(I)(K)
2	Patient label	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(I)(4)

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3	Beyond-use dates	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(I)(4)(b); R4-23-410(B)(3)(d)
4	Equipment	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(F)(G)
5	Product produced in excess	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(B)(2); R4-23-410(J)
6	Component removed from original container	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(I)(6)
7	Compounds for medical practitioners	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-410(B)(3); R4-23-601(D); R4-23-1003(A)(4)
8	Patient written list	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(I)(5)
9	Protective apparel	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(C)(2)(c)
10	Facility	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(E)
11	Components for compounding/storage	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(B)(H)
12	Policies and procedures	☑ S ☐ N/I ☐ V ☐ N/A	R4-23-410(D)(G)(H)(I)(K)

STERILE COMPOUNDING

1	Compounding area	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(A)(E)(F)

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2	Equipment	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(B)
3	Sterile product reference	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(B)(6)
4	Certification hood / environment	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(D)(14)(g)
5	Documentation routine cleaning / maintenance	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(D)(14)(g)
6	Personnel protective clothing	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(E)(3)(F)(2)
7	Annual / semi-annual media fill tests	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(E)(4)(F)(3)
8	Documentation of product compounded	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-410(C)(1)(e); R4-23-410(I)(K)
9	Beyond-use dates	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(D)(14)(d); R4-23-410(B)(3)(d)
10	Process / product validation testing	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(D)(14)(f)
11	Policies and procedures	☐ S ☐ N/I ☐ V ☑ N/A	R4-23-670(C)(D)

AUDIT

Date Of Inventory :	Inventory Taken :	Date Of Audit :
05/01/2024	Close	09/25/2024

S = SATISFACTORY N/I = NEEDS IMPROVEMENT V = VIOLATION N/A = NOT APPLICABLE / NONE OBSERVED

Name & Strength of Drug	Initial Inventory	Total Purchased	Total Accounted For	Closing Inventory	Sales (Rx & log)	Total Can Account for	Difference	Percentage
Testosterone cypionate 200mg/mL 10mL vial	6	14	20	3	17	20	0	0.00
Tramadol 50mg tab	0	500	500	0	500	500	0	0.00
Carisoprodol 350mg tab	200	1000	1200	355	845	1200	0	0.00

NOTES

Hours of operation: Mo-Fr 9:00A-5:30P

No immunizations performed at this site. No OTC pseudoephedrine sales.

Handouts: 2022/2023 Statute/Rule Changes summary, ARS 32-1926 reminder, DEA Form 106 Reporting reminder, AzBOP Newsletter July 2024, Continuing Education Audit information, 2024 CE Requirements for Renewal, AzBOP Scam Alert, DEA reminder on manual signature for prescribers, CSPDMP handout, Hormonal Contraceptive FAQ.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Scottsdale Professional Pharmacy dba. Customedico Pharmacy + Wellness

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): Y007156

Physical Address: 10900 N. Scottsdale Rd. Suite 403

City: Scottsdale State: AZ Zip: 85254

Mailing Address (if different from physical address): –Same–

City: State: Zip:

Telephone: 480-946-9477 Website: www.customedico.com

Licensing Company Email: sarah@customedico.com

Section 2: Personal Information

First: Sarah Middle: K. Last: Simmers

Alias(es, nicknames, name changes, etc.):

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
NORTH DAKOTA STATE UNIVERSITY		08/1994 - 05/2000	
Address	**City**	**State**	**Zip**
1340 ADMINISTRATION AVE	FARGO	ND	58105
Diploma/Degree obtained, if any			
PHARMD			

School Name		From - To (MM/YY – MM/YY)	
PARSHALL HIGH SCHOOL		08/1989 - 05/1994	
Address	**City**	**State**	**Zip**
601 MAIN ST	PARSHALL	ND	58770
Diploma/Degree obtained, if any			
HIGH SCHOOL GRADUATE			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
03/24 - CURRENT				
From - To (MM/YY – MM/YY)				
03/20 - 03/24				
From - To (MM/YY – MM/YY)				
12/15 - 03/20				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

SARAH SIMMERS, PHARMD WORK HISTORY

North Memorial Hospital Pharmacy 3300 Oakdale Ave N Robbinsdale, MN 55422	Staff Pharmacist Decentralized June 2000 – June 2001
Allina Home Infusion (now Option Care) 2750 Arthur St Roseville, MN 55113	Clinical Pharmacist August 2000 – January 2004
Cardinal Health Nuclear Pharmacy Svs 1610 30th Ave S. Moorhead, MN 56560	Certified Authorized Nuclear Pharmacist March 2005 – December 2008
Essentia Health Clinic 1027 Washington Ave Detroit Lakes, MN 56501	Clinic Program Pharmacist October 2006 – November 2009
Customceutical Compounding 5611 E Shea Blvd, Bldg 3 Phoenix, AZ 85013	Owner | Pharmacist-In-Charge October 2010 – November 2020
Customedico Pharmacy + Wellness 10900 N Scottsdale Rd, Ste 403 Scottsdale, AZ 85254	Owner | Compliance Officer Pharmacist January 2017 - Present
First Choice Pharmacy 1850 N. Central Ave, Ste 1020 Phoenix, AZ 85004	Pharmacist-In-Charge December 2021 - Present

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
SEE ATTACHED	

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2/16/2021		MO		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
4:21-cv-00249-SEP		US District Court, Eastern District of Missouri		
Reason/Charge				
Breach of contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Voyant / Epicure Medical / Foxhole				
Name of Business/Industry/Entity				

Provide explanation below:

United States District Court, Eastern District of Missouri (Case: 4:21-cv-00249-SEP), Voyant (Aware Products LLC, doing business as Voyant) filed a complaint on February 16, 2021, against Epicure Medical LLC, Foxhole, and Ori.

Claims were for breach of contract, account stated, promissory estoppel, and unjust enrichment.

The dispute originated from a March 26, 2020, letter of intent (LOI) submitted on Foxhole letterhead by Ori, committing to purchase 1 million units of 2-ounce hand sanitizer at 93 cents per unit for a total of $930,000. The actual purchase order was executed by Epicure Medical. I, Sarah Simmers, was a managing member of Foxhole Medical.
The agreement was made during the early days of the COVID-19 pandemic, with the letter stating it was intended for the immediate procurement of bottles and caps prior to a formal purchase order.

The legal dispute centered on whether a binding contract was formed and breached regarding the procurement and payment for hand sanitizer production. The lawsuit was settled out of court in 2025.

Original Signature (electronic, copies or stamps not accepted)

January 12, 2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sarah Simmers

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/12/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, SARAH SIMMERS, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/12/2026

Date

Subscribed and Sworn to before me this 12th day of January.

LUIS ASTORGA
Notary Public - Arizona
Maricopa County
Commission # 684831
My Comm. Expires May 7, 2029

Notary Public Signature

(Seal)

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 10/23/2024
Receipt Number: 2024189978
Receipt Amount $: 480.00

Pharmacy - Independent

Compounding – Non-Sterile,Retail

PERMIT NO
Y007156

EXPIRES
10/31/2026

Issued to :

Customedico Pharmacy & Wellness
Scottsdale Professional Pharmacy, LTD
10900 N. SCOTTSDALE RD. SUITE 403
SCOTTSDALE, AZ 85254

Customedico Pharmacy & Wellness
10900 N. SCOTTSDALE RD., #403
SCOTTSDALE, AZ 85254

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Scottsdale Professional Pharmacy, LTD
LICENSE NUMBER : Y007156
EXPIRES : 10/31/2026

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	Customedico Pharmacy & Wellness
Address :	10900 N. Scottsdale Rd., #403 Scottsdale AZ 85254
Registration No :	Y007156
Permit Type :	Pharmacy
Sub Type :	Independent
Date Issued :	01/25/2017
Expiration Date :	10/31/2026
Status :	OPEN
Discipline :	No

Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 01/12/2026

4AAA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Y

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☒ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☒ Non-sterile Compounding
			☐ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Infinite Health Pharmacy Inc.

Physical Address: 416 Clematis St, Ste B

City: West Palm Beach State: FL Zip: 33401

Mailing Address (if different from physical address): (same address)

City: _____ State: _____ Zip: _____

Telephone: 833-463-4679 Toll Free # (NAC 639.708, NRS 639.23286): 833-463-4679

Fax: 561-805-7138 Contact Email: infinitehealthrx@gmail.com

Website: N/A

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Thomas Rebhandl

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24533

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Thomas Rebhandl	NV Pharmacist Registration #: 24533
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✔	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: FL

Parent Company (if any): ScriptfulRx, Inc.

Corporation/Organization Name: Infinite Health Pharmacy Inc.

Mailing Address: 416 Clematis St, Ste B

City: West Palm Beach State: FL Zip: 33401

Telephone: 833-463-4679 Email: infinitehealthrx@gmail.com

Contact Person Name: Thomas Rebhandl

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President and PIC (title) for Infinite Health Pharmacy Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Thomas Rebhandl

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2/10/26

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Thomas Rebhandl hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President and PIC (title) for Infinite Health Pharmacy Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 10th day of February, 2026

Notary Public

Notary Public State of Florida
Debra A Burghardt
My Commission HH 401258
Expires 5/22/2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Thomas Rebhandl

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

2/10/26

Date

Board Use Only	Date Received: 2/13/26	Amount: $550 CK 209

ScriptfulRx, Inc. (100% Owner of HP, Inc.)	
Officers	Title
Peter Gillooly	President/Treasurer/Director
Address	[redacted]

Infinite Health Pharmacy Inc.	
Officers	Title
Thomas Rebhandl	President, PIC
Peter Gillooly	Director

Officers	Address
Thomas Rebhandl	[redacted]

State of Florida
Department of State

I certify from the records of this office that INFINITE HEALTH PHARMACY INC. is a corporation organized under the laws of the State of Florida, filed on April 3, 2020, effective August 21, 2019.

The document number of this corporation is P20000029646.

I further certify that said corporation has paid all fees due this office through December 31, 2025, that its most recent annual report/uniform business report was filed on February 13, 2025, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fifth day of November, 2025



Secretary of State

Tracking Number: 9669209631CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Infinite Health Pharmacy Inc.

Pharmacy/Wholesaler License # (if applicable) new application

Physical Address 416 Clematis St, Ste B

City West Palm Beach State FL Zip 33401

Mailing Address (if different from physical address) (same address)

City _____ State _____ Zip _____

Telephone 833-463-4679 Website N/A

Licensing Company Email infinitehealthrx@gmail.com

Section 2: Personal Information

First Thomas Middle _____ Last Rebhandl

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
St. John's University			08/93 – 05/98	
Address	City		State	Zip
8000 Utopia Parkway	Queens		NY	11439
Diploma/Degree obtained, if any				
Bachelor of Science in Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
Eldred Junior Senior High School			09/84 06/93	
Address	City		State	Zip
600 Route 55	Eldred		NY	12732
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is [redacted])

From - To (MM/YY – MM/YY)				
10/15 – Curre[redacted]				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Infinite Health Pharmacy Inc.			03/25 - Present
Business Address	**City**	**State**	**Zip**
416 Clematis Street Ste B	West Palm Beach	FL	33401
Phone	**Title**		**Number of Employed Hours**
561-621-1770	PIC/RPh		
Description of Duties			
PLEASE SEE Resume			

Business Name			From - To (MM/YY – MM/YY)
Center City Pharmacy Inc.			08/04 - 03/25
Business Address	**City**	**State**	**Zip**
416 Clematis Street	West Palm Beach	FL	33401
Phone	**Title**		**Number of Employed Hours**
561-805-7135	Owner/PIC		
Description of Duties			
Please See Resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	X	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
5/25/12		FL	Palm Beach Gardens	Palm Beach
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2012CT12635AXX				
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				

Provide explanation below:

Please see Criminal Record Disclosure included with this package. Thank you.

Original Signature (electronic, copies or stamps not accepted)

2.25.26
Date

I, Thomas Rebhandl, **certify that as the designated representative for**

Infinite Health Pharmacy Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TR I am at least 21 years of age;
3. TR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Thomas Rebhandl

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/25/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Thomas Rebhandl

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/25/26

Date

Please have this section completed in the presence of a Notary Public.

State of FL, ss. County of Palm Beach

I, Thomas Rebhandl, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/25/26

Date

Subscribed ~~and~~ Sworn to before me this 25th day of February 2026

Debra A Burghardt

Notary Public Signature

Notary Public State of Florida
Debra A Burghardt
My Commission HH 401258
Expires 5/22/2027

(Seal)

Thomas Rebhandl, R.Ph.

[redacted]

Professional Summary

Dedicated and results-driven pharmacist with over 25 years of experience in retail and independent pharmacy operations. Proven expertise in medication therapy management, regulatory compliance, immunizations, and patient counseling. Skilled in optimizing pharmacy workflows, managing teams, and ensuring safe, effective, and compliant drug dispensing. Recognized for attention to detail, strong clinical judgment, and commitment to quality patient care.

Professional Experience

Infinite Health Pharmacy, Inc. – West Palm Beach, FL
Pharmacist
Mar 2025 – Present

- Review and interpret physician orders to ensure accuracy and detect therapeutic incompatibilities.
- Compound, package, and label pharmaceuticals in compliance with regulations.
- Monitor drug therapies and advise on interventions to improve patient outcomes.
- Oversee daily pharmacy operations, inventory control, and staff management.
- Ensure compliance with FDA, state, and federal regulations.
- Provide patient counseling and administer immunizations.

Center City Pharmacy, Inc. – West Palm Beach, FL
Pharmacist
Aug 2004 – Mar 2025

- Delivered comprehensive pharmacy services, including prescription review, dispensing, and patient counseling.
- Managed all aspects of independent pharmacy operations including staffing, workflow optimization, and financial oversight.
- Maintained strict adherence to state, federal, and FDA regulations.
- Administered immunizations and led community health initiatives.
- Supervised and trained pharmacy staff to ensure compliance and quality service.

Publix – Palm Beach County, FL
Pharmacist
Oct 1998 – Aug 2004

- Reviewed and accurately filled physician prescriptions while identifying potential drug interactions.
- Dispensed medications in accordance with safety, legal, and professional standards.
- Provided drug therapy monitoring and consultation to physicians and patients.
- Contributed to pharmacy productivity and maintained high-quality customer service.

Harpell Chemists – Whitestone, NY
Pharmacist Intern
1995 – 1998

- Assisted licensed pharmacists in preparing, dispensing, and distributing medications.
- Conducted clinical monitoring and provided drug information to healthcare providers.
- Gained experience in community pharmacy operations and regulatory compliance.

Education

St. John's University – Jamaica, NY
Bachelor of Science in Pharmacy (R.Ph.)
1993 – 1998

Eldred Central School – Eldred, NY
High School Diploma
Graduated 1993

Skills

- Pharmacology & Patient Care
- Administering Medications & Immunizations
- Drug Therapy Monitoring
- Regulatory Compliance (FDA, State & Federal)
- Inventory & Process Management
- Analytical & Critical Thinking
- Verbal Communication & Patient Counseling
- Attention to Detail & Quality Focus

Languages

- English

IN THE COUNTY COURT OF THE FIFTEENTH JUDICIAL CIRCUIT
IN AND FOR PALM BEACH COUNTY FLORIDA

STATE OF FLORIDA, CASE NO.: 2012CT12635AXX

vs.

THOMAS KEENANDL,
Defendant.

AGREED MOTION TO CONVERT 25 HOURS OF COMMUNITY SERVICE INTO A FINE

COMES NOW, Defendant, by and through the undersigned counsel, and the State Attorney agree to the following: Defendant is on probation for Reckless Driving. Defendant was ordered to complete fifty hours of community service. Defendant works approximately sixty hours a week. Defendant wishes to convert twenty-five hours of community service into a fine at the rate of $10 per hour.

William S. Abramson
Attorney for Defendant
Fla Bar No.: 967904

Pam Ford
Assistant State Attorney
Fla Bar No.: 896903

JAN 23 2013 EP

ORDER

THE COURT BEING FULLY ADVISED, hereby orders and adjudges that Defendant is authorized to pay out twenty five community service hours at the rate of ten dollars an hour.

DONE AND ORDERED, in chambers, Palm Beach Gardens, Palm Beach County, FL, this 24 of Jan, 2013.

LAURA JOHNSON
COUNTY COURT JUDGE

FILED
JAN 23 2013
CIRCUIT & COUNTY COURTS
(CRIM. DIV.)

FILED
13 JAN 24 PM 2:05

CERTIFIED COPY

DATE DATE DATE

Name: Rebbandi Thomas

CASE NUMBER(S): 12CT012135MJA

Charge(s): Petty Theft Disorderly Intoxication

Rebbandi [ ] [ ] Adj/Wh/Dis

[ ] [ ] Adj/Wh/Dis

[ ] [ ] Adj/Wh/Dis

[ ] [ ] Adj/Wh/Dis

Adjudicated [ ] Withheld [ ] Date

SPECIAL CONDITIONS OF PROBATION:

A) [ ] Restitution ordered (hearing & counsel objections waived): Payments to be made to: _____

_____ monthly payments of _____ per month to commence on _____

B) Fine: $250 Court costs: _____

C) Treatment:

[ ] Complete DUI School and any recommended treatment. (Enroll within 30 days).

[ ] Complete substance abuse evaluation and recommended treatment. (Enroll within 30 days).

D) Incarceration:

[ ] Day for day credit on in-patient alcohol or drug treatment facility _____ Credit for _____

[ ] Work release at _____ hours per week _____

[ ] Jail time to work release

E) Prior to interpretation of _____ Traffic _____ Pretrial Intervention

F) Community Service (Enroll within 30 days) (Date to be completed) _____

50 hours of community service to be performed at _____ hours per month

_____ hours per month _____ Driver Improvement Program

G) ✓ Total Abstinence of the Use of Intoxicating Beverages or consumption of alcohol on the date of sentencing and for the term of Probation. (Enroll within 30 days)

H) _____

I) _____

OTHER CONDITIONS OF PROBATION:

[ ] No possession or consumption of intoxicating beverages or any controlled substance, with or without a prescription, except as ordered by a physician. Defendant must sign a release for PRIOR and any prescription drug prescribed to defendant. Defendant must submit to urinalysis or breathalyzer test at the discretion of the Probation Officer. Defendant is prohibited from entering establishments where intoxicating beverages are the primary item for sale.

[ ] AA Meetings

[ ] Other: _____

[ ] _____

DEFENDANT: DEFENDANT UNDERSTANDS AND HEREBY AGREES THAT IF (HE) IS PLACED ON PROBATION, (SHE) IS (OR) IS NOT UNDER THE TERMS OF THIS PLEA AGREEMENT TO COMPLY WITH ALL CONDITIONS AND IF THE DEFENDANT SHOULD VIOLATE THE TERMS AND CONDITIONS OF THIS AGREEMENT, PROBATION MAY BE REVOKED FOR A JAIL SENTENCE OF UP TO 90 days AND/OR A FINE OF UP TO $ 500.00 THAT IS IMPOSED.

THE COURT FINDS THAT THE PLEA IS FREELY AND VOLUNTARILY MADE, THAT THE DEFENDANT UNDERSTANDS THE NATURE AND CONSEQUENCES OF THE PLEA AND THAT THERE IS A FACTUAL BASIS FOR THE PLEA.

DATE: 9/10/12

JUDGE, COUNTY COURT

ASSISTANT STATE ATTORNEY ATTORNEY FOR DEFENDANT DEFENDANT

FILED
OCT 10 2012
CIRCUIT & COUNTY COURTS
(CRIM. DIV.)

FILED
SEP 10 2012

UNOFFICIAL COPY

Habitat for Humanity® Palm Beach County

25 Celebrating 25 Years Building Homes, Building Hope Est. 1986

February 13, 2013

Regarding: Thomas Rebhandl

To Whom It May Concern

This is a letter confirming that **Thomas Rebhandl** has volunteered with Habitat for Humanity of Palm Beach County, his volunteer hours are **25** hours with Habitat. He volunteered at our Thrift Store, under the supervision of store Manager, Cindy Capitanelli, and staff.

If you have any questions, please do not hesitate to contact me at 561-253-2080 Ext. 120.

Sincerely,

Marcella Pinsky
Volunteer Coordinator

FILED
13 FEB 20 PM 2:36
SHARON R. BOCK, CLERK
PALM BEACH COUNTY, FL
MOTION FOR RECONSIDERATION
POSTAGE PAID
COURTESY COPY

6758 North Military Trail, Suite 301, West Palm Beach, FL 33407 • Phone: (561) 253-2080 Fax: (561) 253-7858 www.habitatpbc.org

CASE NO. 12CT012635 AXX STATE OF FLORIDA Vs. ID

Name Lebland, Thomas DOB 3-9-75 Race ____ Sex ____ Area ____

Re 1- Reckless
2 Speed
Amended cf

Cite 3655 6XB3 Date ____ Iss ____ No show correct court

Bond Rec ____ Type ____ Amt ____ Ref ____ A/C ____

Date 10-10-12 Judge Johnson State ____

Interp: Spanish/Creole Present/Needed Deft ____ Atty/Counsel/PD D. Johnson

☐ RECALL CAPIAS ☐ CAPIAS ORDERED Bond Set $ ____ ☐ Bond Forf/Disch/Remains

Obtain / Waive Atty ☐ Advised of rights ☐ Sworn & Testified ☐ Indigent/Not Indigent

Plea: ☐ Not Guilty ☐ Private Counsel ____ Appt. ☐ PD Appt'd $50 Fee ☐ PD Discharged

☐ CT ____ ☐ NC CT ____ Adj CT ____ NG CT ____ ☐ W/Hold CT ____

☐ PLEA TO COURT ☐ Bond Int. ☐ Action/plea/bond forfeiture cf ____ vacated & set aside ☐ Sentencing Passed

☐ Nolle Prosequi CT ____ ☐ Dismiss CT ____

☐ SEE Order Amending Costs/Judgment ☐ Report Immediately to Clerks Office To Complete collections agreement

Total deduct $ ____ from cash bond in case # ____ Apply To ____

Jail sent. Consec/Concur w/ ____

Prob ____ Yrs/Mos Consec/Concur W/ ____

☐ Prob Term/Rev/Continue ☐ ____ Day Immobilization ☐ AA/NA mtg ____ ☐ Drivers Lic. Susp. ____ Mos/Yrs.

Early term after ____ Mos/upon conditions are met ____ Hrs Comm Service in lieu of fine/costs

50 Hrs Comm Service/enroll w/in 30 days ☐ W/PBCCS Program/Non-prof. Org. ☐ SIP/enroll w/in ____ days

☐ DUI School/enroll w/in 30 days/copy rec. req. ☐ DV/F/enroll w/in ____ days ☐ No Contact/Poss Alcohol/Drug/Misc Alcohol Ords. w/in RX

☐ Psych/drug/alcohol eval/treat as needed ☐ FIVE/FREP ☐ Random Alcohol/Drug Test at Defs Expense ☐ HIV/STD/Hep A,B,C test/clinic

☐ No Victim Contact w/Victim (Restitution ordered/reserved ____ TO ____

We would consent to the record

Arraign Cs Dispo NG Trial Trial Plea Cal Conf Prelim Final Sent Rest Hrg on ____ Div ____ at ____ M

☐ Deft pres waived/required Also held on: ____ on ____ Div ____ at ____ M

☐ Clerk to notice ☐ PD to notice ☐ Waiver Of ____ ☐ File to Judges Office ☐ St/Def Motion for cont granted/denied.

Bondsman: ____ Prob: ____ CAL: ____

By: ____ Deputy Clerk Def Counsel: X ____

Mailed To: ____

Def X ____

☐ Please ____ County Courthouse 205 N. Dixie, West Palm Beach

☐ Please ____ Co County Courthouse 200 W. Atlantic Ave., Delray Beach

☐ Please ____ Co County Courthouse 3188 PGA Blvd. Palm Beach Gardens

☐ Courtroom, Criminal Justice Bldg. 401 N. Sixth Street FL, Belle Glade

☐ Courtroom, Criminal Justice Complex 3228 Gun Club Rd., West Palm Beach

If you are a person with a disability who needs any accommodation in order to participate in this proceeding, you are entitled, at no cost to you, to the provision of certain assistance. Please contact Krista Garber, Americans with Disabilities Act Coordinator, Palm Beach County Courthouse, 205 North Dixie Highway West Palm Beach, Florida, 33401; telephone number (561) 355-4380 at least 7 days before your scheduled court appearance, or immediately upon receiving this notification if the time before the scheduled appearance is less than 7 days; if you are hearing or voice impaired, call 711.

ORDER PLACING DEFENDANT ON PROBATION

STATE OF FLORIDA (plaintiff)
—VS—
Rebhandl, Thomas (defendant)

IN THE COUNTY COURT, CRIMINAL DIVISION
IN AND FOR PALM BEACH COUNTY, FL

CASE NO. 2012CTD126354AMJ

This cause coming on this day to be heard before me, and you, the defendant Rebhandl, Thomas being now present before me, and you having:

☑ ENTERED A PLEA OF GUILTY TO ☐ ENTERED A PLEA OF NOLO CONTENDERE TO ☐ BEEN FOUND GUILTY OF

the offense of C12. Reckless driving

this court here by: ☑ ADJUDGES YOU TO BE GUILTY OF SAID OFFENSE ☐ WITHHOLDS ADJUDICATION OF GUILT,

It appearing to the satisfaction of the Court that you are not likely again to engage in a criminal course of conduct, and that the ends of justice and the welfare of society do not require that you should suffer the penalty authorized by law,

Now, therefore, it is ordered and adjudged that the imposition of sentence is hereby withheld, and that you are hereby placed on probation for a period of 6 Months under the supervision of Professional Probation Services, Inc. Probation Office, such supervision to terminate upon the expiration of said period, subject to the provisions of the laws of the State. It is further ordered that you shall comply with the following conditions of probation:

(1) You will not change your residence or employment or leave the county of your residence without first procuring the consent of your Probation Supervisor.
(2) You will report to your Probation Supervisor as instructed, making a full and truthful report.
(3) You will not possess, carry or own any firearm unless authorized by the Court.
(4) You will live and remain at liberty without violating any laws and you will not associate with any person or persons engaged in criminal activities. A conviction in a court of law shall not be necessary to constitute a violation of probation.
(5) You will not use intoxicants to excess and you will not possess or consume any drug or narcotic unless prescribed and administered or directed by a physician. You will not possess or consume any illegal drugs and will not visit places where intoxicants, drugs or other dangerous substances are unlawfully sold, dispensed or used. To determine the presence of alcohol or controlled substances you are required to submit to testing at your own expense as directed by probation.
☑ (If Checked) You will not possess nor consume any type of alcohol; you will not consume any food or take any medication that contains alcohol.
☑ (If Checked) You will submit to random testing as directed by probation at your own expense.
(6) You will work diligently at a lawful occupation and support any dependents to the best of your ability.
(7) You will promptly and truthfully answer all inquiries directed to you by the Court or the Probation Supervisor, and allow the Supervisor to visit in your home, at your employment site or elsewhere, and you will comply with all instructions he or she may give you.
(8) You will pay $ 50.00 per month toward the cost of this supervision beginning on the date set by your Probation Officer.
(9) All conditions of Probation must be completed and verification received by probation no later than _____.
(10) You will perform 50 hours of community service within _____ days and complete a minimum of _____ hours per month (CSP required Y / N).
☐ (11) (If checked) You must obtain a substance abuse/mental/psychological evaluation within _____ days and successfully complete any recommended treatment or educational program at your own expense. 943.20
☑ (12) You will pay any fine and/or court cost as ordered by the Court. ☐ (If Checked) You may complete additional community service work in lieu of monetary payment of the fine and / or court cost at the rate of $ _____ per hour.
☐ (13) You will serve _____ days / months at the Palm Beach County Jail commencing on _____.
(14) You must pay restitution for damage or loss in an amount and manner determined by the Court.
☐ (15) (If checked) You must enroll in the State Approved DUI School by 3 months and comply with the rules of the program and successfully complete the program and any recommended treatment at your own expense.
☐ (16) (If checked) You may petition for early termination of your probation after _____ months.
☑ (17) (If checked) You must attend the Victim Impact Panel at your own expense no later than 6 Months and you must comply with the rules of the program which prohibits the consumption of alcohol on the date of attendance.
☐ (18) (If checked) You must have your vehicle immobilized for _____ days at your own expense.
☐ (19) (If checked) You must attend AA and / or NA meetings per _____ and submit written verification of your attendance to probation.

You are hereby placed on notice that the Court may, at any time rescind or modify any of the conditions of your probation or may extend the period of probation as authorized by law, or may discharge you from further supervision; and that if you violate any of the conditions of your probation, you may be arrested and the Court may revoke your probation and impose any sentence which it might have imposed before placing you on probation.

It is further ordered that the Clerk of the Court file this order in his office, and record the same in the Minutes of the Court.

DONE AND ORDERED IN OPEN COURT, this the 19th day of September, 20 12

Signed this 3 day of Oct. 20 12

JUDGE

I acknowledge that the conditions of probation have been explained to me, and that it is my responsibility to provide documentation of completion. Florida Statute Section 948.09 requires: Any person placed on misdemeanor probation by a county court must contribute not less than $40 per month.

This 19th day of September, 20 12

Instructed by: Suzanne P

PROBATIONER

Reinstructed by: _____ Date: _____

+ / Johnson

SCANNED OCT 17 2012

Florida Department of Law Enforcement

DNA Database

Offender Search

Rapid-ID DNA Collection Instructions

List of DNA Collectible Offenses
Compliance Reports
Adult Offenders Sentenced to Community Supervision .
SUMMARY REPORT
REPORT BY COUNTY
Reports Updated: May 14, 2012
You will need Acrobat Reader to read the reports

The following offender records are listed in descending order from the last the submissions are received. Click a link to view the full record

No records found

New Search

NOT A CERTIFIED COPY

SCANNED
MAY 29 2012

SUBJECT: Rabhanl Hlums CASE NUMBER: 12-00243

QUESTIONS AND ANSWERS

I AM NOW GOING TO ASK YOU SOME QUESTIONS. WITH THESE RIGHTS IN MIND, YOU MAY ANSWER SOME OF, ALL OF, OR NONE OF THE FOLLOWING QUESTIONS AS YOU LIKE.

WERE YOU OPERATING A MOTOR VEHICLE AT THE TIME OF THE STOP/ACCIDENT? _____

WHERE WERE YOU GOING? _____

WHAT STREET OR HIGHWAY WERE YOU ON? _____

DIRECTION OF TRAVEL? _____ WHERE DID YOU START? _____

WHAT TIME DID YOU START? _____ WHAT TIME IS IT NOW? _____

WHAT IS TODAY'S DATE? _____ WHAT DAY OF THE WEEK IS IT? _____

WHAT COUNTY AND CITY ARE YOU IN NOW? _____

WHEN DID YOU LAST EAT? _____ WHAT DID YOU EAT? _____

WHAT HAVE YOU BEEN DOING FOR THE LAST THREE HOURS? _____

HOW MUCH DO YOU WEIGH? _____ HAVE YOU BEEN DRINKING? _____ WHAT? _____

HOW MUCH? _____ WHERE? _____ WITH WHOM? _____

WHEN DID YOU HAVE YOUR FIRST DRINK? _____ AND YOUR LAST DRINK? _____

HOW DID YOU CONSUME YOUR LAST TWO DRINKS? _____

CAN YOU FEEL THE EFFECTS OF THE ALCOHOL? _____ ARE YOU UNDER THE INFLUENCE? _____

HAVE YOU CONSUMED ANY ALCOHOL SINCE THE ACCIDENT? _____ HOW MUCH? _____

WHAT? _____ WHERE? _____ WHEN? _____

WHAT LINE OF WORK ARE YOU IN? _____ WHEN DID YOU LAST WORK? _____

DO YOU HAVE ANY PHYSICAL DEFECTS OR INJURIES? _____ WHAT? _____

ARE YOU SICK OR INJURED? _____ WHAT'S WRONG? _____

DO YOU LIMP? _____ DID YOU RECEIVE A BUMP ON THE HEAD RECENTLY? _____

WERE YOU IN AN ACCIDENT TODAY? _____

HAVE YOU TAKEN ANY DRUGS OR SMOKED ANY MARIJUANA TODAY? _____ WHEN? _____

HAVE YOU SEEN A DOCTOR OR DENTIST TODAY? _____ WHO? _____ WHY? _____

ARE YOU TAKING ANY PRESCRIPTION MEDICINES? _____ WHAT? _____ WHEN? _____

DO YOU HAVE:
- EPILEPSY? _____
- GLASS EYE? _____
- FALSE TEETH? _____
- EAR INFECTION? _____
- INNER EAR TROUBLE? _____
- DIABETES? _____

DO YOU HAVE ANY PROBLEMS WITH YOUR EYES THAT ARE NOT CORRECTED BY GLASSES? _____

DO YOU TAKE INSULIN? _____ IF SO, WHEN WAS YOUR LAST INJECTION? _____

HAVE YOU EVER HAD A DRIVER'S LICENSE IN ANY OTHER STATE? _____ WHERE? _____

INTERVIEWER: _____

WHITE - STATE ATTY. YELLOW - DHSMV PINK - CENTRAL RECORDS GOLD - JAIL

FDCD 001230 REV. 8/03

NOT CERTIFIED COPY

SCANNED
MAY 29 2012

SUBJECT: Rebbard | Thomas CASE NUMBER: 12-000843

IMPLIED CONSENT FOR DUI IN A MOTOR VEHICLE

NOTE: READ ONLY THE PARAGRAPH APPLICABLE TO THE TYPE OF TEST YOU ARE REQUESTING.

I am now requesting that you submit to a lawful test of your BREATH for the purpose of determining its alcohol content.

-OR-

I am now requesting that you submit to a lawful test of your URINE for the purpose of detecting the presence of chemical or controlled substances.

-OR-

I am now requesting that you submit to a lawful test of your BLOOD for the purpose of detecting its alcohol content and the presence of chemical or controlled substances.

NOTE: READ ONLY IF THE SUBJECT DOES NOT COMPLY WITH YOUR REQUEST.

I am Ofc Melinda Hamilton 3rd of the Bradenton PD

If you fail to submit to the test I have requested of you, your privilege to operate a motor vehicle will be suspended for a period of one (1) year for a first refusal, or eighteen (18) months if your privilege has been previously suspended as a result of a refusal to submit to a lawful test of your breath, urine or blood. Additionally, if you refuse to submit to the test I have requested of you and if your driving privilege has been previously suspended for a prior refusal to submit to a lawful test of your breath, urine or blood, you will be committing a misdemeanor. Refusal to submit to the test I have requested of you is admissible into evidence in any criminal proceedings.

SUBJECT'S SIGNATURE: (X) Refused Consent

CONSTITUTIONAL WARNINGS

I AM REQUIRED TO WARN YOU BEFORE YOU MAKE ANY STATEMENTS THAT YOU HAVE THE FOLLOWING RIGHTS:

1. You have the right to remain silent and not answer any questions.
2. Any statement must be freely and voluntarily given.
3. You have the right to the presence of a lawyer of your choice before you make any statement and during any questioning.
4. If you cannot afford a lawyer, you are entitled to the presence of a court appointed lawyer before you make any statements and during any questioning.
5. If at any time during the interview you do not wish to answer any questions, you are privileged to remain silent.
6. I can make no threats or promises to induce you to make a statement. This must be of your own free will.
7. Any statement can and will be used against you in a court of law.

SCANNED
MAY 29 2012

SUSPECT'S SIGNATURE: (X) Refused Consent

WHITE - STATE ATTY. YELLOW - DHSMV PINK - CENTRAL RECORDS GOLD - JAIL

TESTING FACILITY TASK REPORT

AGENCY: P.B.S.C.

SUBJECT: Rethund l, Thomas

CASE NUMBER: 12-078915

DATE: 5.25.2012

VIDEO TAPE NUMBER: 5322Lp

BEGINNING TIME: 03:05

ENDING TIME: 03:08

BREATH TESTS RESULTS: 1) R. TIME 03:07 A.M./P.M. 2) l. TIME / A.M./P.M.

3) / TIME / A.M./P.M. 4) / TIME / A.M./P.M.

BREATH OPERATOR: C Engel #9576

MAINTENANCE TECHNICIAN: Cpl. Croucher #3167

TESTING OFFICER'S OBSERVATIONS

SPEECH: Soft spoken

ATTITUDE: Quiet

CLOTHING: Blue Jeans. Blue + white shirt. Glasses + sneakers

MEDICAL CONDITIONS: none - depress - allergies

MEDICATIONS: Zoloft. claritin - Klonopin 1 x day

OTHER: A Eyes are Red + glassy

COMMENTS: A/C conducted certain observation starting @ 2:45

A/C requested A to submit to breath test A declined

Also read Implied Consent, A understood + refused

@ 03:07 hrs.

A/C read Constitutional Warnings, A understood.

A/C asked DL + A, A understood + refused.

REVISED

CERTIFIED COPY

NOT

SCANNED

MAY 29 2012

WHITE - STATE ATTY. YELLOW - DMSMV PINK - CENTRAL RECORDS GOLD - JAIL

WITNESS LIST

CASE NUMBER: 12-002843

ARRESTING OFFICER: Melinda Hanton #305
ADDRESS: [redacted] Palm Beach Gardens, FL 33410
PHONE NUMBERS (HOME): [redacted] (WORK) [redacted]
CAN TESTIFY TO: stop, observations, arrest
NAME: Officer B. Merrifield
ADDRESS: Jupiter Police Department
PHONE NUMBERS (HOME) (WORK)
CAN TESTIFY TO: backup for roadsides
NAME: Stacy Schwartz
ADDRESS [redacted]
PHONE NUMBERS (HOME) [redacted] (WORK)
CAN TESTIFY TO: was riding in my vehicle
NAME:
ADDRESS
PHONE NUMBERS (HOME) (WORK)
CAN TESTIFY TO:
NAME:
ADDRESS
PHONE NUMBERS (HOME) (WORK)
CAN TESTIFY TO:
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NAME:
ADDRESS
PHONE NUMBERS (HOME) (WORK)
CAN TESTIFY TO:

NOT A CERTIFIED COPY

SCANNED
MAY 29 2012

SUBJECT: REBHANDL,THOMAS CASE NUMBER: 12-002843

ROADSIDE TASKS

HORIZONTAL GAZE NYSTAGMUS:

☑ LEFT EYE DOES NOT FOLLOW SMOOTHLY ☑ RIGHT EYE DOES NOT FOLLOW SMOOTHLY

☑ LEFT EYE JERKS AT 45 DEGREE ANGLE OR LESS ☑ RIGHT EYE JERKS AT 45 DEGREE ANGLE OR LESS

☑ DISTINCT JERKING LEFT EYE MAXIMUM DEVIATION ☑ DISTINCT JERKING RIGHT EYE MAXIMUM DEVIATION

CAN NOT DO, WHY? swaying, kept moving hands and head, had approximate angle of onset of 30 degrees, did have vgn

WALK AND TURN:

demonstrated and explained, during instructions he was using arms for balance and not holding starting stance, he stated, "you know this is hard right?" As I was demonstrating and explaining, Rebhandl began somewhat arguing with me, I asked Rebhandl if he was refusing the tasks and he said yes. I advised Rebhandl that if he refused, his refusal can and will be used against him in court he said he understood and after trying to argue with me he eventually refused the rest of the tasks

CAN NOT DO, WHY? _____

ONE LEG STAND:

refused

CAN NOT DO, WHY? _____

FINGER TO NOSE:

refused

CAN NOT DO, WHY? _____

ROMBERG/ALPHABET:

refused

CAN NOT DO, WHY? _____

BREATH TEST RESULTS: refused

STATE OF FLORIDA
COUNTY OF PALM BEACH
THE FOLLOWING INSTRUMENT WAS NOTARIZED OR SWORN BEFORE ME THIS 05/25/12 (DATE)
BY. Ofc. Hanton is personally known to me

Catherine Engel
NOTARY/CLERK OF COURT OFFICER (F.S. 117.10)

SIGNATURE OF ARRESTING OFFICER

Notary Public State of Florida
Catherine A Engel
My Commission EE145078
Expires 12/03/2015

NOT A CERTIFIED COPY

SCANNED
MAY 29 2012

D.U.I. PROBABLE CAUSE AFFIDAVIT

ON THE 25th DAY OF May 20 12 AT 0146

SUBJECT: REBHANDL,THOMAS

AGENCY: Palm Beach Gardens Police Department CASE NUMBER: 12-002843

ARRESTING OFFICER: Melinda Henton #305

PERSONAL CONTACT

DRIVING PATTERN: ACTUAL PHYSICAL CONTROL (PHYSICAL EVIDENCE OR STATEMENTS PUTTING DEF. BEHIND WHEEL OF VEHICLE)

On 5/25/12 at 1:45 a. m. I was running stationary radar on S. R. 811 (Alternate A1A) at 13354, Frenchmans Reserve Security gate. While monitoring the north and south bound lanes I observed a white vehicle northbound that appeared to be traveling at a high rate of speed. I visually estimated the vehicle to be traveling at 70 miles per in a posted 50 mile per hour zone. I activated my stationary Genesis VP (serial #08507) radar and heard the Doppler tone and a visual reading of 69 miles per hour in the posted 50 mile per hour zone. I pulled out behind the white BMW 325I bearing Florida tag ND25SC. I activated my emergency red and blue lights to stop the vehicle and the BMW proceeded north without slowing or stopping. The BMW approached the red traffic light at Donald Ross Road and he pulled into the left turn lane to head west onto Donald Ross Road. The BMW's final rest was in the turn lane. I made contact with the white male driver and white male passenger. I identified the driver by the photograph on his Florida drivers license as Thomas Rebhandl.

OBSERVATION OF DRIVER:

strong odor of an unknown alcoholic beverage coming from his breath as he spoke, his speech was slurred and mumbled, his face appeared flush, his eyes were glassy and when he exited he was unsteady on his feet, swaying the entire time. Also had to repeat instructions like not moving head and keeping hands out of pockets

DRIVER'S STATEMENTS:

stated he had 3-4 drinks, stated he is a Pharmacist and that he is a second away from home and that his girlfriend broke up with him a couple of weeks ago.

ODORS:

strong odor of an unknown alcoholic beverage coming from breath as he spoke

GENERAL OBSERVATIONS

SPEECH: slurred, mumbled

ATTITUDE: lethargic, cooperative

CLOTHING: striped shirt, jeans, white shoes

MEDICAL PROBLEMS: mood disorder, depression

MEDICATIONS: Risperdal, Zoloft

OTHER:

NOT A CERTIFIED COPY

SHARON R. BOCK, CLERK
PALM BEACH COUNTY, FL
GUN CLUB BRANCH
2012 MAY 25 PM 5:14

SCANNED
MAY 29 2012

0434118

ARREST / NOTICE TO APPEAR
Juvenile Referral Report

1. Arrest 2. N.T.A. 3. Request for Warrant 4. Request for Capias

PCA 12-635

757

Juvenile

ADMINISTRATIVE

OSTS Number

Agency ORI Number: FLO 502600

Agency Name: Palm Beach Gardens Police Department

Agency Report Number (N.T.A.'s only): 78- 12-002843

Charge Type: Check as many as apply. 1. Felony 2. Traffic Felony 3. Misdemeanor 4. Traffic Misdemeanor 5. Ordinance 6. Other

Weapon Used / Type: 1. Yes 2. No

Multiple Clearance Indicator

Location of Arrest (Including Name of Business): Alternate A1A/Donald Ross Road

Location of Offense (Business Name, Address): Same as Arrest

Date of Arrest: 05/25/12

Time of Arrest: 0202

Booking Date / Booking Time / Jail Date / Jail Time

Location of Warrant: All Florida

DEFENDANT

Name (Last, First, Middle): REBHANDL,THOMAS

Alias (Name, DOB, Soc. Sec. #, Etc.)

Race (W - White I - American Indian B - Black A - Oriental/Asian): W

Sex: M

Date of Birth: [redacted]

Height: 600

Weight: 185

Eye Color: brown

Hair Color: brown

Complexion: fair

Build: thin

Scars, Marks, Tattoos, Unique Physical Features (Location, Type, Description): none

Current Address (Number, Street, Apt. Number): [redacted] (City) Jupiter (State) FL (Zip) 33458

Marital Status: single

Religion: Catholic

Business Use / Alcohol Involved / Drugs Involved: Y A D

Permanent Address (Number, Street, Apt. Number): Same as Local Address (City) (State) (Zip)

Phone: [redacted]

Residence Type: 1. Own 2. Rent 3. Parent 4. Out of State: 2

Business Address (Name, Street): Center City Pharmacy (City) WPB (State) FL (Zip) 33401

Phone: ( ) Same

Business Type: Pharmacist

D.L. Number, State: R153820750890 FL

Soc. Sec. Number: [redacted]

IRS Number

Place of Birth (City/State/Country): Queens, NY

Citizenship: US

CO-DEF

Co-Defendant Name (Last, First, Middle)

Race / Sex / Date of Birth

Co-Defendant Name (Last, First, Middle)

Race / Sex / Date of Birth

JUVENILES

Parent / Legal Guardian / Other: Name (Last) (First) (Middle)

Address (Number, Apt, Number) (City) (State) (Zip)

Address for (Name)

Released To (Name) Relationship Date / Time

This above person was released on [ ] bond or [ ] own recognizance (O.R.) [ ] Defendant's parents notified that child was released. [ ] Yes [ ] No (Name)

Property Seized? [ ] Yes [ ] No

Description of Property

Seized / Attached By / Where

Value of Property

CHARGE

Drug Activity: N Drug Type: N Amount / Unit: NA

Charge Description: DUI

Statute / Ordinance Number: 316.193(1)

Violation of ORO #

Warrant / Capias Number

Bond

Offense #

Statute Violation Number

Domestic Violence [ ] Y [ ] N

Charge Description

Drug Activity / Drug Type / Amount / Unit / Offense # / Statute Violation Number / Violation of ORO #

Warrant / Capias Number / Bond

Charge Description

Drug Activity / Drug Type / Amount / Unit / Offense # / Statute Violation Number / Violation of ORO #

Warrant / Capias Number / Bond

Charge Description

Drug Activity / Drug Type / Amount / Unit / Offense # / Statute Violation Number / Violation of ORO #

Warrant / Capias Number / Bond

NOTICE TO APPEAR

Location (Court, Room, Address): North County Courthouse 3188 PGA Blvd, Palm Beach Gardens, FL

Court Date and Time: Month 06 Day 27 Year 2012 Time

I AGREE TO APPEAR AT THE ABOVE PLACE DESIGNATED TO ANSWER THE CHARGE(S) CHARGED OR TO PAY THE FINE AND COURT COSTS. I UNDERSTAND THAT IF I WILFULLY FAIL TO APPEAR OR PAY THE COURT COSTS AND FINE AS REQUIRED, THAT I MAY BE HELD IN CONTEMPT OF COURT AND A CAPIAS SHALL BE ISSUED FOR MY ARREST.

Signature of Defendant for Juvenile and Parent (Custodian)

Date Signed: MAY 25 2012

ADMIN

HOLD for other Agency

Name of Arresting Officer (Print): Melinda Hanson

I.D. #: 305

Name Verified (Printed by Arrestee)

Signature of Arresting Officer

Name of Releasing Officer (Print)

I.D. #

Telephone Number of Officer: Melinda Hanson

I.D. #: 305

Agency: PBGPD

Witness to all signatures signed with an "X"

Page 1 of 1

DISTRIBUTION: WHITE - COURT COPY GREEN - STATE ATTORNEY YELLOW - AGENCY PINK - ARRESTEE GOLD - DEFENDANT (N.T.A.'s ONLY)

SCANNED

IN THE COUNTY COURT OF THE FIFTEENTH JUDICIAL CIRCUIT
IN AND FOR PALM BEACH COUNTY FLORIDA

STATE OF FLORIDA, CASE NO.: 2012CT12635AXX

vs.

THOMAS REBHANDL
Defendant.

SHARON R BOCK, CLERK
PALM BEACH COUNTY, FLORIDA
2012 JUN 11 PM 03:08

NOT A CERTIFIED COPY

PRAECIPE OF APPEARANCE

The Clerk of Court will please enter the Appearance of the undersigned attorney for Defendant in the above-titled cause.

I DO HEREBY CERTIFY that a true and correct copy hereof has been furnished to the State Attorney's Office, 3188 PGA BLVD, Palm Beach Gardens; this 15 day of June, 2012.

Respectfully Submitted,

William S. Abramson
Attorney at Law
324 Datura Street, Suite 208
West Palm Beach, FL 33401
(561)650-1898
(561)650-1018 fax
Fla Bar No.: 967904

SCANNED
JUN 1 = 2012
NB

IN THE COUNTY COURT OF THE FIFTEENTH JUDICIAL CIRCUIT
IN AND FOR PALM BEACH COUNTY, STATE OF FLORIDA

DIVISION "H"

STATE OF FLORIDA

vs.

CASE NO. 2012CT012635ANB
BOOKING NO. 2012022414

THOMAS REBHANDL, W/M, 03/03/1975, [redacted]

AMENDED
INFORMATION FOR:

1) RECKLESS DRIVING

In the Name and by Authority of the State of Florida:

PETER ANTONACCI, State Attorney for the Fifteenth Judicial Circuit, Palm Beach County, Florida, by and through his undersigned Assistant State Attorney, charges that:

COUNT 1: THOMAS REBHANDL on or about May 25, 2012, in the County of Palm Beach and State of Florida, did drive a vehicle in willful or wanton disregard for the safety of persons or property, contrary to Florida Statute 316.192(1)(a). (WISD)

PETER ANTONACCI
STATE ATTORNEY

By: PAMELA A. FORD
FL. BAR NO. 0895608
Assistant State Attorney
Fifteenth Judicial Circuit

STATE OF FLORIDA
COUNTY OF PALM BEACH

Appeared before me, PAMELA A. FORD, Assistant State Attorney for Palm Beach County, Florida, personally known to me, who, being first duly sworn, says that is prosecution is instituted in good faith.

Assistant State Attorney

Sworn to and subscribed to before me this 10 day of September, 2012.

DAMARIS JORDAN
Commission # DD 928811
Expires August 4, 2014

NOTARY PUBLIC, State of Florida

FILED
SHARON R. BOCK
CLERK & COMPTROLLER
PALM BEACH COUNTY, FL
2012 SEP 11 PM 2:39

NOT A CERTIFIED COPY

PF/dj

FCIC REFERENCE NUMBERS:
1) RECKLESS DRIVING 5405

DEF:A 1) DRIVING UNDER THE INFLUENCE (316.193 1) (*M), DISPO: NP

NOTICE OF CONFIDENTIAL INFORMATION WITHIN COURT FILING

Pursuant to Florida Rule of Judicial Administration 2.420(d)(2), the filer of this court record (information) indicates that confidential information is included within the document being filed; to wit: Social Security Number, § 119.0714.

Case No. 2012CT012635ANB
STATE OF FLORIDA
COUNTY OF PALM BEACH

Appeared before me, MATTHEW WILDNER, Assistant State Attorney for Palm Beach County, Florida, personally known to me, who, being first duly sworn, says that this prosecution is instituted in good faith.

Assistant State Attorney

Sworn to and subscribed to before me this 05 day of June, 2012.

NOTARY PUBLIC, State of Florida

CARLA M. MACON
Commission # DD 929737
Expires November 7, 2013

FCIC REFERENCE NUMBERS:
1) DRIVING UNDER THE INFLUENCE 5499

NOTICE OF CONFIDENTIAL INFORMATION WITHIN COURT FILING

Pursuant to Florida Rule of Judicial Administration 2.420(d)(2), the filer of this court record (Information) indicates that confidential information is included within the document being filed; to wit: Social Security Number, § 119.0714.

NOT A CERTIFIED COPY

IN THE COUNTY COURT OF THE FIFTEENTH JUDICIAL CIRCUIT
IN AND FOR PALM BEACH COUNTY, STATE OF FLORIDA

CRIMINAL DIVISION

STATE OF FLORIDA

vs.

CASE NO. 2012CT012635ANB
CITATION NO: 9125XBI7

THOMAS REBHANDL, W/M, 03/09/1975, [redacted]

SHARON R. BOCK, CLERK
2012 JUN 18 AM 8:27
PALM BEACH COUNTY, FLORIDA
COUNTY CRIMINAL

INFORMATION FOR:

1) DRIVING UNDER THE INFLUENCE

In the Name and by Authority of the State of Florida:

PETER ANTONACCI, State Attorney for the Fifteenth Judicial Circuit, Palm Beach County, Florida, by and through his undersigned Assistant State Attorney, charges that:

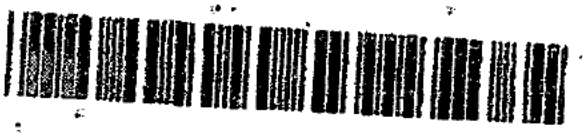
COUNT I: THOMAS REBHANDL on or about May 25, 2012, in the County of Palm Beach and State of Florida, did drive or was in actual physical control of a vehicle, while under the influence of alcoholic beverages or chemical substances as set forth in Florida Statute 877.111, or a controlled substance as set forth in Florida Statute 893 or any combination thereof, and was affected to the extent that his normal faculties were impaired; or while having a blood, or breath alcohol level of .08 or higher, contrary to Florida Statute 316.193(1). (MISD)

PETER ANTONACCI
STATE ATTORNEY

By: MATTHEW WILDNER
FL. BAR NO. 085580
Assistant State Attorney
Fifteenth Judicial Circuit

NOT A CERTIFIED COPY

SCANNED
JUN 18 2012
TAP



FLORIDA UNIFORM TRAFFIC CITATION

3655-GXB 3

COUNTY OF Palm Beach

CITY (IF APPLICABLE) Palm Beach Gardens

☐ (1) F.H.P. ☐ (2) P.D. ☐ (3) S.O. ☐ (4) OTHER

AGENCY NAME

AGENCY #

IN THE COURT DESIGNATED BELOW THE UNDERSIGNED CERTIFIES THAT HE/SHE HAS JUST AND REASONABLE GROUNDS TO BELIEVE AND DOES BELIEVE THAT ON

COMPLAINT (RETAINED BY COURT)

DAY OF WEEK Friday MONTH 05 DAY 25 YEAR 2012 AT 1:46 ☐ A.M. ☐ P.M.

NAME (FIRST, MIDDLE, LAST) [redacted]

STREET ADDRESS [redacted] CITY [redacted] STATE [redacted] ZIP [redacted]

TELEPHONE NUMBER [redacted] DATE OF BIRTH MO 03 DAY 09 YR 1975 SEX M RACE W HGT 6'05 WGT 245

DRIVER LICENSE NUMBER R152382075088 STATE FL CLASS E CDL LICENSE ☐ YES ☒ NO

VEHICLE YR 2009 VEHICLE MAKE STYLE COLOR COMMERCIAL VEHICLE ☐ YES ☐ NO

VEHICLE LICENSE NO. TRAILER TAG NO. STATE VEHICLE DEFUNCT ☐ YES HAZARDOUS MATERIAL ☐ YES ☐ NO

UPON A PUBLIC STREET OR HIGHWAY, OR OTHER LOCATION, NAMELY A1A at Alt A1A Burns Rd Garden

BUS PASSENGER ☐ YES ☐ NO

MOTORCYCLE ☐ YES ☒ NO

COMMERCIAL DRIVER'S LICENSE ☐ YES ☐ NO

FT. MILES N S E W OF NODE

DID UNLAWFULLY COMMIT THE FOLLOWING OFFENSE: CHECK ONLY ONE OFFENSE EACH CITATION.

☐ UNLAWFUL SPEED LOCAL OR POSTED SPEED APPLICABLE MPH

(☐ INTERSTATE ☐ 4-LANE HWY WITH 20 FT. MEDIAN ☐ OUTSIDE URB. OR RES. DIST.)

☐ CARELESS DRIVING
☐ VIOLATION OF TRAFFIC CONTROL DEVICE
☐ FAILURE TO STOP AT A TRAFFIC SIGNAL
☐ IMPROPER LANE CHANGE OR COURSE
☐ NO PROOF OF INSURANCE
☐ VIOLATION OF RIGHT-OF-WAY
☐ IMPROPER PASSING
☐ CHILD RESTRAINT
☐ SAFETY BELT VIOLATION
☐ DEFECTIVE OR UNSAFE EQUIPMENT
☒ EXPIRED TAG ≤ SIX (6) MONTHS
☐ EXPIRED TAG > SIX (6) MONTHS
☐ DRIVING UNDER THE INFLUENCE BAL
☐ EXPIRED DRIVER LICENSE
☐ > SIX (6) MONTHS
☐ NO VALID DRIVER LICENSE
☐ DRIVING WHILE LICENSE SUSPENDED OR REVOKED

OTHER VIOLATIONS OR COMMENTS PERTAINING TO OFFENSE Reckless 3.16.1925

☐ AGGRESSIVE DRIVING IN VIOLATION OF STATE STATUTE SECTION SUBSECTION

CRASH ☐ YES ☐ NO PERSONAL INJURY ☐ YES ☐ NO INJURY TO ANOTHER ☐ YES ☐ NO WITNESS ☐ YES ☐ NO

☐ CRIMINAL VIOLATION; COURT APPEARANCE REQUIRED, AS DESCRIBED BELOW.
☐ SUPERVISED COURT APPEARANCE REQUIRED, AS DESCRIBED BELOW.
☐ INFRACTION WHICH DOES NOT REQUIRE APPEARANCE IN COURT.

CIVIL PENALTY IS $

3655-GXB CHECK DIGIT 3

COURT INFORMATION DATE TIME COURT LOCATION

ARREST ENFORCED TO

I AGREE AND PROMISE TO COMPLY AND ADHERE TO THE CHARGES AND INSTRUCTIONS SPECIFIED IN THIS CITATION. WILLFUL REFUSAL TO ACCEPT AND SIGN THIS CITATION MAY RESULT IN ARREST. I UNDERSTAND BY SIGNATURE IS NOT AN ADMISSION OF GUILT OR WAIVER OF RIGHTS. IF YOU NEED REASONABLE ACCOMMODATIONS TO COMPLY WITH THIS CITATION, CONTACT THE CLERK OF THE COURT. DATE

X SIGNATURE OF VIOLATOR (I ACKNOWLEDGE RECEIPT OF SUMMONS TO APPEAR IN COURT)

RANK - SIGNATURE OF OFFICER BADGE NO. ID NO. TROOP/UNIT

☐ I CERTIFY THIS CITATION WAS DELIVERED TO THE PERSON CITED ABOVE

HSMV 75001 (Rev. 2/10)

Your license number is PH 32212.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

Florida HEALTH

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO	CONTROL NO
FEBRUARY 7, 2025	PH 32212	153156

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

EXPIRATION DATE: FEBRUARY 28, 2027

INFINITE HEALTH PHARMACY INC.
416 CLEMATIS STREET
SUITE B
WEST PALM BEACH, FL 33401

QUALIFICATION(S)
Schedule II & III
Community Pharmacy

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE No.	CONTROL NO.
FEBRUARY 7, 2025	PH 32212	153156

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

INFINITE HEALTH
PHARMACY INC.

Expiration Date: FEBRUARY 28, 2027

REGISTRANT SIGNATURE

Department of Health

Infinite Health Pharmacy Inc.

License Number: PH32212

Data As Of 3/4/2026

Profession	Pharmacy
License	PH32212
License Status	Clear/
Qualifications	Community Pharmacy Schedule II & III
License Expiration Date	2/28/2027
License Original Issue Date	07/01/2019
Address of Record	416 Clematis Street Suite B WEST PALM BEACH, FL 33401
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
REBHANDL, THOMAS	PHARMACY AFFILIATE	PHARMACY AFFILIATE		02/01/2022
REBHANDL, THOMAS	RX DPT MGR/COR/POR	PHARMACIST	33826	10/01/2025

Click on the License Number to view License Details for that Practitioner

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Infinite Health Pharmacy Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): new application

Physical Address: 416 Clematis St, Ste B

City: West Palm Beach State: FL Zip: 33401

Mailing Address (if different from physical address): (same address)

City: State: Zip:

Telephone: 833-463-4679 Website: N/A

Licensing Company Email: infinitehealthrx@gmail.com

Section 2: Personal Information

First: Thomas Middle: Last: Rebhandl

Alias(es, nicknames, name changes, etc.):

[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
St. John's University			08/93 - 05/98	
Address		City	State	Zip
8000 Utopia Parkway		Queens	NY	11439
Diploma/Degree obtained, if any				
Bachelor of Science in Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
Eldred Junior Senior High School			09/84 - 06/93	
Address		City	State	Zip
600 Route 55		Eldred	NY	12732
Diploma/Degree obtained, if any				
High School Regents Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/15 - Current	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Infinite Health Pharmacy Inc.			03/25 - Present
Business Address	**City**	**State**	**Zip**
416 Clematis Street Ste B	West Palm Beach	FL	33401
Phone	**Title**		
561-621-1770	PIC/RPh		
Description of Duties			
Review + interpret physican orders to ensure + detect therapeutic incompatibilities. Monitor drug therapies and advise on interventions to improve Patient outcomes. Oversee daily pharmacy operations, inventory control + staff management			

Business Name			From - To (MM/YY – MM/YY)
Center City Pharmacy Inc.			08/04 - 03/25
Business Address	**City**	**State**	**Zip**
416 Clematis Street	West Palm Beach	FL	33401
Phone	**Title**		
561-805-7135	owner/PIC		
Description of Duties			
Please see Resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	X	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
5/25/12		FL	Palm Beach Gardens	Palm Beach
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2012CT12635AXX				
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				

Provide explanation below:

Please see Criminal Record Disclosure, included with this package. Thank you

Original Signature (electronic, copies or stamps not accepted)

2/25/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Thomas Rebhandl

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/25/26

Date

Please have this section completed in the presence of a Notary Public.

State of FLORIDA, ss. County of Palm Beach

I, Thomas Rebhandl, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/25/26

Date

Subscribed and Sworn to before me this 25th day of February 2026.

Debra A. Burghardt

Notary Public Signature

Notary Public State of Florida
Debra A Burghardt
My Commission HH 401258
Expires 5/22/2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Infinite Health Pharmacy Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): new application

Physical Address: 416 Clematis St, Ste B

City: West Palm Beach State: FL Zip: 33401

Mailing Address (if different from physical address): (same address)

City: State: Zip:

Telephone: 833-463-4679 Website: N/A

Licensing Company Email: infinitehealthrx@gmail.com

Section 2: Personal Information

First: Peter Middle: Thomas Last: Gillooly

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Columbia University		09/15 - 05/18	
Address	**City**	**State**	**Zip**
130 Amsterdam Avenue	New York	NY	10027
Diploma/Degree obtained, if any			
Master of Science - Chemical Engineering			

School Name		From - To (MM/YY – MM/YY)	
University of North Carolina		09/07 - 12/10	
Address	**City**	**State**	**Zip**
174 Country Club Rd	Chapel Hill	NC	27514
Diploma/Degree obtained, if any			
Bachelor of Science - Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Wahconah Regional High School			
Address	**City**	**State**	**Zip**
150 Old Windsor Rd	Dalton	MA	01226
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/25 - Present	[redacted]			
09/22 - 12/25				
05/21 - 08/22				
07/17 - 04/21				
02/16 - 06/17				
08/15 - 01/16				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
TWC 2022 Inc		07/22 - Present	
Business Address	**City**	**State**	**Zip**
433 Plaza Real, Ste 275	Boca Raton	FL	33432
Phone	**Title**		
1 (800) 758-1584,	President & CEO		
Description of Duties			
Chief executive officer in charge of all business operations			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	X	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # __5___. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
7/11/2025	N/A	ID	Pocatello	Pocatello

Case #	Governing, licensing, Arresting Presiding Body/Agency/
4:25-cv-00379-DCN	Court U.S. District Court District of Idaho

Reason/Charge	Trademark Infringement

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Melaleuca, Inc. v. TWC 2022, Inc.	Lawsuit

Name of Business/Industry/Entity
TWC 2022 Inc.

Provide explanation below:

Melaleuca has sued TWC 2022, Inc. in the District of Idaho for federal and state trademark infringement and unfair competition based on TWC's use of "The Wellness Company" and "Vitality" branding for its health products. TWC vigorously denies any wrongdoing, asserting multiple defenses including that Melaleuca's claimed "THE WELLNESS COMPANY" mark is generic and thus unenforceable, there is no likelihood of consumer confusion, and that Melaleuca has suffered no cognizable damages or irreparable harm. In addition, TWC has filed counterclaims seeking a declaratory judgment of non-infringement as to Melaleuca's asserted registrations and common-law rights, and asks the court to dismiss all claims with prejudice and award TWC its attorneys' fees and costs based on the substantive weakness of Melaleuca's case

Original Signature (electronic, copies or stamps not accepted)

2/26/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Peter Gilooly

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/26/26

Date

Please have this section completed in the presence of a Notary Public.

State of FL, ss. County of Palm Beach

I, Peter Gilooly, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/26/26

Date

Subscribed and Sworn to before me this 26th day of February 2026

Debra A. Burghardt

Notary Public Signature

Notary Public State of Florida
Debra A Burghardt
My Commission HH 401258
Expires 5/22/2027

(Seal)

Department of Health

THOMAS REBHANDL

License Number: PS33826

Data As Of 2/5/2026

Profession	Pharmacist
License	PS33826
License Status	Clear/Active
Qualifications	Certified To Administer Immunizations
License Expiration Date	9/30/2027
License Original Issue Date	10/08/1998
Address of Record	416 CLEMATIS ST Ste B WEST PALM BEACH WEST PALM BEACH, FL 33401
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Subordinate Practitioners

Name	Relationship	Profession	License	Effective Date
INFINITE HEALTH PHARMACY INC.	PDM/CORSUBORDINATE	PHARMACY	32212	10/1/2025

Click on the License Number to view License Details for that Practitioner

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and

Pharmacy Name:	Infinite Health Pharmacy
Pharmacy Address:	416 Clematis St Ste.B, West Palm Beach, FL 33401
NABP Business e-Profile ID:	1833352
VPP Inspection Date(s):	12/30/2025
Sharing Acknowledgment:	YES — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Updates/New SOPs or P&Ps	13	15.00	Corrected. Shipping controls updated to prevent dispensing/shipping to non-licensed states. See attached CAPA and licensed-state verification documentation.	1/13/2026	Y	2025-12-30-001 Infinite Health Pharmacy Corrective and Preventive Action (CAPA) Form & ListofLicensedStates
Updates/New SOPs or P&Ps	20	47.06	Approved Vendor List with documented licensure verification prior to purchasing. See attached approved vendor list log and SOP.	1/5/2026	Y	Infinite Pharmacy Tracker.xlsx - Approved Vendor List
Updates/New SOPs or P&Ps	21	47.07	Approved Vendor List with documented licensure verification prior to purchasing. See attached approved vendor list log and SOP.	1/5/2026	Y	Infinite Pharmacy Tracker.xlsx - Approved Vendor List
Clarification or Further Explanation	25	65.00	Attached example of prescription sheet with PHI removed.		Y	Escripts _2025_emergencyscript
Clarification or Further Explanation	26	65.02	All patients go through a thourough screening process with provider including PMH, Allergies, other medications and supplements.		N	
Clarification or Further Explanation	26	67.00	Pharmacist prospective DUR is required prior to dispensing and is documented at final verification. As we also stated during the inspection we have access to the entire patient's medical history.		N	
Clarification or Further Explanation	27	67.01	Pharmacist prospective DUR is required prior to dispensing and is documented at final verification. As we also stated during the inspection we have access to the entire patient's medical history.		N	
Clarification or Further Explanation	37	93.00	Annual consumer survey process implemented and will be trended for CQI review.		N	
Clarification or Further Explanation	50	10.0	795 room is in a completely seperate room from rest of pharmacy and compounds only 1 product.		N	
Clarification or Further Explanation	51	10.3	We purchase a new temperature monitor every year to ensure calibrated.		N	
Other	51	10.4	Temperature monitor for continous monitoring was purchased. Frigga M2D Temperature Data Logger Multi-Use USB Digital Temperature Recorder		N	
Other	64	28.0	MFR template updated to include all USP <795> required elements and current MFRs revised accordingly. See attached updated MFR template and sample completed MFR	1/23/2026	Y	C-Ivermectin12mg_MFR
Other	64	28.3	MFRs were updated to specify the required container–closure system (type/size/material/closure) for each CNSP. See attached updated MFR template and sample updated MFR	1/23/2026	Y	C-Ivermectin12mg_MFR
Other	64	28.4	MFRs were revised to include complete, detailed compounding instructions (equipment/supplies, order of mixing, and any process details required for repeatability such as mixing time/speed	1/23/2026	Y	C-Ivermectin12mg_MFR
Other	65	28.5	MFRs were updated to include an expected physical description of the final CNSP (appearance/texture/clarity/uniformity and special characteristics such as phase separation if applicable). See attached	1/23/2026	Y	C-Ivermectin12mg_MFR
Other	65	28.7	MFRs were updated to include the BUD assignment rationale and supporting reference source (USP <795> and/or stability/literature/manufacturer guidance as applicable). See attached	1/23/2026	Y	C-Ivermectin12mg_MFR

Other	65	28.10	MFRs were updated to include required QC procedures (e.g., visual inspection, pH testing, weight checks/yield when applicable) and expected results/acceptance criteria. See attached updated MFR.	1/23/2026	Y	C-Ivermectin12mg_MFR
Other	65	29.0	Pharmacy implemented a standardized Compounding Record (CR) and now completes a CR for all CNSPs, including MFR reference, ingredients/lot numbers, QC results, and final product inspection.	1/23/2026	Y	CompoundFormulaWorksheet
Other	67	29.12	Compounding Record updated to require documentation of the final preparation's physical description. See attached updated CR template/sample.	1/23/2026	Y	CompoundFormulaWorksheet
Other	67	29.13	Compounding Record updated to capture required QC steps and results (pH, weights, yield, visual). See attached updated CR template/sample.	1/23/2026	Y	CompoundFormulaWorksheet
Other	67	29.14	Compounding Record updated to include required MFR reference (ID/version). See attached updated CR template/sample.	1/23/2026	Y	CompoundFormulaWorksheet
Other	84	58.0	Attached the slideshows from our nonsterile training program. The inspector commented on site that he liked our training program. This was marked no due to the MFR. See attached training/competency	1/23/2026	Y	co_ref_20260118_192025_ns2-compounding-compounded-non-sterile-preparations 1-4 & C-Ivermectin12mg_MFR
Other	86	58.14	QC requirements standardized in MFRs and documented on Compounding Records for each applicable CNSP. See attached updated MFR/CR and completed example.	1/23/2026	Y	C-Ivermectin12mg_MFR
Other	86	58.15	Container-closure requirements added to MFRs and documented on the Compounding Record and final pharmacist check. See attached updated MFR/CR.	1/23/2026	Y	C-Ivermectin12mg_MFR
Other	87	59.0	MFRs updated to include expected appearance and pharmacists now document observed appearance at final verification. See attached updated MFR.	1/23/2026	Y	C-Ivermectin12mg_MFR
Other	87	59.1	MFRs updated to include expected appearance and pharmacists now document observed appearance at final verification. See attached updated MFR.	1/23/2026	Y	C-Ivermectin12mg_MFR

State	Issue date	Pharmacy License #
Arizona	6/14/2024	Y009861
Colorado	6/5/2024	OSP.0007949
Florida	7/1/2019	PH 32212 (community)
Illinois	3/11/2025	0 54023111
Indiana	11/7/2024	64003656A
Iowa	8/29/2024	5766
Maine	12/31/2024	MO40003741
Missouri	8/17/2024	2024033447
Montana	7/17/2025	PHA-MOP-LIC-117859
New Jersey	12/3/2024	28RO00261400
New Mexico	6/27/2024	PH00006015
North Carolina	12/30/2025	16308
North Dakota	2/3/2025	Phar2238
Pennsylvania	12/9/2024	NP002245
Rhode Island	4/28/2025	PHN12691
South Dakota	11/15/2024	400-2518
Wisconsin	8/8/2024	3404-43

Pharmacy Corrective and Preventive Action (CAPA) Form

CAPA Information

CAPA ID	Date Raised	Department/Location
2025-12-30-001	Dec 30, 2025	Infinite Health Pharmacy
Raised By	**Date Approved**	**Approval Authority**
NABP Inspector	1/13/2026	PIC

1. Problem Description

During review of the inspection finding, the pharmacy identified that one prescription was inadvertently shipped to the state of Washington in November 2025, and the pharmacy did not hold a Washington non-resident pharmacy license at the time of shipment.

2. Immediate Actions Taken

1. Immediately stopped all prescription shipment activity to Washington upon discovery of the licensure gap.
2. Reviewed recent shipment history to confirm this was an isolated occurrence and to identify any additional shipments to Washington.
3. Implemented a temporary shipping hold / block to prevent future shipments to Washington until licensure is confirmed and documented.

3. Root Cause Analysis

The shipment occurred due to insufficient controls within the shipping workflow to prevent dispensing/shipping into a state where the pharmacy is not actively licensed. Specifically:

- The pharmacy did not have a hard stop in the prescription processing and/or shipping workflow to verify non-resident licensure status prior to shipment.

- Washington was not included on the pharmacy's licensed-state validation reference used during order processing.

4. Data Collection and Evidence

- Shipping log / transaction record confirming shipment to Washington (November 2025)
- Copy of current Florida pharmacy license and DEA certificate (posted and current)
- Current non-resident license binder copy/index (showing all active non-resident licenses currently held)
- "Licensed States List" (controlled document) implemented for shipping verification
- Shipping restriction in the dispensing/shipping workflow "Shipping State List" posted at shipping station

5. Corrective Actions

Specific actions implemented to correct the immediate problem and prevent its recurrence. Include who is responsible and the target completion date.

Corrective Action	Responsible Person	Target Completion Date	Status
Immediately stop all shipments to Washington until non-resident licensure is obtained and documented	PIC	Dec 30, 2025	Complete
Review shipment history for the prior 90 days to confirm if any additional shipments occurred to Washington or other non-licensed states	PIC	Jan 3, 2026	Complete
Implement shipping block: "Do Not Ship to WA" restriction at shipping station + staff communication acknowledgment	PIC	Jan 5, 2026	Complete
Update shipping workflow to require verification of destination state against	PIC	Jan 9, 2026	Complete

Corrective Action	Responsible Person	Target Completion Date	Status
"Licensed States List" prior to shipment			
Create and implement Monthly Shipping Destination Audit for state licensure compliance verification	PIC	Jan 12, 2026	In Progress

6. Preventive Actions

1. State Shipping Eligibility Verification Process
    a. A current "Licensed States List" has been established and is maintained as a controlled document.
    b. Staff must verify the destination state is licensed prior to shipment.
2. System/Workflow Controls
    a. The pharmacy will implement and maintain a shipping restriction (hard stop) for all non-licensed states within the dispensing/shipping workflow (system-based).
3. Licensure Binder + Tracking Enhancements
    a. Non-resident licenses will continue to be maintained in the licensure binder.
    b. The binder will now include:
        i. A state-by-state active license checklist
        ii. Current license copies and expiration dates
        iii. Responsible staff member assigned for routine review
4. Ongoing Monitoring
    a. The pharmacy will complete a monthly audit of shipping destination states to ensure shipments occurred only to licensed jurisdictions.
    b. Any discrepancies will be documented and addressed through corrective action.

7. Review and Monitoring

Ongoing Monitoring

1. The pharmacy will complete a monthly audit of shipping destination states to ensure shipments occurred only to licensed jurisdictions.
2. Any discrepancies will be documented and addressed through corrective action.

Schedule a review meeting to discuss the effectiveness of the implemented actions: 1/30/2026

8. Sign-offs and Approvals

Role	Name	Signature	Date
Initiator	PIC	Thomas Rebhandl	1/13/2026
Quality/Compliance Approval	PIC	Thomas Rebhandl	1/13/2026

Formula Worksheet
1/23/2026 2:28 PM

Infinite Health Pharmacy Inc.
416 Clematis St, Ste B
West Palm Beach, FL 33401-5312
(833) 463-4679

Rx #: _____

C-IVERMECTIN 12MG TABS

Flavor: None
Total Quantity: 1.000 EA
Date Made: ____/____/____
Lot Number: _____
BUD: ____/____/____ Time: ____:____
Pharmacist: _____ Initials: ____
Technician: _____ Initials: ____

Schedule:
Class: Rx

Route: Oral
Dosage Form: Tablet

Time to expiration: 180.000 Days

Warnings:

Ingredient Name	NDC	Quantity	Qs	(actual)	Active	Optional
Ivermectin USP (for Human Use)	51927-5152-00	0.012 GM	☐	_____	☑	☐
Mfg: _____	Lot #: _____	Exp. Date: ____/____/____	Supplier: _____			
Checked: ☐	By: _____					
Glidetab FX	72467-0223-65	0.138 GM	☑	_____	☑	☐
Mfg: _____	Lot #: _____	Exp. Date: ____/____/____	Supplier: _____			
Checked: ☑	By: _____					

Mixing Directions:

Compounding Steps:
1. Verify component identity/lot/expiration and balance calibration.
2. Weigh ivermectin and Glidetab FX.
3. Sieve each powder through a metal strainer.
4. Blend via geometric dilution in mortar/pestle with trituration (60 sec between additions; 2 min final blend).
5. Sieve the final blend through a metal strainer.
6. Load blend into tablet press hopper and compress tablets per LFA RTP 118.
7. Weigh 10 tablets at startup and at defined intervals; document results and confirm within acceptance criteria.

Physical Description (Finished Tablets):
- Tablets should be:
  - Intact and uniform in appearance
  - Free from cracks, chips, capping, sticking, or lamination
  - Consistent color/finish throughout the batch
  - No visible powder segregation or mottling

Storage:
- Store in a tight, light-resistant container
- Controlled room temperature 20–25°C (USP Controlled Room Temperature)
- Protect from excessive heat and moisture

Final Container-Closure:
- Container: Tight, light-resistant Amber bottle
- Closure: Child-resistant cap

Equipment List
- Class A prescription balance
- Mortar and pestle
- Spatula(s)
- Powder funnel (optional)
- Metal strainer / sieve
- Weigh boats / weigh paper
- Tablet press
- Tablet tooling (die/punch set) appropriate for target tablet size
- Cleaning supplies (per equipment cleaning SOP)

Reference Source

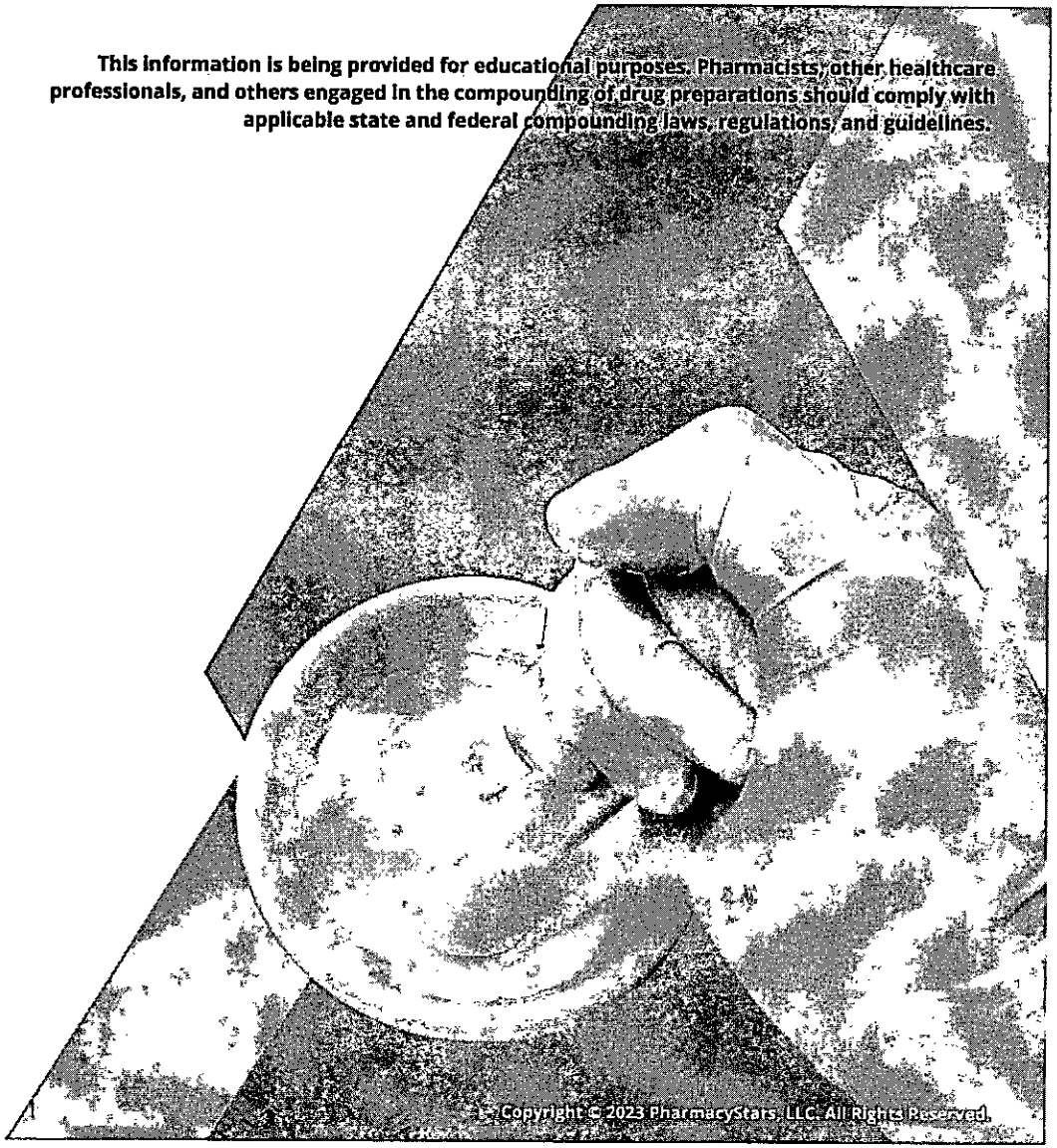
BUD Assignment (Tablets/Capsules):
- Up to 6 months, or the earliest expiration date of any ingredient, whichever is earlier for nonsterile solid oral dosage form
- USP <795> Pharmaceutical Compounding—Nonsterile Preparations (BUD guidelines)

Pharmacy Stars

TRAINING MODULE

Module NS3

Compounding Compounded Non-Sterile Preparations (CNSPs)



This information is being provided for educational purposes. Pharmacists, other healthcare professionals, and others engaged in the compounding of drug preparations should comply with applicable state and federal compounding laws, regulations, and guidelines.

Although PharmacyStars strives to provide you with complete and accurate advice, it cannot warrant that its content is free of typographical or editorial mistakes. Accordingly, Pharmacy Stars reserves the right to revise content to correct, and disclaims liability for, any such mistakes. Pharmacy Stars also disclaims all warranties, express or implied, relating to the completeness or accuracy of content provided by third parties. If you believe any Pharmacy Stars or third-party content contains any errors or inaccuracies, or if you have any questions or concerns regarding such content, please contact us at 608-351-2664.

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Components and Documentation of CNSP Compounding

Compounding Compounded Non-Sterile Preparations (CNSPs) Series

(Module and Video 3 of 4)

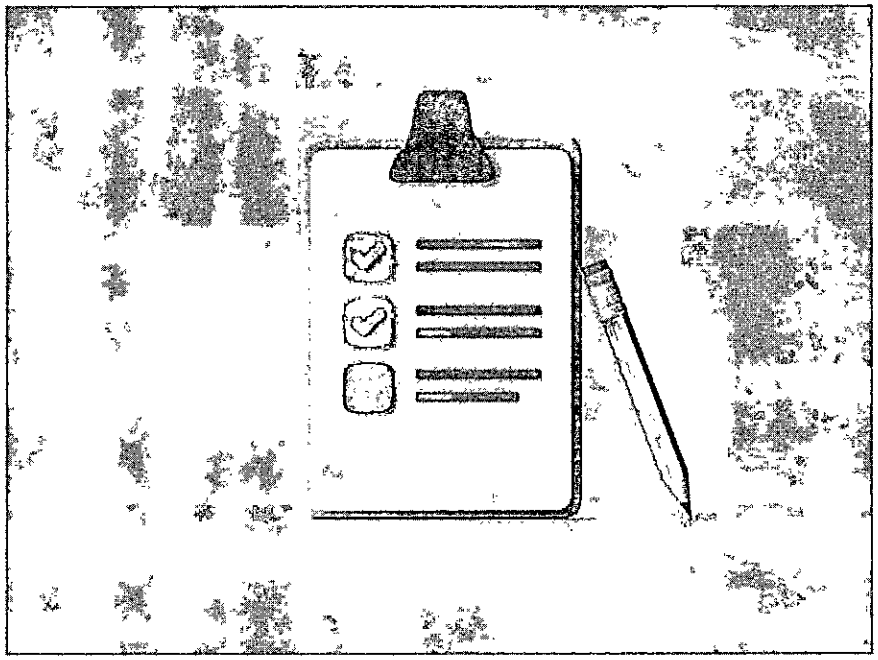
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Learning Objectives

Recall	Review	Compare and Contrast	Explain
the requirements for compounding personnel and Safety Data Sheets	the standards for selecting appropriate ingredients and components	the requirements and purpose for Master Formulation Records and Compounding Records	CNSP packaging and transporting requirements

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SOP Check



- **Written SOP for the selection and inventory control of all components from receipt to use in a CNSP**

References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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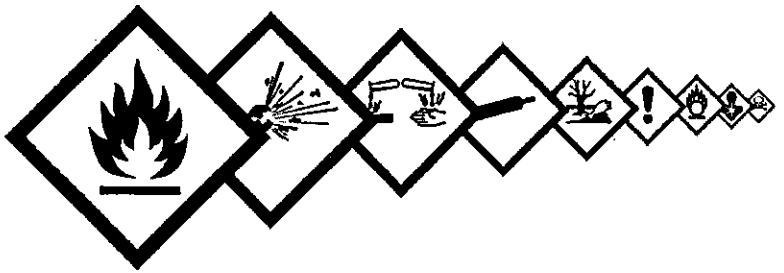
Ingredients, Components and Equipment

Safety Data Sheets (SDS)

"Safety Data Sheets must be readily accessible to all personnel working with components located in the compounding facility."

Personnel must be instructed on how to retrieve and interpret needed information.

USP <795>



What is a SDS?

A document required of chemical manufacturers and distributors, that provides hazard information in a standardized format.

References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
US Occupational Safety and Health Adminstration. Hazarda Communication Safety Data Sheets. https://www.osha.gov/sites/default/files/publications/OSHA3493QuickCardSafetyDataSheet.pdf

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References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
US Occupational Safety and Health Administration. Hazardo Communication Safety Data Sheets. https://www.osha.gov/sites/default/files/publications/OSHA3493QuickCardSafetyDataSheet.pdf

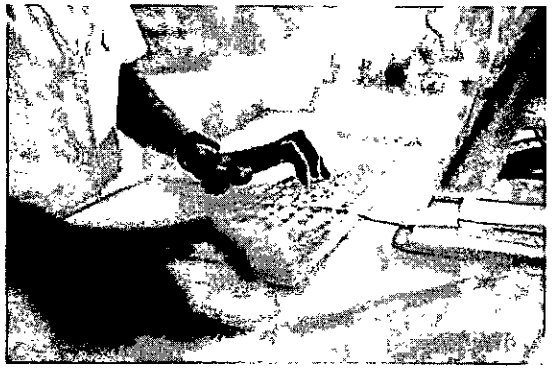
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Designated Person Reminder: *Component Selection*

Who	Designated person(s)
What	Selecting components to be used in compounding • Active Pharmaceutical Ingredients • All components other than APIs • Water used for compounding
When	Prior to use for compounding

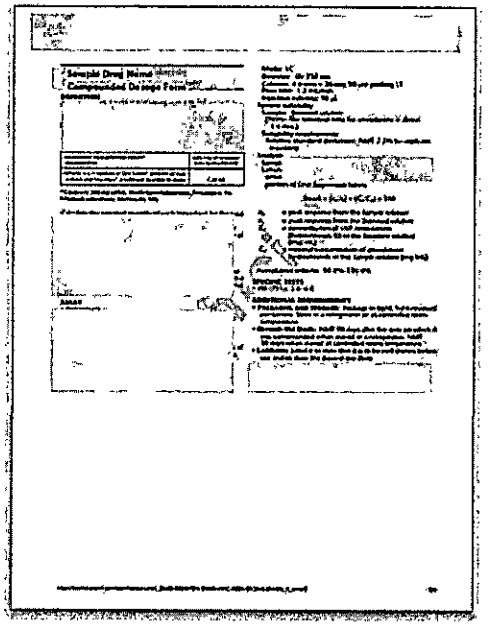
Where/ How	• From available published information
	  • USP-NF monograph
	• From supplier documentation
	  • COA
	• Through direct challenge

Why?	To ensure suitability and quality requirements are met



References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Compounding Monograph



A publication that specifies instructions and quality standards for a compounded preparation (and analysis) in which if followed are expected to yield a safe preparation of the product.

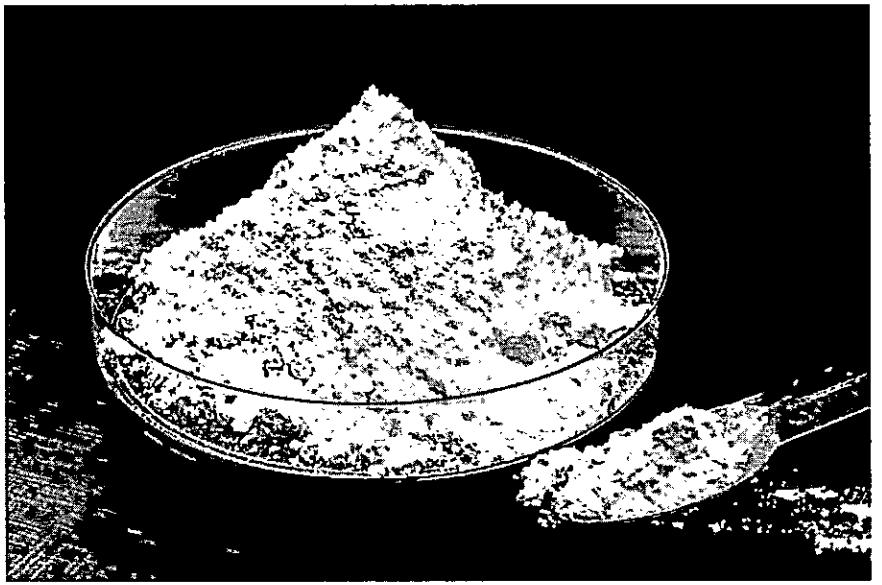
References:
US Pharmacopeia. Compounded Preparation Monographs https://www.usp.org/compounding/compounded-preparation-monographs
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Selection, Handling, and Storing

Ingredients, Components and Equipment

Active Pharmaceutical Ingredients (APIs)

- Must comply *USP–NF* monograph, if one exists
- Must have a Certificate of Analysis
- In the United States, must be manufactured by an FDA-registered facility
- Outside of the United States, must comply with the laws and regulations of the applicable regulatory jurisdiction



References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Selection, Handling, and Storing

Appropriate Ingredients, Components and Equipment

Active Pharmaceutical Ingredients (APIs)

- Certificates of Analysis must contain:
  - Specifications
  - Compendial requirements for quality
  - Test results for the components that meets specifications



References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Selection, Handling, and Storing

Appropriate Ingredients, Components and Equipment

All ingredients other than APIs

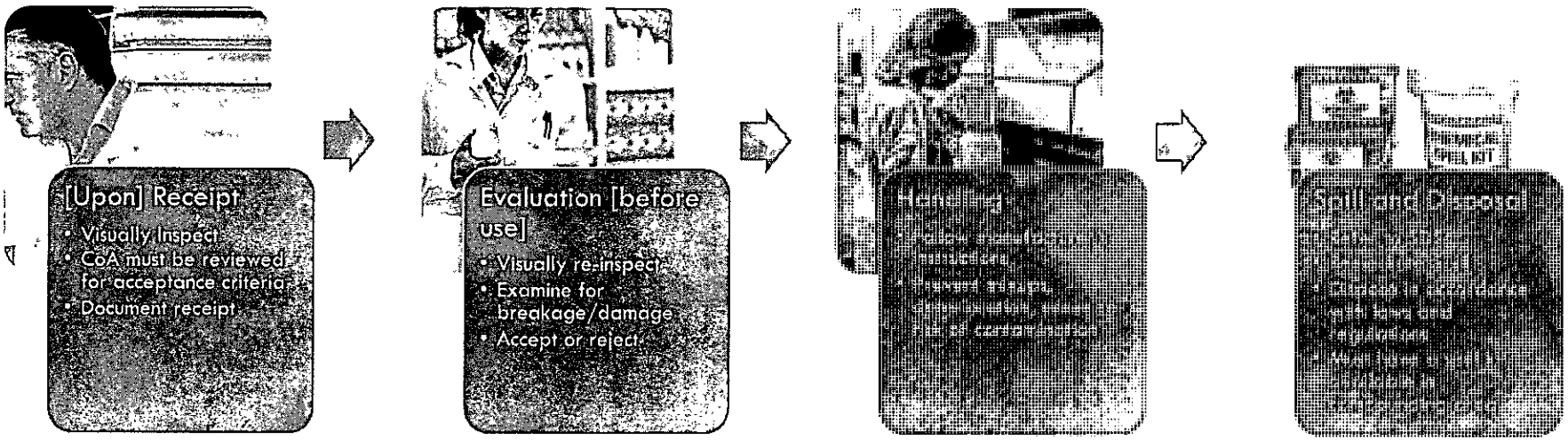
- Must have a Certificate of Analysis that verifies USP-NF monograph if one exists
  - Any other specifications for the component
- In the United States, must be manufactured by an FDA-registered facility
- Outside of the United States, must comply with the laws and regulations of the applicable regulatory jurisdiction



References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Selection, **Handling**, and Storing

Appropriate Ingredients, Components and Equipment



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Selection, **Handling**, and Storing

Appropriate Ingredients, Components and Equipment

Component Receipt

- ❑ Review CoA to ensure component meets specifications
- ❑ Examine package integrity and verify that the component appropriately matches the description
- ❑ Verify the necessary storage conditions
- ❑ Document:
  - ❑ Receipt Date
  - ❑ Quantity Received
  - ❑ Supplier Name
  - ❑ Lot Number
  - ❑ Expiration Date
  - ❑ Results of any testing (in-house or third party)
  - ❑ Whether or not the component is accepted or rejected
- ❑ Store according to the necessary storage conditions



References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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SOP Check



- **Management of and documentation of component spills and disposal**
- **SOP must require no less than annual training for any personnel that *might* need to potentially responds to a spill**

References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Knowledge Check



Critical Thinking Question

Why do you think it's necessary to re-inspect components if they were already inspected and accepted upon receipt?

To check for damage or deterioration that occurred during storage

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Selection, **Handling**, and Storing

Appropriate Ingredients, Components and Equipment

Re-Inspection of Components before compounding use

- ❑Container breakage
- ❑Looseness of the cap or closure
- ❑Deviation from expected appearance or texture of the contents
- ❑Correct identity and label
- ❑Stored in the required conditions



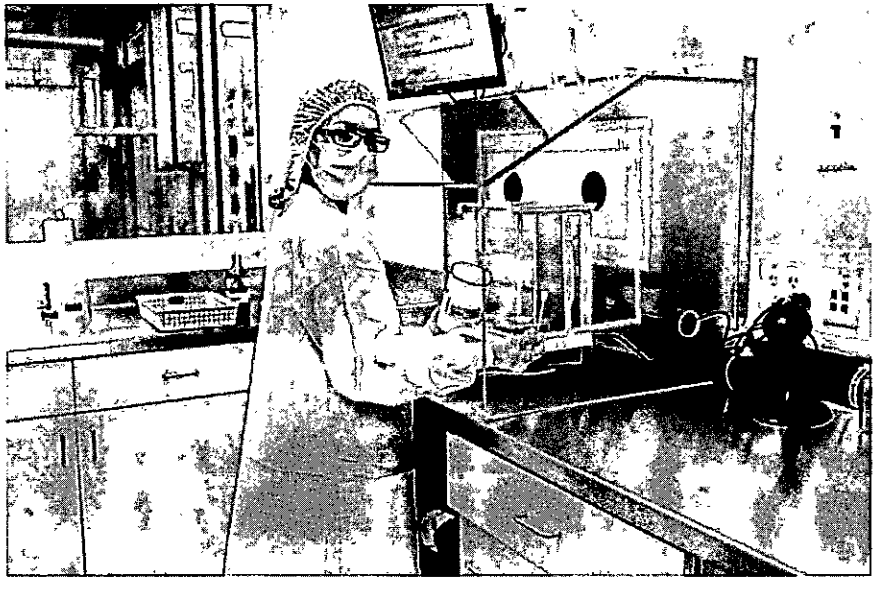
References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Selection, **Handling**, and Storing

Appropriate Ingredients, Components and Equipment

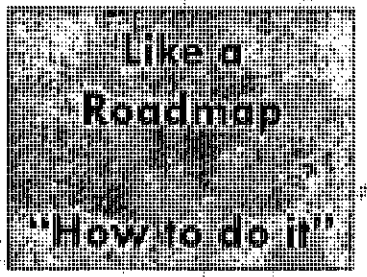
Handling Ingredients and Components

- ❑handle in accordance with the manufacturer's instructions or per laws and regulations of the applicable regulatory jurisdiction
- ❑Handle in a manner to minimize the risk of contamination, mix-ups, and deterioration (e.g., loss of identity, strength, purity, or quality).
- ❑Once removed from the original container, any component not used in compounding (e.g., excess after weighing) should be discarded and not returned to the original container to minimize the risk of contaminating the original container.



References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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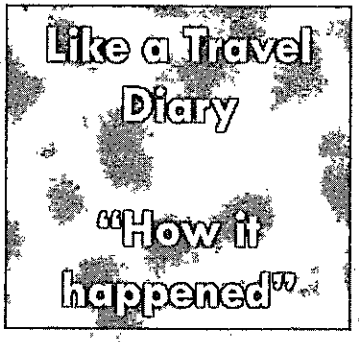
Documentation: Compounding Process



Master Formulation Record
A detailed record of procedures that describes how the CNSP is to be prepared.

Master Formulation Record (MFR) should be created **before compounding a preparation for the first time.**

Required for each unique formulation.



Compounding Record

A record of the preparation of each CNSP

Compounding Record (CR) should be completed **each time a preparation is compounded.**

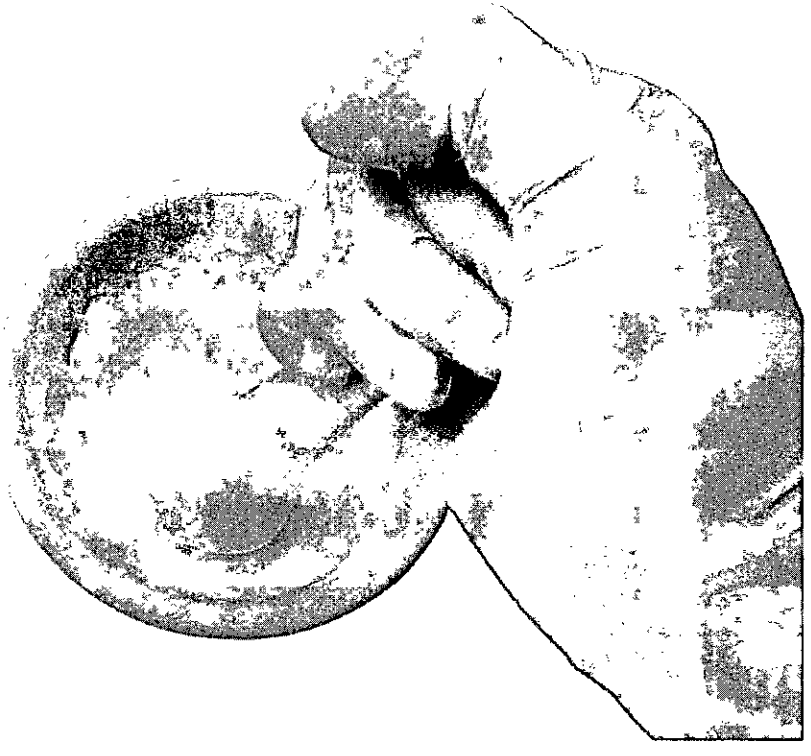
Required for all CNSPs.

References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Documentation: Master Formulation Record (MFR)

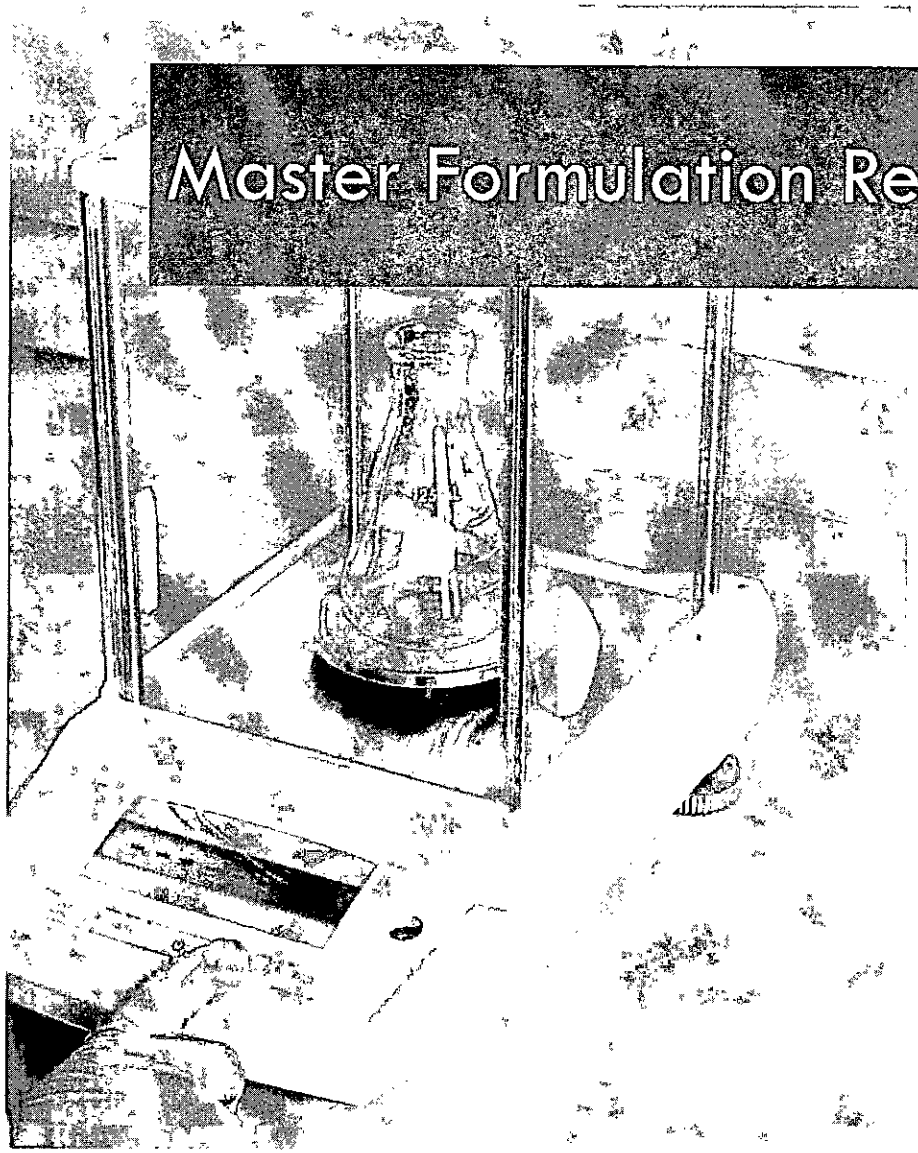
Why have MFRs?

To describe how to prepare and check a CNSP and to provide a basis for reproducibility



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Master Formulation Record: Required Information



Formulation and Identification/Labeling

- Name, strength or activity, and dosage form of the CNSP

Components

- Identities and amounts of all components; if applicable, relevant characteristics of components
- Container closure system(s)

Compounding Instructions

- Complete instructions for preparing the CNSP including equipment, supplies, and description of compounding steps

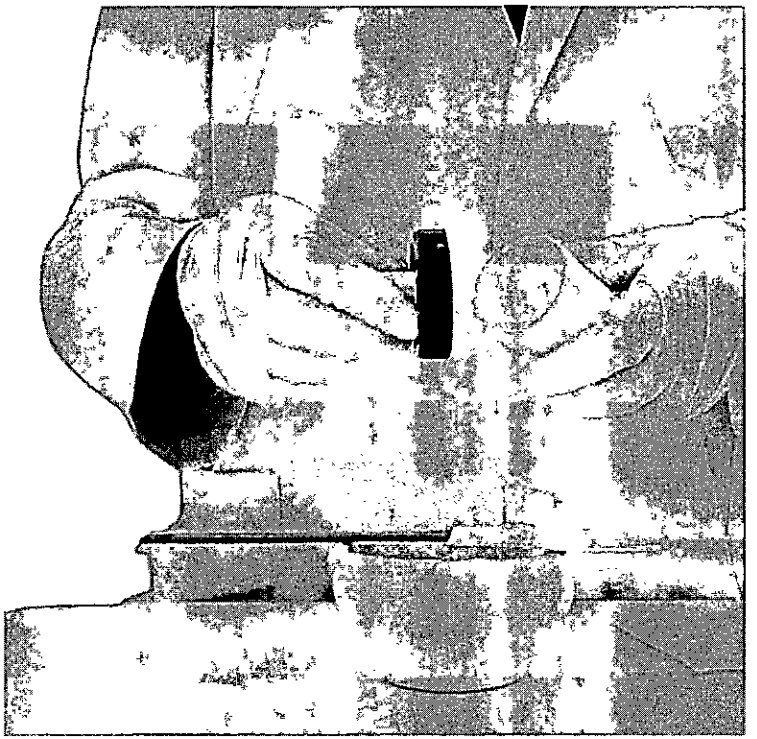
Quality Control (QC)

- Physical description of the final CNSP
- Beyond-use date (BUD) and storage requirements
  - Reference source to support the assigned BUD
- If applicable, calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s)
- Labeling requirements
- Quality control (QC) procedures and expected results
- Other information needed to describe the compounding process and ensure repeatability

Documentation: Compounding Records (CR)

Why have Compounding Records?

Record exactly how a CSNP was prepared and to permit traceability of all components in the case of a recall or other known quality issue.



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Compounding Record: Required Information



Formulation and Identification/Labeling

- Name, strength or activity, and dosage form
- Date and time of preparation
- Assigned internal ID number

Components

- Name, vendor or manufacturer, lot number, and expiration date of each component

Quantity/Yield

- Total quantity compounded

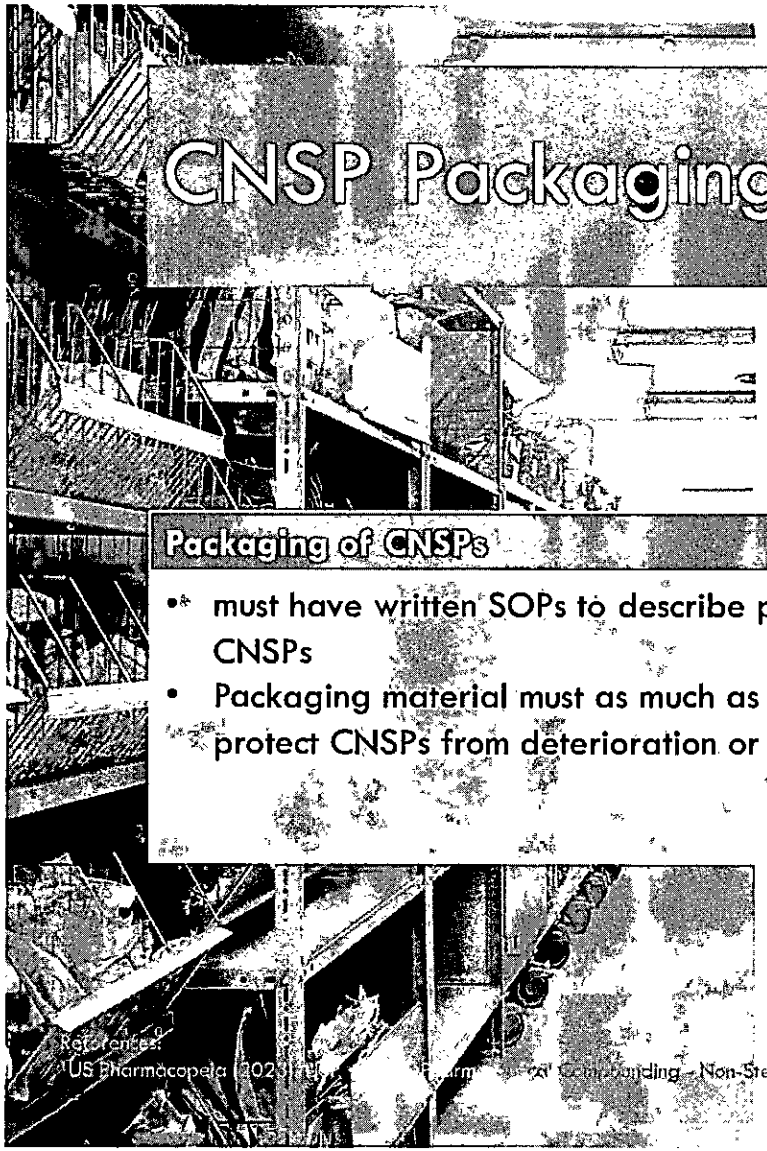
Preparer and Approver Info

- Method to identify individuals involved in compounding process
- Method to identified individuals involved in verifying final CNSP

Quality Control (QC)

- Assigned beyond-use date (BUD) and storage requirements
  If applicable, calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s)
- Physical description of the final CNSP
- Results of quality control procedures (e.g., pH testing and visual inspection)
- MFR reference for the CNSP

CNSP Packaging and Transporting



Packaging of CNSPs

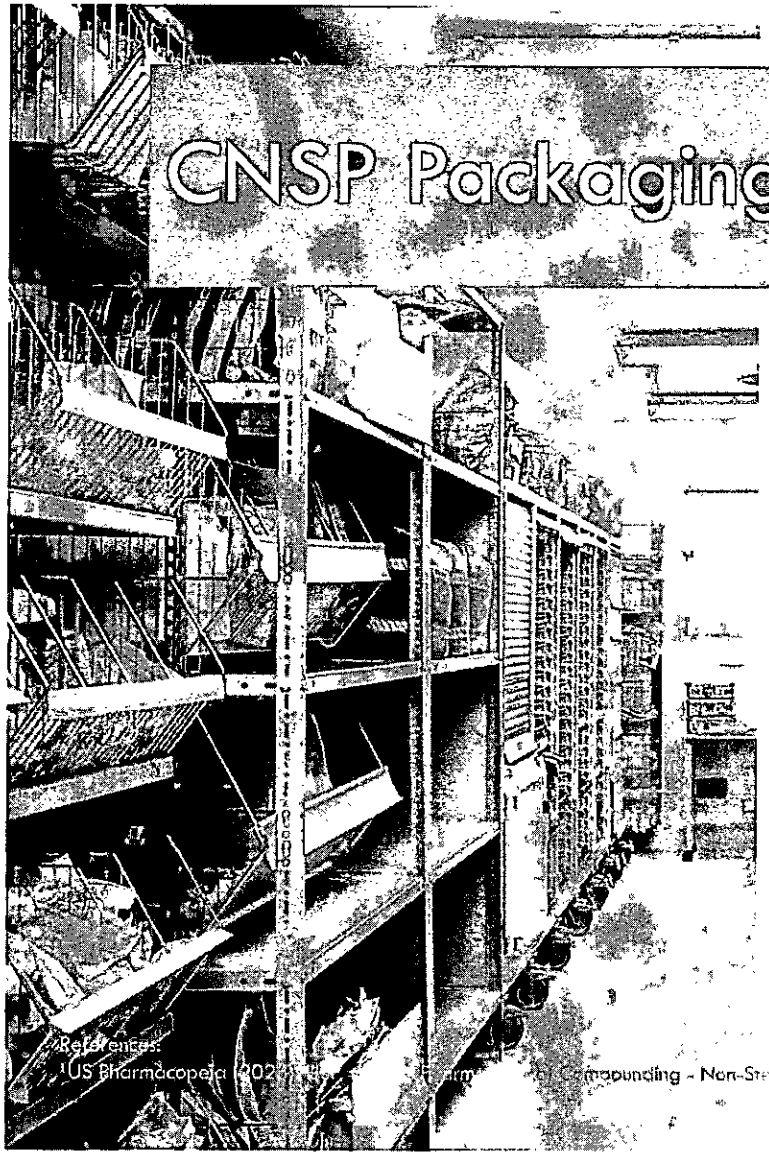
- must have written SOPs to describe packaging of CNSPs
- Packaging material must as much as possible, protect CNSPs from deterioration or damage

Transporting of CNSPs

- must have written SOPs to describe the mode of transportation
- any special handling
- instructions, and whether temperature monitoring devices are needed.

References:
US Pharmacopeia (2023) [illegible] Compounding—Non-Sterile Preparations
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CNSP Packaging and Transporting



- Personnel should select and use packaging materials that will maintain the physical and chemical integrity and stability of the CNSPs.
- Packaging materials must protect CNSPs from damage, leakage, contamination, and degradation, while simultaneously protecting personnel from exposure.

References:
1. US Pharmacopeia 202[illegible] Compounding - Non-Sterile Preparations.

Thank you for watching.

Please proceed to the associated quiz and to your next assigned module.

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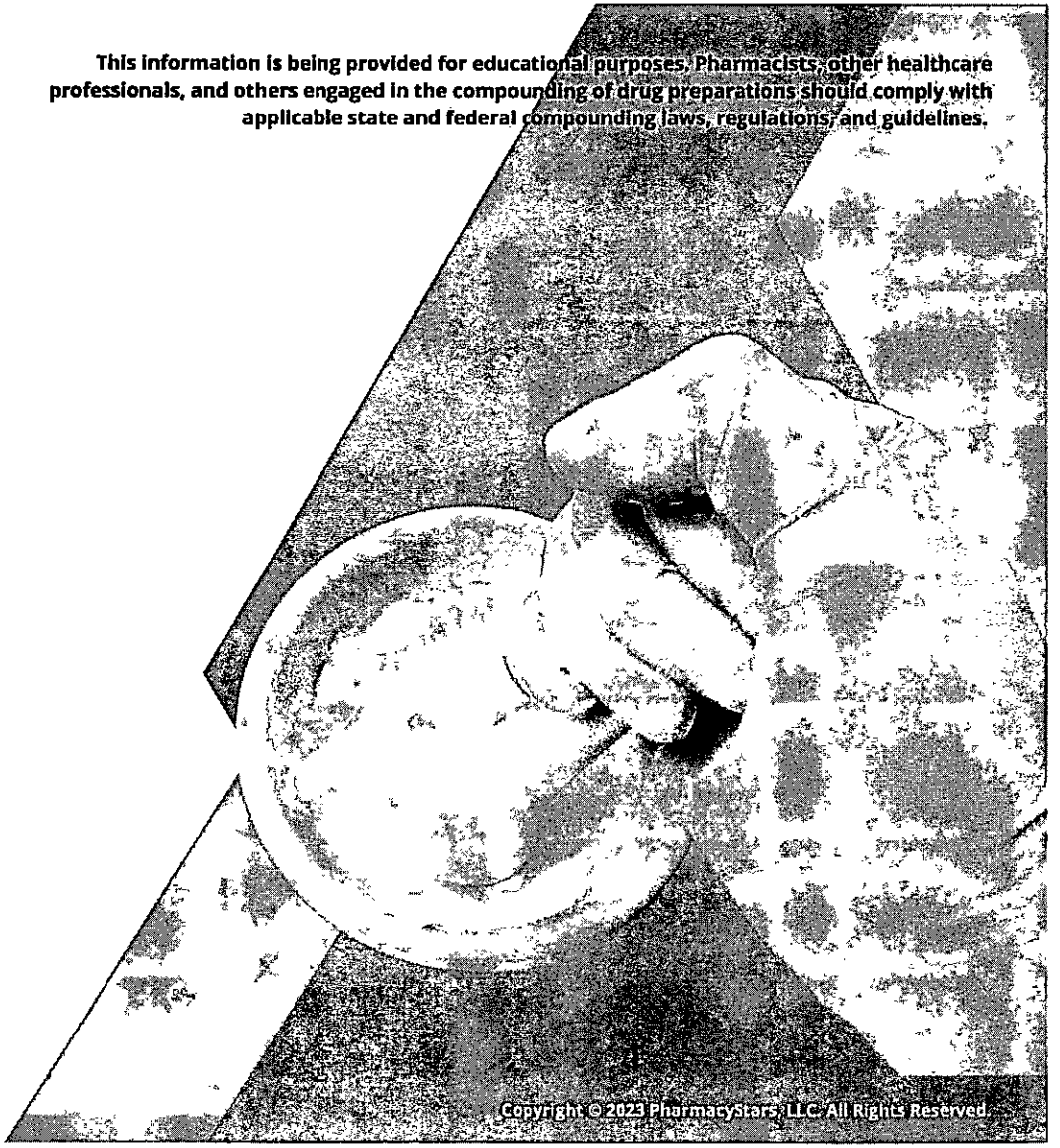
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TRAINING MODULE

Module NS4

Compounding Compounded Non-Sterile Preparations (CNSPs)

This information is being provided for educational purposes. Pharmacists, other healthcare professionals, and others engaged in the compounding of drug preparations should comply with applicable state and federal compounding laws, regulations, and guidelines.



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Quality Control, Quality Assurance and Establishing BUDs for CNSPs

Compounding Compounded Non-Sterile Preparations (CNSPs) Series

(Module and Video 4 of 4)

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Learning Objectives

Recall	Review	Compare and Contrast	Explain	Apply
the process control requirements that contribute to a CNSP Quality Program	the requirements for the documentation of CNSP compounding	Quality Control and Quality Assurance of CNSPs	The processes for handling complaints and adverse events related to CNSPs	knowledge to correctly assign BUD to example CNSPs

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SOP Check



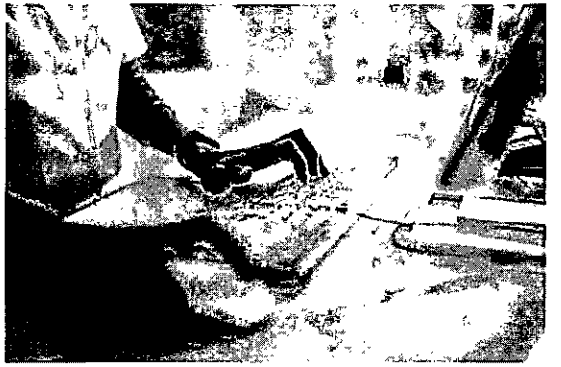
USP <795> Requirements for SOPs

- Facilities preparing CNSPs must develop SOPs on all aspects of the compounding operation.
- All personnel who conduct or oversee compounding activities must be trained in the facility's SOPs and be responsible for ensuring that they are followed.
- One or more person(s) must be designated (Designated Person) to ensure that the facility's SOPs are fully implemented.

References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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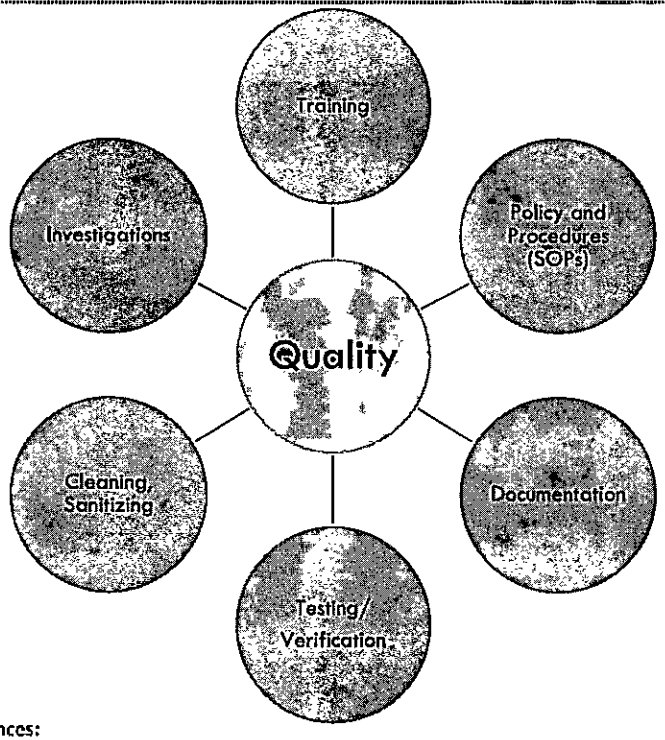
Designated Person Reminder:
SOP Implementation

Who	Designated person(s)
What	Ensure that facility's SOPs are fully implemented and ensures follow ups occur
When	If problems, deviations, or errors or non-compliance with SOPs occur and are detected.



References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Quality System & Program



QA and QC Program

- Adherence to Procedures
- Prevention and Detection of Errors and other Quality Problems
- Evaluation of Complaints and Adverse Events
- Appropriate Investigations and Corrective Actions

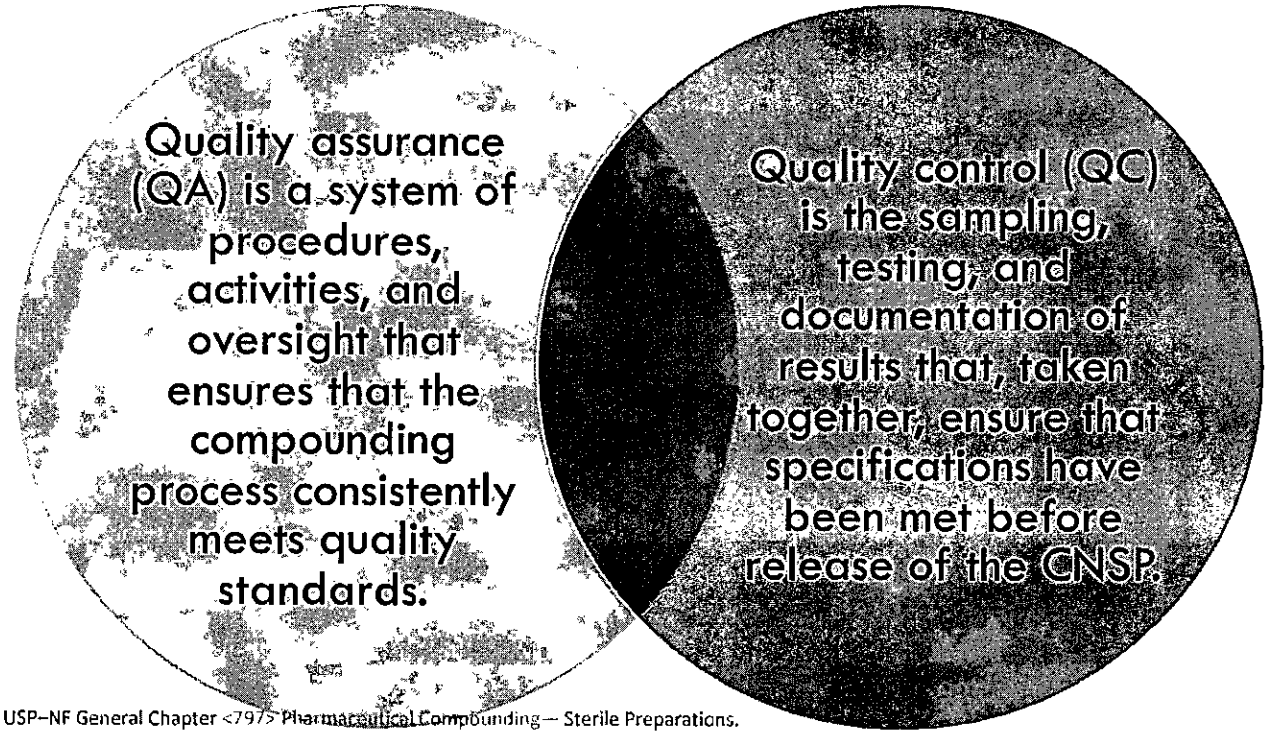
References:

US Pharmacopeia. (2023). USP–NF General Chapter <797> Pharmaceutical Compounding— Sterile Preparations.

US Pharmacopeia. (2020). USP-NF General Chapter <1163> Quality Assurance in Pharmaceutical Compounding

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Quality System & Program



References:
US Pharmacopeia. (2023). USP–NF General Chapter <797> Pharmaceutical Compounding— Sterile Preparations.
US Pharmacopeia. (2020). USP-NF General Chapter <1163> Quality Assurance in Pharmaceutical Compounding

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Role of a Designated Person

Must ensure that the facility has formal, written QA and QC programs

What is the role of a Designated Person?

To be responsible for the QA Program

Who is the Designated Person (DP)?

Person(s) who have been selected and given the responsibility and authority for Quality program

References:
[1]US Pharmacopeia. (2023). USP–NF General Chapter <795> Pharmaceutical Compounding— Sterile Preparations.
US Pharmacopeia. (2020). USP-NF General Chapter <1163> Quality Assurance in Pharmaceutical Compounding

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SOP Check



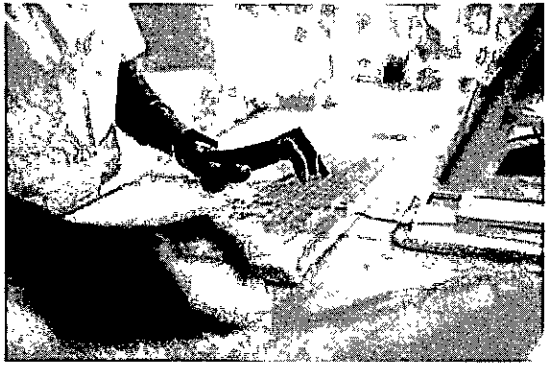
USP <795> Requirements for Quality Program SOP

- ☑ Describes quality roles & duties
- ☑ Describes quality personnel training

References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Designated Person Reminder: *Complaint Review*

Who	Designated person(s)
What	Review all complaints
When	If problems, deviations, or errors or non-compliance with SOPs occur and are detected, this are remediated.
Why	To determine whether the complaint indicates a quality problem with a CNSP and prevent harm or further harm
How	• Considering if the quality problem extends to other CNSPs • Implementing corrective actions/preventative actions



References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Handling CNSP Complaints

What is considered a complaint?

Report of a concern regarding quality, labeling, or possible adverse reactions related to a specific CNSP

Quality Problem Identified = Investigation Required

DP must consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected.

References:
US Pharmacopeia. (2023). USP–NF General Chapter <797> Pharmaceutical Compounding— Sterile Preparations.

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Documentation of a Complaint

Required Information

- name of the complainant or other unique identifier
- date the complaint was received
- nature of the complaint
- response to the complaint

Additional Information

recommended to be recorded if available

- name and strength of the CNSP
- assigned internal identification number (e.g., prescription, order, or lot number)
  - The record must also include the findings of any investigation and any follow-up.
  - Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained in accordance with the record-keeping requirements

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Adverse Events

What does the FDA consider an adverse event?

An adverse event is any undesirable experience associated with the use of a medical product in a patient.

Examples include:

- serious drug side effects
- product use errors
- product quality problems
- therapeutic failures

References:
US Pharmacopeia. (2023). USP–NF General Chapter <797> Pharmaceutical Compounding— Sterile Preparations.

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Requirements for Reporting Adverse Events

Manufacturers of drugs (and 503B Outsourcing Facilities) are *required* to send Adverse Event reports to the FDA as specified by regulations.

Reporting of adverse events by **healthcare professionals** and consumers is *voluntary* in the United States.

When the event is "serious", it should be reported via a Safety Report to the FDA using the FAERS system.

- Why should I report CNSPs prepared by my hospital?
  - If there is a potential safety concern, FDA will do further evaluation and monitor data for emerging trends.
  - Submission of an Adverse Event is not considered an admission of malpractice or admission of a contribution to the event.

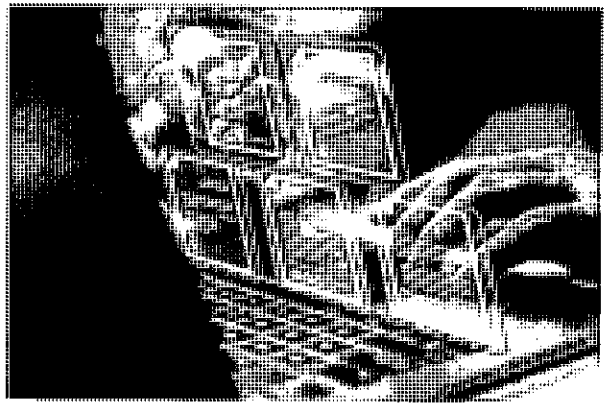
References:
FDA's Open FDA Drug Adverse Event Overview https://open.fda.gov/apis/drug/event/
FDA Safety Page | Medwatch | What is a Serious Adverse Event? https://cacmap.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event

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References and Resources for Establishing BUD for a CNSP

Water Activity Determination

- USP <1112> Application of Water Activity Determination to Nonsterile Pharmaceutical Products
  - Informational Chapter



Quality Control & Assurance (including Testing)

- USP <1163> Quality Assurance in Pharmaceutical Compounding
  - Informational Chapter

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Terminology related to Stability

BUD

- Date/time after which a CNSP must not be used
- Determined from the date/time CNSP preparation is started

Must be on the CNSP label

Expiration Date

- Time during which a conventionally manufactured product or API can be expected to meet the requirements of its monograph and maintain quality (when stored properly)

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Labeling

Required Contents

- Assigned internal identification number (e.g., barcode, prescription, order, or lot number)
- Active ingredient(s), and their amount(s), activity(ies), or concentration(s)
- Storage conditions if other than controlled room temperature
- BUD
- Dosage form
- Total amount or volume if it is not obvious from the container

Labeling on the dispensed CNSP

- Route of administration
- Indication that the preparation is compounded
- Any applicable special handling instructions
- Any applicable warning statements
- Compounding facility name, and contact information if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded

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Labeling

General Labeling Requirement

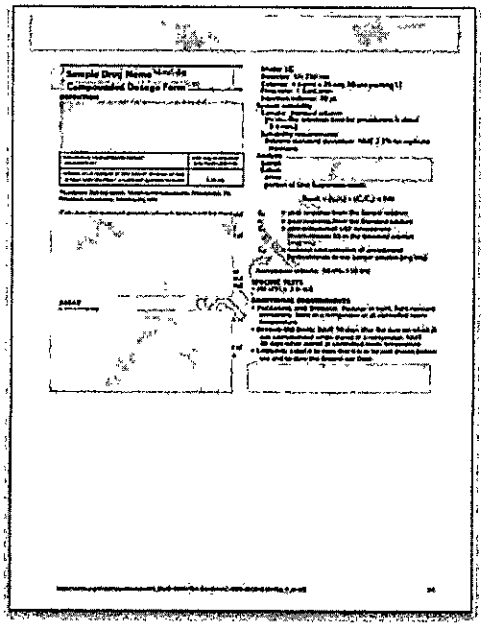
Every CNSP must be labeled with appropriate, legible identifying information to prevent errors during storage, dispensing, and use.

Labeling Procedures

- Must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups
- Must include verification process for the label to ensure that it conforms with:
  1. Prescription or medication order;
  2. Master Formulation Record
  3. Compounding Record

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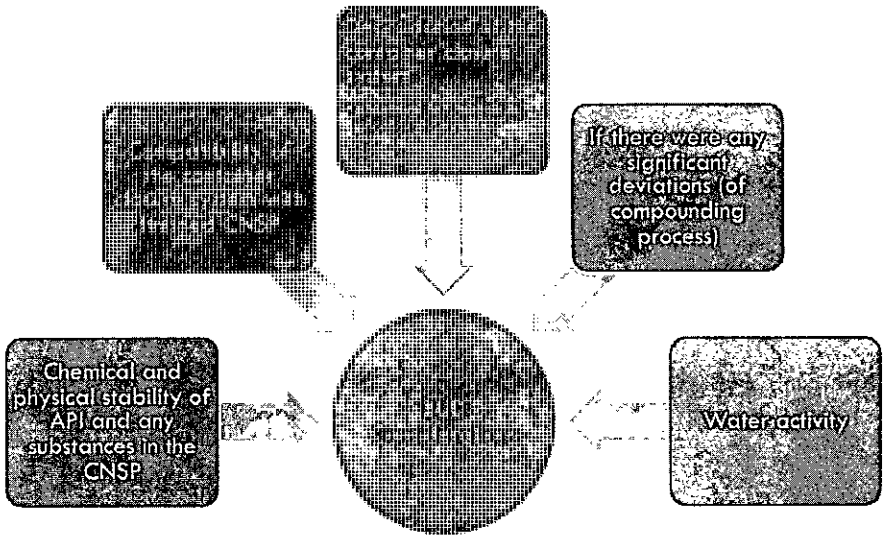
Compounding Monograph



A publication that specifies instructions and quality standards for a compounded preparation (and analysis) in which if followed are expected to yield a safe preparation of the product.

References:
US Pharmacopeia. Compounded Preparation Monographs https://www.usp.org/compounding/compounded-preparation-monographs
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BUD Establishment: Stability and Bioburden



Beyond Use Dates

Should be established conservatively...

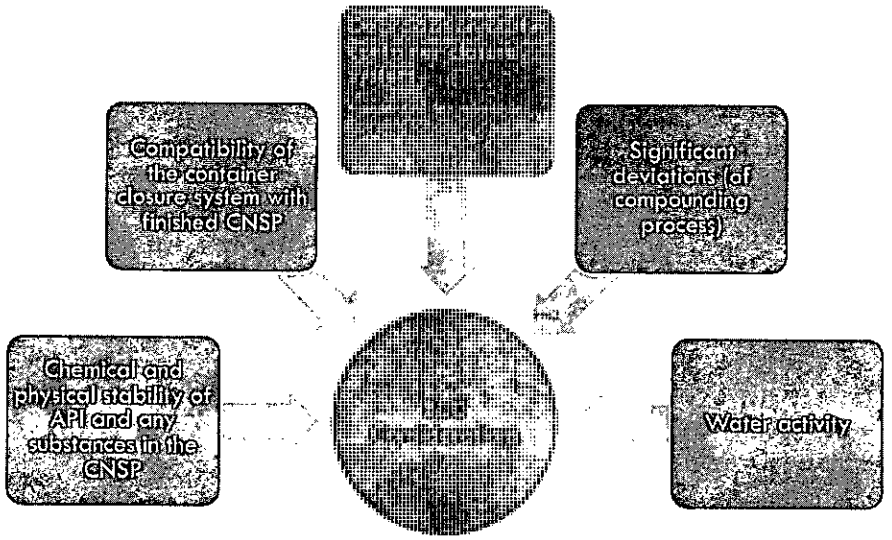
Because compounded preparations are intended for administration immediately or following only short-term storage periods

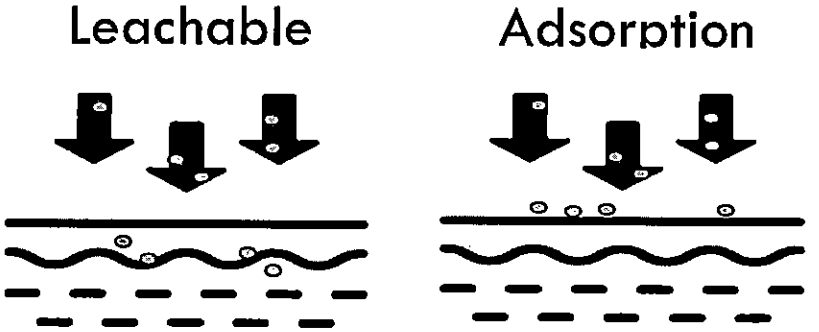
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to ensure that the preparation maintains its required characteristics to minimize the risk of contamination or degradation.

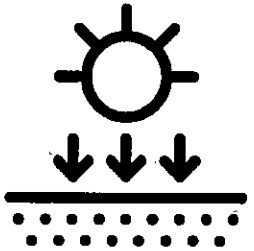
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B.U.D Considerations: Container Compatibility and Degradation of Container Closures





Heat/Light Degradation



Plastic = susceptible to penetration

Different Plastics have different permeability



References:
FDA Guidance for Industry Container Closure Systems for Packaging Human Drugs and Biologics https://www.fda.gov/media/70788/download

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Establishing a BUD for a CNSP: Water Activity, a_w

What is Water Activity?

Quantitative value which aids in assessing the susceptibility of CNSPs to microbial contamination and the potentially for API degradation due to hydrolysis.



Why do we care?

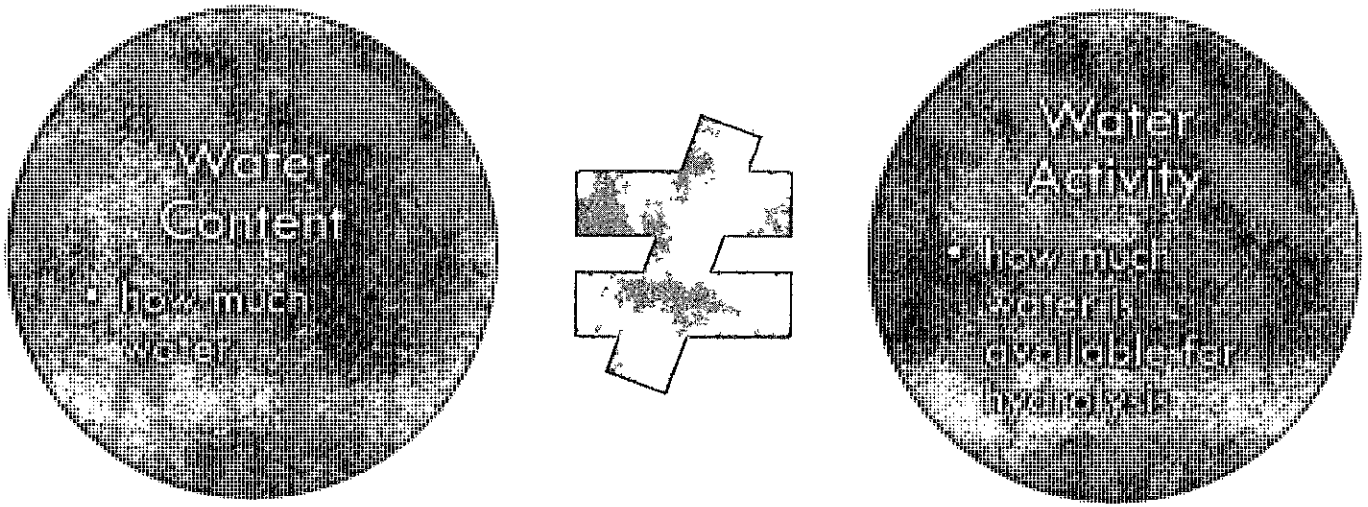
Higher the Water Activity

- More water available to support microbial growth
  - Higher susceptibility for microbial contamination
- More water available for hydrolysis
  - Higher potential for API degradation via hydrolysis

References:
Chapter 3 - Aqueous Chemistry. (2012) Key Concepts in Environmental Chemistry.

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Establishing a BUD for a CNSP: Water Activity a_w



References:
1US Pharmacopeia (2023). USP <1112> Application of Water Activity Determination to Nonsterile Pharmaceutical Products
2US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.

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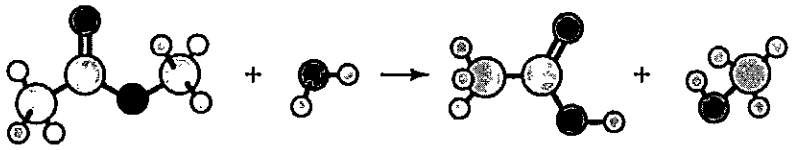
Establishing a BUD for a CNSP: Water Activity a_w

What is Hydrolysis?

"a chemical reaction in which the action of water (or its ions) breaks down a substance into smaller molecules."[1]

Hydrolysis of ester

$CH_3COOCH_3 + H_2O \rightarrow CH_3COOH + CH_3OH$



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https://www.britannica.com/science/hydrolysis#/media/1/278896/159290

Why do we care?

Higher the Water Activity

- More water available to support microbial growth
  - Higher susceptibility for microbial contamination
- More water available for hydrolysis
  - Higher potential for API degradation via hydrolysis

References:
[1]Chapter 3 - Aqueous Chemistry. (2012) Key Concepts in Environmental Chemistry. https://doi.org/10.1016/B978-0-12-374993-2.10003-2
Understanding the chemical basis of drug stability and degradation. (2010). The Pharmaceutical Journal. https://pharmaceutical-journal.com/article/ld/understanding-the-chemical-basis-of-drug-stability-and-degradation

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BUD Establishment: BUD vs. Expiration Date

Critical Thinking Moment



How does the water activity relationship affect food?

Dried Fruit

Syrups

Dried Meat

Picked Vegetables



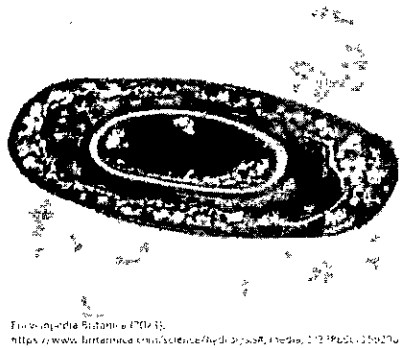
References:

1US Pharmacopeia (2023). USP <1112> Application of Water Activity Determination to Nonsterile Pharmaceutical Products

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Establishing a BUD for a CNSP: Water Activity a_w

"However, it should be noted that more resistant microorganisms, including spore forming Clostridium spp., Bacillus spp., Salmonella spp. and filamentous fungi, although they may not proliferate in a drug product with a low water activity, may persist within the product."[1]



Why do we care?

Higher the Water Activity

- More water available to support microbial growth
  - Higher susceptibility for microbial contamination
- More water available for hydrolysis
  - Higher potential for API degradation via hydrolysis

Lower the Water Activity

- greater control of microbial growth
- makes materials self preserve

References:
1US Pharmacopeia (2023). USP <1112> Application of Water Activity Determination to Nonsterile Pharmaceutical Products

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Ways to Determine BUD to CNSP

1. **Use USP-NF Monograph**
   - Easiest/Least Risk
   - Might not exist
   - Must not exceed BUD specified in the monograph if using monograph

2. **Reference CNSP-specific Stability Study**
   - Must use stability-indicating analytical method for the API(s), CNSP formulation, and material of composition of the container closure that will be used
   - BUD indicated by the study may be used in lieu of the BUDs specified in USP <795> limit table for aqueous and nonaqueous dosage forms
   - May not exceed 180 days

3. **Based on water activity, refer to BUD limits table in USP <795> to assign BUD**
   - Must do due diligence to determine if literature exists showing showing stability of a CNSP that is less than those in the table
   - Must assign the shorter of the BUDs (conservatively)

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Knowledge Check
Determining Water Activity



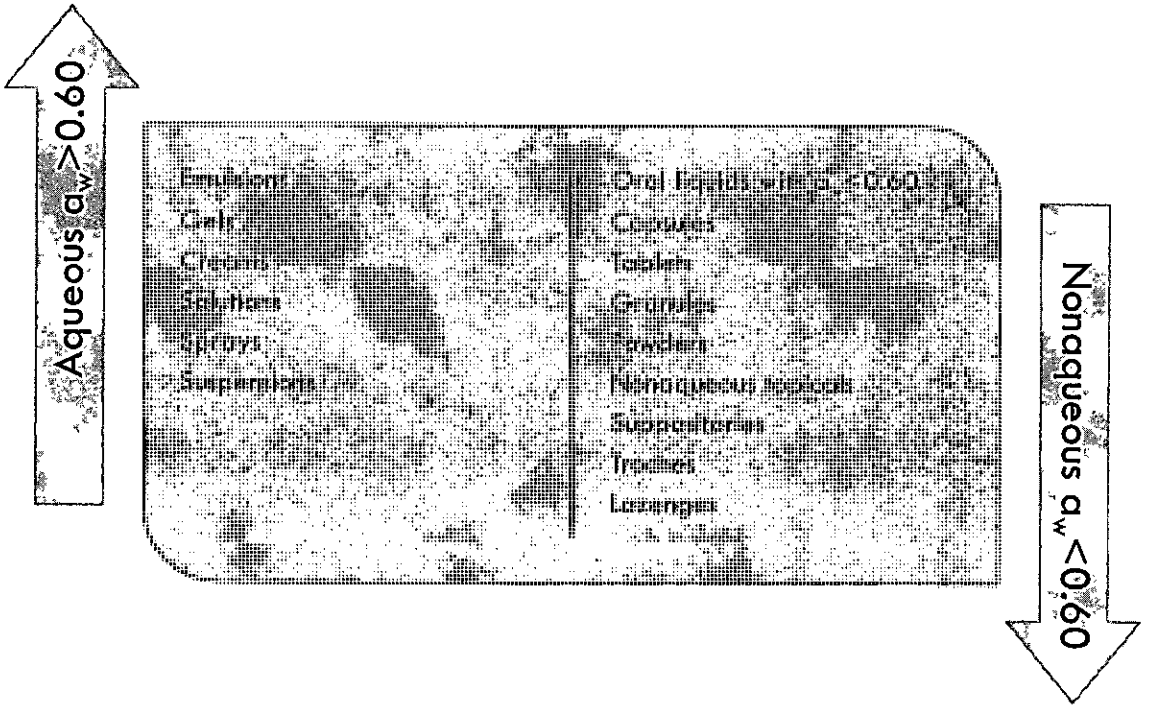
True or False?

Compounders are not required to measure water activity for CNSPs.

USP <1112> and <795> provide examples of dosage forms that have an aw < 0.6 and those that have an aw > 0.6 and can assist personnel in determining the BUD by dosage form

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Establishing a BUD for a CNSP: Aqueous vs Nonaqueous



References:
1US Pharmacopeia (2023). USP <1112> Application of Water Activity Determination to Nonsterile Pharmaceutical Products

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Establishing a BUD for a CNSP: USP <795> Limits

In absence of Monograph, a CNSP-specific Stability Data or supplemental to CNSP-specific stability data

Type of CNSP	Maximum BUD (Limit) in Days	Storage Temperature
Aqueous Dosage Forms		
Nonpreserved aqueous dosage forms	14	Refrigerated (2-8 degrees Celsius)
Preserved aqueous dosage forms	35	Controlled Room Temp (20-25 degrees Celsius)
Nonaqueous Dosage Forms		
Oral liquids (nonaqueous)	90	Refrigerated (2-8 degrees Celsius)
Other non-aqueous dosage forms	180	Controlled Room Temp (20-25 degrees Celsius)

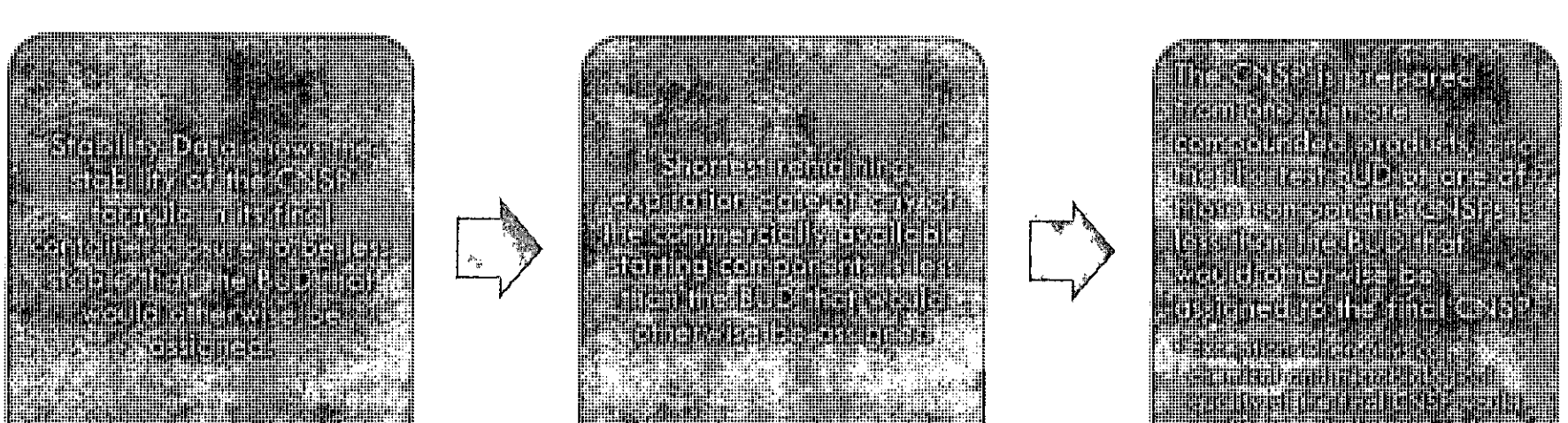
$a_w > 0.60$ (Aqueous)

$a_w < 0.60$ (Nonaqueous)

References:
US Pharmacopeia. (2023). USP <795> Pharmaceutical Compounding – Nonsterile Preparations

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When CNSPs Require a Shorter BUD



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Do I need to add antimicrobial preservative(s)? Conditions

Yes, add carefully selected antimicrobial agent.

- If you have a CNSPs with an $a_w \geq 0.6$
  - You want to assign a BUD from USP <795> for "preserved" aqueous dosage forms
    - **Must add carefully selected antimicrobial agent**
- Why?
  - to protect against the proliferation of bacteria, yeast, and mold contamination that may be inadvertently introduced anytime during the compounding process or throughout the BUD under appropriate handling and storage conditions.

No, it is contraindicated.

- When antimicrobial preservatives are contraindicated in a CNSP
  - Storage of the preparation (nonpreserved) in a refrigerator is required
    - As long as such storage does not change the physical or chemical properties of the CNSP (i.e., precipitation).
  - Shorter "non preserved" BUD limit from USP <795> must be assigned

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When extending BUD beyond USP <795> limits Antimicrobial Effectiveness Testing (AET)

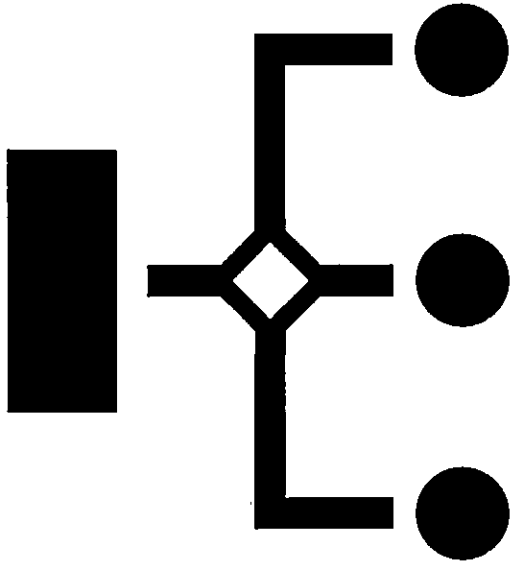
- If extending the BUD of a preserved aqueous CNSP (i.e. an aqueous CNSP with an antimicrobial agent added) beyond t*he limits in the table provided by USP 795*
  - The CNSP must tested for antimicrobial effectiveness.
  - Testing information is found in USP <51>.

The designated person(s) may rely on antimicrobial effectiveness testing that is:

- **conducted once (or contracted for)**
  - for each formulation in the particular container closure system—including materials of composition of the container closure system—in which it will be packaged
- **provided by an FDA-registered facility**
- **published in peer-reviewed literature**
  - CNSP formulation (including any preservative(s), container closure materials must be identical.
    - The concentration/strength may only differ if the literature includes a bracketing study in which the concentration prepared is within the range of the bracket.

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When extending BUD beyond USP <795> limits Antimicrobial Effectiveness Testing (AET)



What is a Bracketed study?

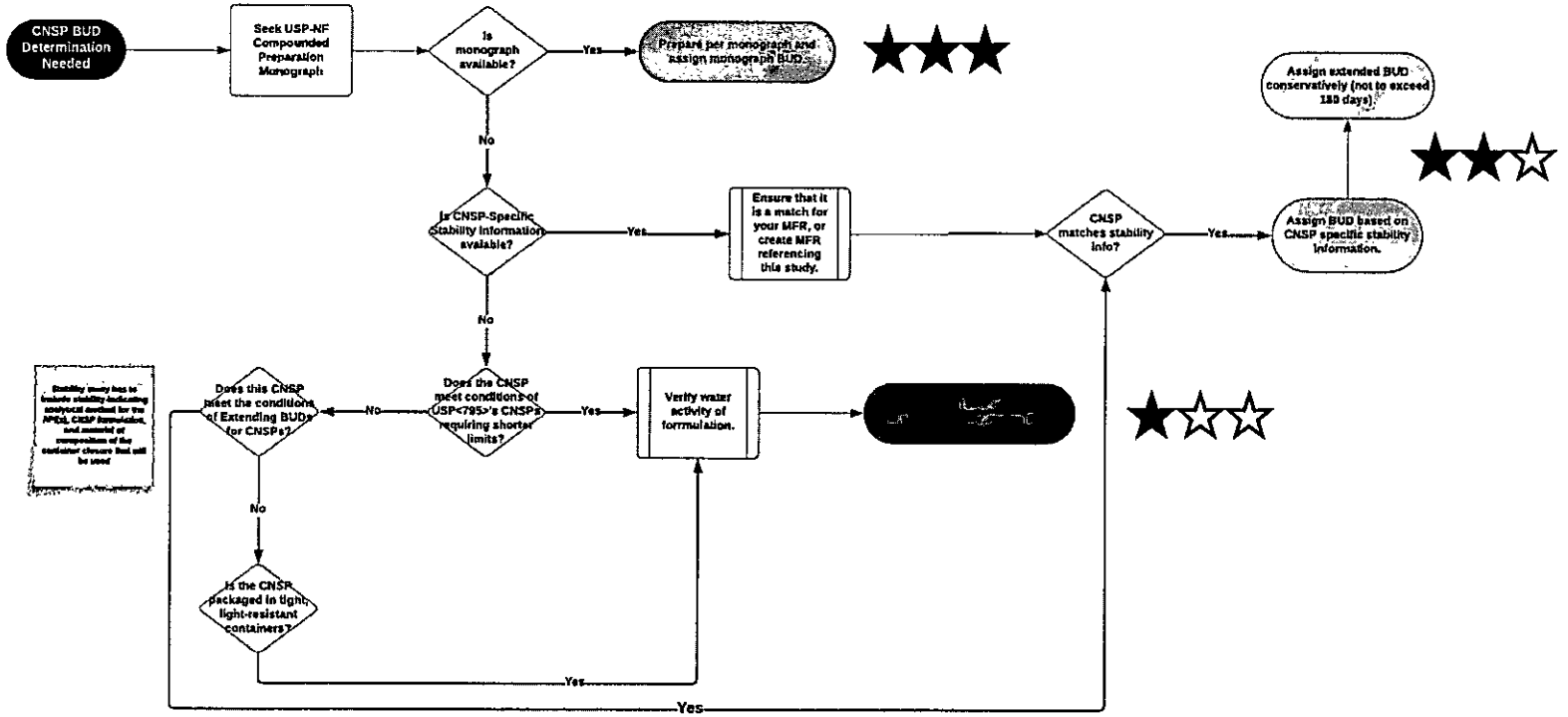
- Effectiveness testing performed on
  - a low concentration of the active ingredient in the formulation
  - a high concentration of the active ingredient in the formulation

Purpose of bracketed study

- To establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.

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Establishing a BUD for a CNSP

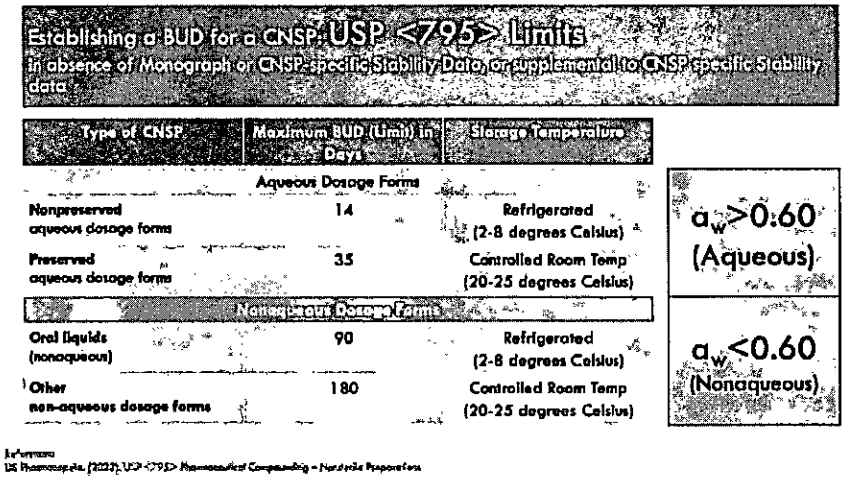


References:
1US Pharmacopeia, (2023). USP <795> Pharmaceutical Compounding – Nonsterile Preparations

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Knowledge Check
Establishing BUD Example



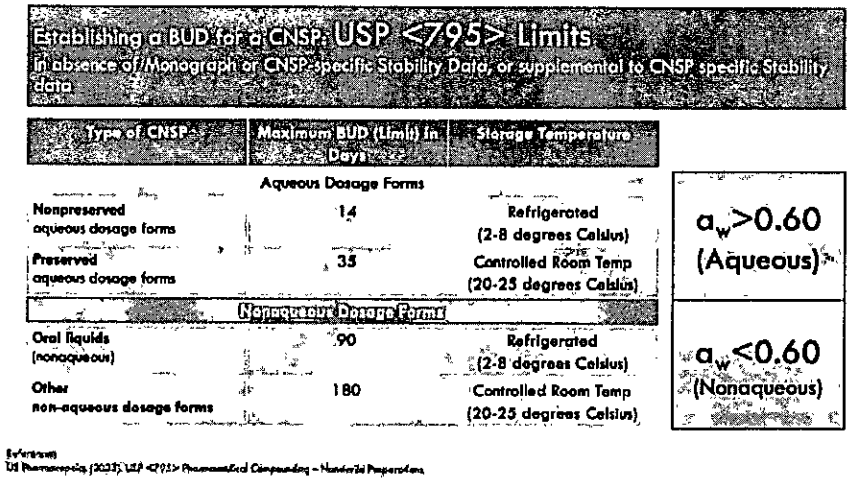


You have a non-preserved aqueous dosage form, what is the maximum refrigerated BUD that it can be assigned?

14 days

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Knowledge Check
Establishing BUD Example



Establishing a BUD for a CNSP: USP <795> Limits
In absence of Monograph or CNSP-specific Stability Data, or supplemental to CNSP specific Stability data

Type of CNSP	Maximum BUD (Limit) in Days	Storage Temperature
Aqueous Dosage Forms		
Nonpreserved aqueous dosage forms	14	Refrigerated (2-8 degrees Celsius)
Preserved aqueous dosage forms	35	Controlled Room Temp (20-25 degrees Celsius)
Nonaqueous Dosage Forms		
Oral liquids (nonaqueous)	90	Refrigerated (2-8 degrees Celsius)
Other non-aqueous dosage forms	180	Controlled Room Temp (20-25 degrees Celsius)

a_w>0.60 (Aqueous)

a_w<0.60 (Nonaqueous)

You have an aqueous dosage form in which you add an antimicrobial agent to. The USP-NF monograph says it is stable for up to 30 days. What is the maximum BUD you can assign it?

30 days

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Knowledge Check
Establishing BUD Example



Establishing a BUD for a CNSP: USP <795> Limits
In absence of Monograph or CNSP-specific Stability Data, or supplemental to CNSP specific Stability data

Type of CNSP	Maximum BUD (Limit) in Days	Storage Temperature
Aqueous Dosage Forms		
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Preserved aqueous dosage forms	35	Controlled Room Temp (20-25 degrees Celsius)
Nonaqueous Dosage Forms		
Oral liquids (nonaqueous)	90	Refrigerated (2-8 degrees Celsius)
Other non-aqueous dosage forms	180	Controlled Room Temp (20-25 degrees Celsius)

$a_w > 0.60$ (Aqueous)

$a_w < 0.60$ (Nonaqueous)

References
[1] [illegible] (2023). USP <795> Pharmaceutical Compounding – Nonsterile Preparations

At room temperature, what is the maximum BUD you can assign a CNSP in tablet form if you have CNSP specific stability study which says it is stable for up to one year.

180 days

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Congratulations!

This is the last video of the NS series. Please proceed to your associated quiz for this final module.

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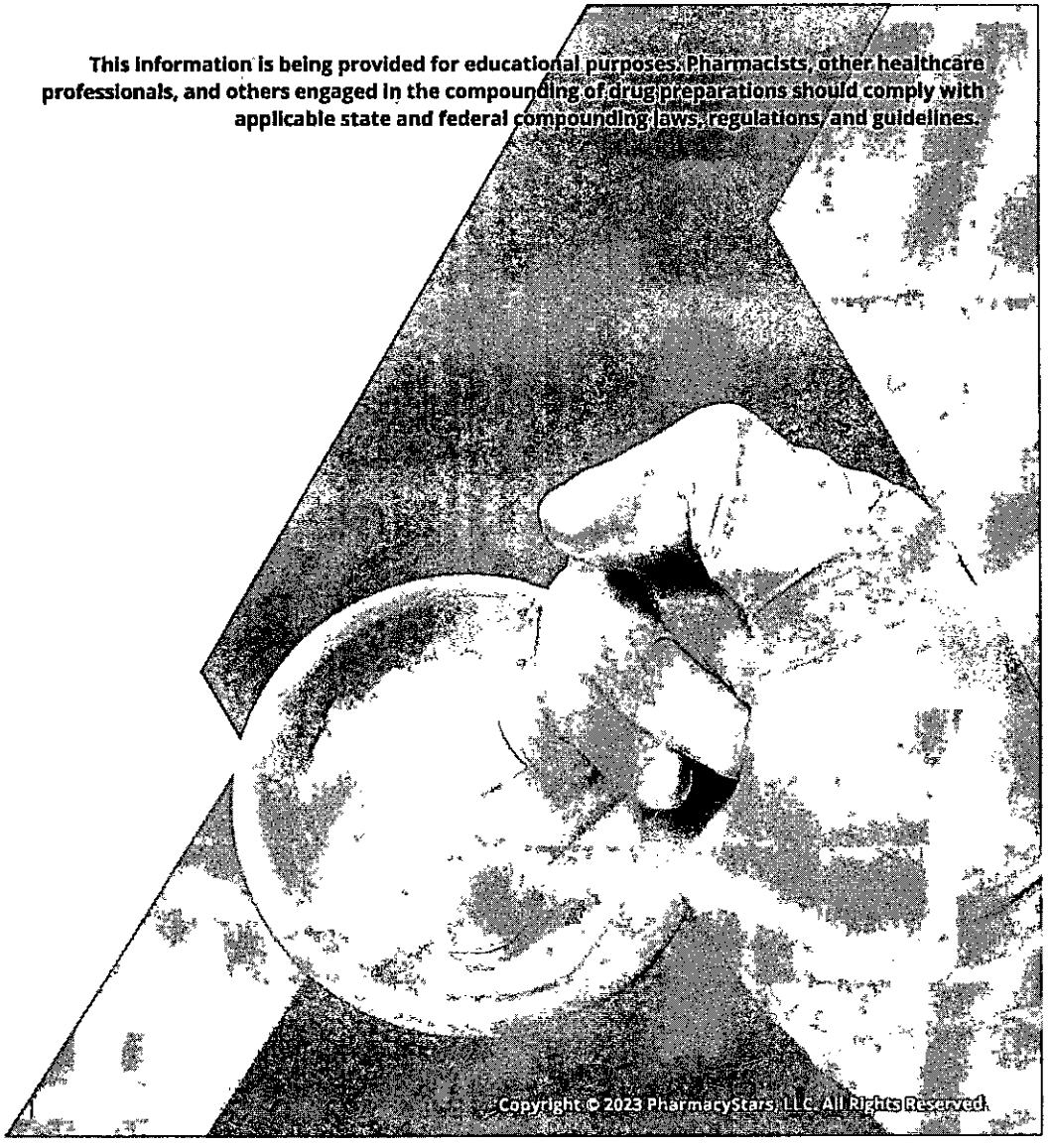
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TRAINING MODULE

Module NS1

Compounding Compounded Non-Sterile Preparations (CNSPs)

This information is being provided for educational purposes. Pharmacists, other healthcare professionals, and others engaged in the compounding of drug preparations should comply with applicable state and federal compounding laws, regulations, and guidelines.



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Personnel Responsibilities and Requirements

Compounding Compounded Non-Sterile Preparations (CNSPs) Series

(Module and Video 1 of 4)

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Learning Objectives

Define	Discuss	List	Recall
compounding and when it is necessary to compound	the responsibilities of personnel involved in compounding	some of the responsibilities of the Designated Person	the Personal Training and Evaluation requirements for those that prepare or aid in the preparation of CNSPs

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When we compound



Compounding preparations (sterile or non-sterile) is performed when there is no suitable commercially available product or when practitioners determine a change to a commercially available drug would yield a desirable significant clinical effect for an intended patient.

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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What is compounding?



Compounding is defined as the combining, admixing, diluting, reconstituting or otherwise altering a drug product.

Manipulations performed strictly according to manufacturer's labeling is not considered compounding.

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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What is non-sterile compounding?



- Solid oral preparations
- Liquid oral preparations
- Rectal preparations
- Vaginal preparations
- Topical preparations
  - Creams
  - Gels
  - Ointments
- Nasal and sinus preparations
  - Nasal sprays
  - Nasal irrigation
- Otic preparations
  - Excluding use in perforated eardrums

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Compounding Personnel Responsibilities: Designated Person



One or more individuals that are responsible for the performance and operation and oversight of the compounding facility.

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Compounding Personnel Responsibilities: Designated Person

Performance and Operations includes:

- Oversight of training program for compounding personnel
- Component selection
- Monitoring and observing of activities and compounding environments
  - Taking immediate action if deficient practices are observed
  - Determining if individuals with conditions that risk contaminating the CNSPs should be excluded from the compounding areas until conditions resolve.
- Ensuring SOPs are fully implemented and followed
  - Following up when there are deviations or errors
- Establishing, monitoring, documenting procedures for handling and storage
  - CNSPs
  - CNSP components

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding – Non-Sterile Preparations.
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Who is responsible for safe compounding?

Compounding personnel: Personnel trained to compound or oversee compounding of preparations.



- All persons who prepare CNSPs
  - Pharmacists
  - Pharmacy Technicians
  - Nurses
  - Physicians
  - Veterinarians
- Locations where these persons compound
  - Hospitals
  - Other Healthcare institutions
  - Veterinary Offices

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Compounding Personnel Responsibilities: Why?

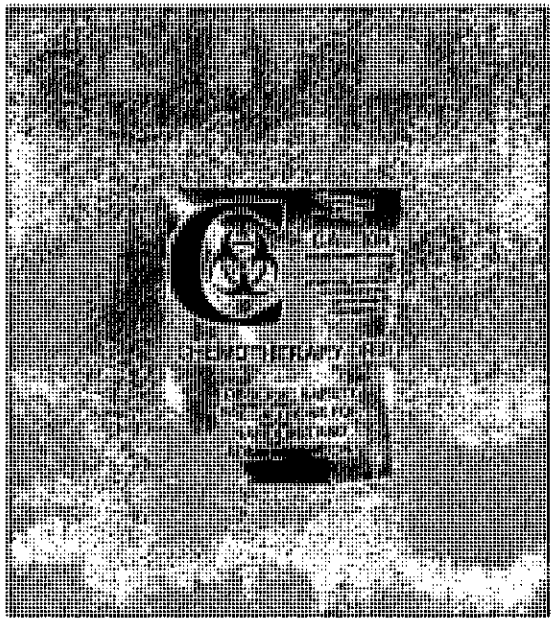


Responsibilities of compounding personnel are in place to minimize harm to human and animal patients that could result from....

- Excessive microbial contamination
- Variability from the intended strength of correct ingredients
- Physical and chemical incompatibilities
- Chemical and physical contaminants
- Use of ingredients of inappropriate quality (or identity)

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Compounding Personnel Responsibilities: HDs



Hazardous Drug: Any drug identified by at least one of the following six criteria:

- Carcinogenicity
- Teratogenicity or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low doses in humans or animals
- Genotoxicity
- New drugs that mimic existing hazardous drugs in structure or toxicity [for examples see current National Institute for Occupational Safety and Health (NIOSH) publications].

References:
US Pharmacopeia (2023). USP <800> Handling Hazardous Drugs in Healthcare Settings.
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.

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Compounding Personnel Responsibilities: HDs



Handling of hazardous drugs (sterile or non-sterile) must additionally comply with USP <800> Hazardous Drugs – Handling in Healthcare settings (including the use of appropriate PPE).

References:
US Pharmacopeia (2023). USP <800> Handling Hazardous Drugs in Healthcare Settings.
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.

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Personnel Training and Evaluation : Who?

Who must be trained?

- **All compounding personnel involved in:**
  - Preparation (Compounding)
  - Supportive functions
    - In-process checks
    - Final verification
    - Dispensing of CNSPs
- **Any personnel with direct oversight of compounding CNSPs**



References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Personnel Training and Evaluation: When?

Who must be trained?

- **All compounding personnel involved in:**
  - **Preparation (Compounding)**
  - Supportive functions
    - In-process checks
    - Final verification
    - Dispensing of CNSPs
- **Any personnel with direct oversight of compounding CNSPs**

How often must direct compounding & oversight personnel be trained?

Initially +
At least every 12 months

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Personnel Training and Evaluation: When?

Who must be trained?

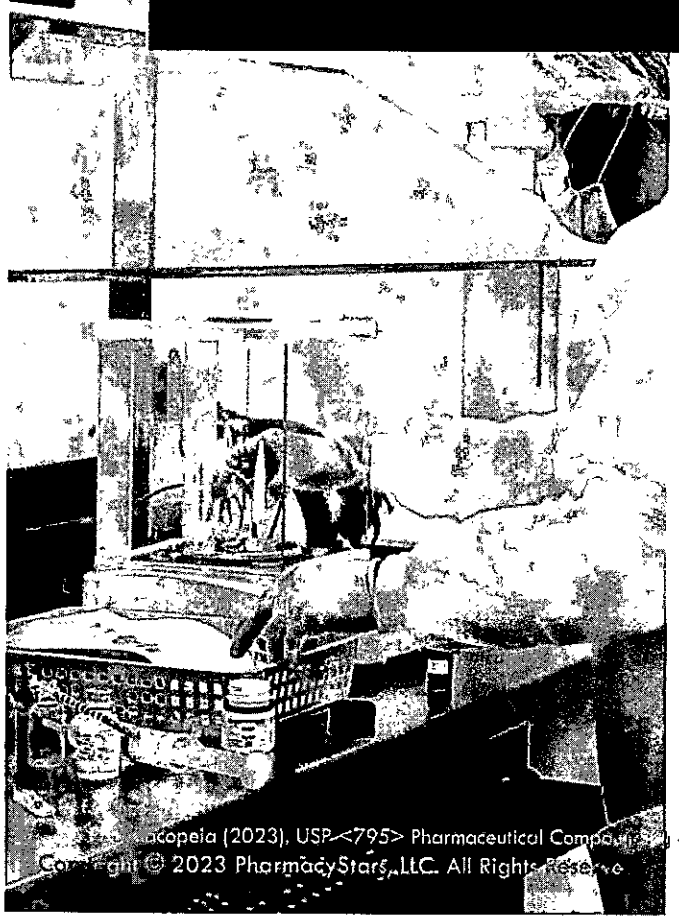
- All compounding personnel involved in:
  - Preparation (Compounding)
  - **Supportive functions**
    - **In-process checks**
    - **Final verification**
    - **Dispensing of CNSPs**
- Any personnel with direct oversight of compounding CNSPs

How often must supporting personnel be trained?

As required by the facility's SOP

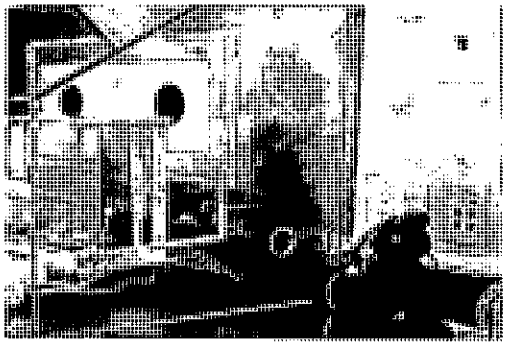
References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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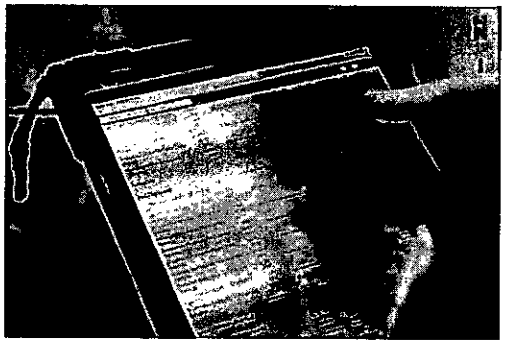
Personnel Training and Evaluation: What?



Core Competencies

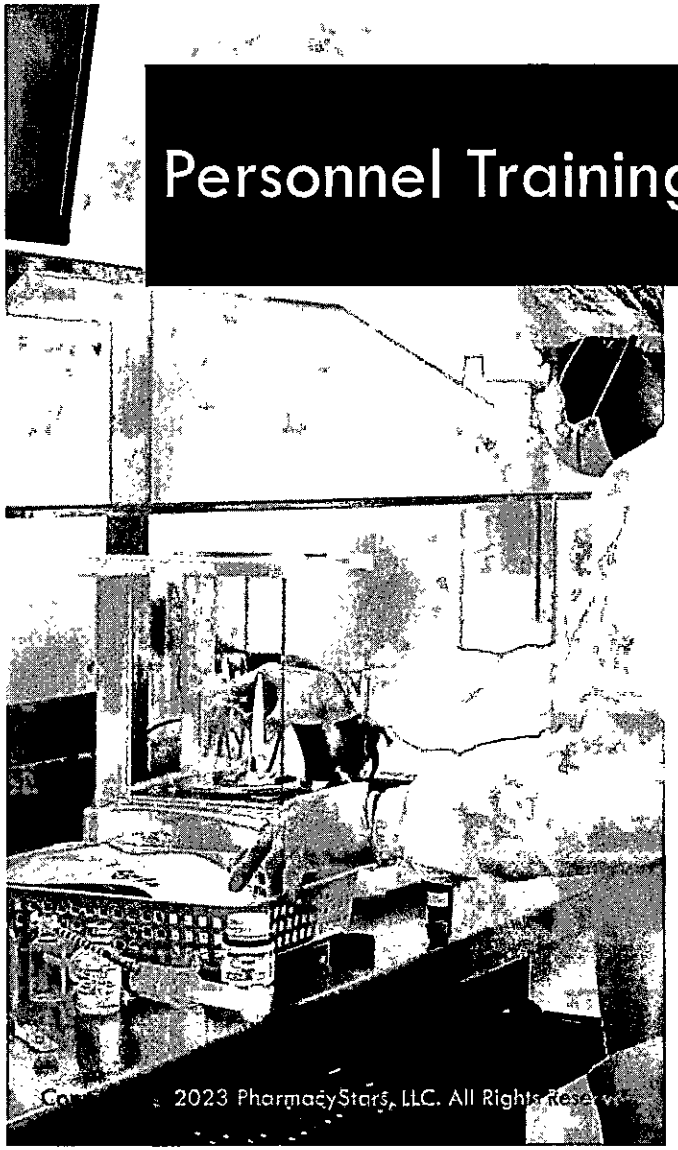
- Hand Hygiene
- Garbing
- Cleaning and Sanitizing
- Handling and transporting components and CNSPs
- Measuring and Mixing
- Proper Use of Equipment and Devices
- Documentation of the Compounding Process





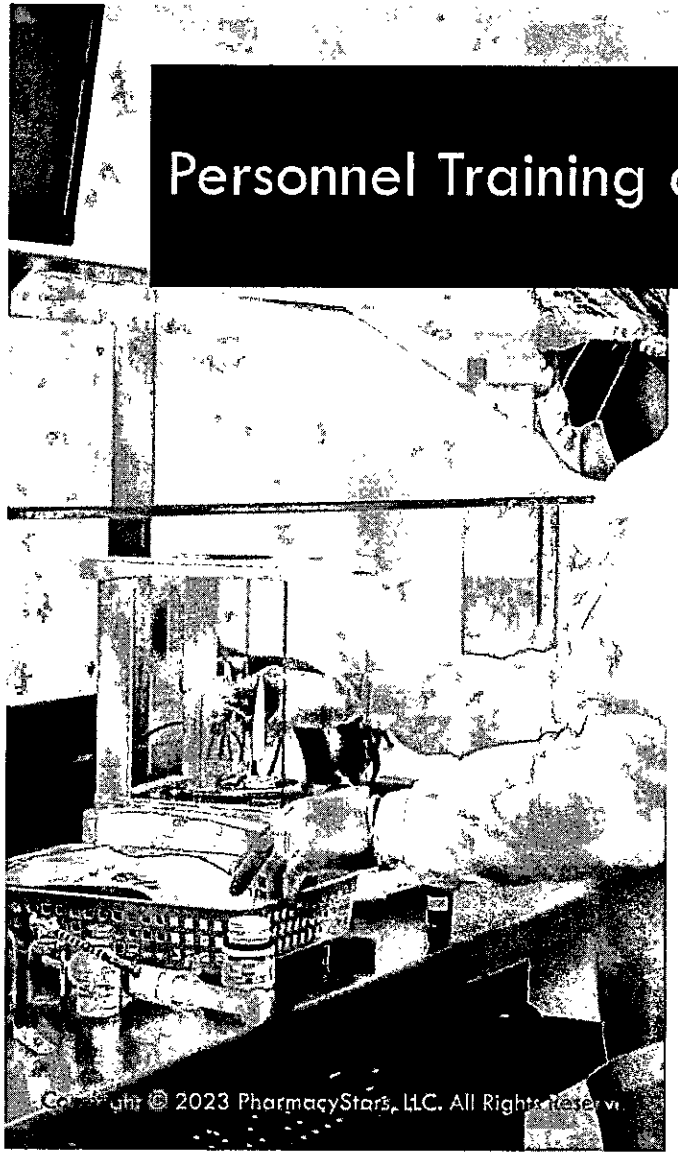
acopeia (2023), USP-<795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Personnel Training and Evaluation: SOPs

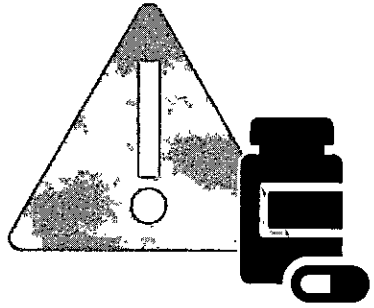


Read and become familiar with your facility's SOPs related to compounding

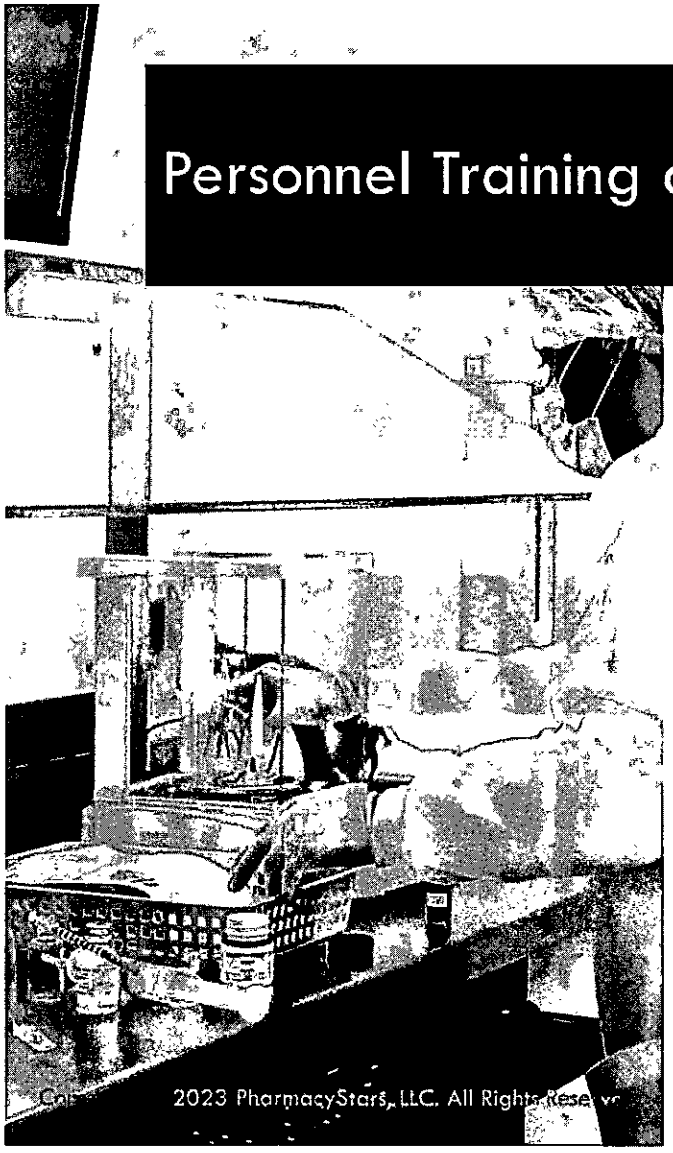
Personnel Training and Evaluation: HD SOPs


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Read and become familiar with your facility's SOPs related to handling hazardous drugs (if applicable)



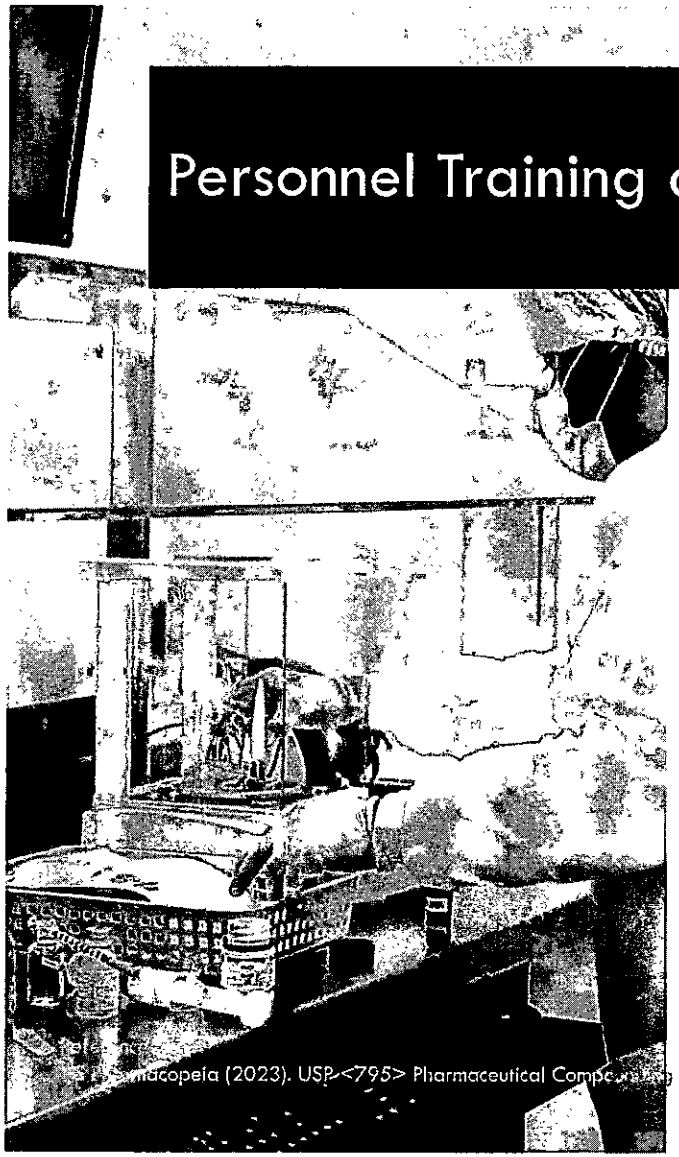
Personnel Training and Evaluation: HD SOPs



Receive instruction on how to retrieve and interpret needed information from Safety Data Sheets (SDS).



Personnel Training and Evaluation: Sequence



Perform and be observed and guided while performing compounding procedures (Observational Audit)

Observe trainer demonstrate compounding procedures

Read and understand the facility's Compounding SOPs

If applicable, successfully complete HD Drug Training (See USP <800>)

Qualified to independently compound when…

- **Complete the training program**
- **Designated Person (DP) and/or the Assigned Trainer (AT) is satisfied with the employee's knowledge and proficiency**
- **DP and/or the AT documents they have been trained and successfully completed competency assessments.**

macopeia (2023). USP-<795> Pharmaceutical Compo... - Non-Sterile Preparations.

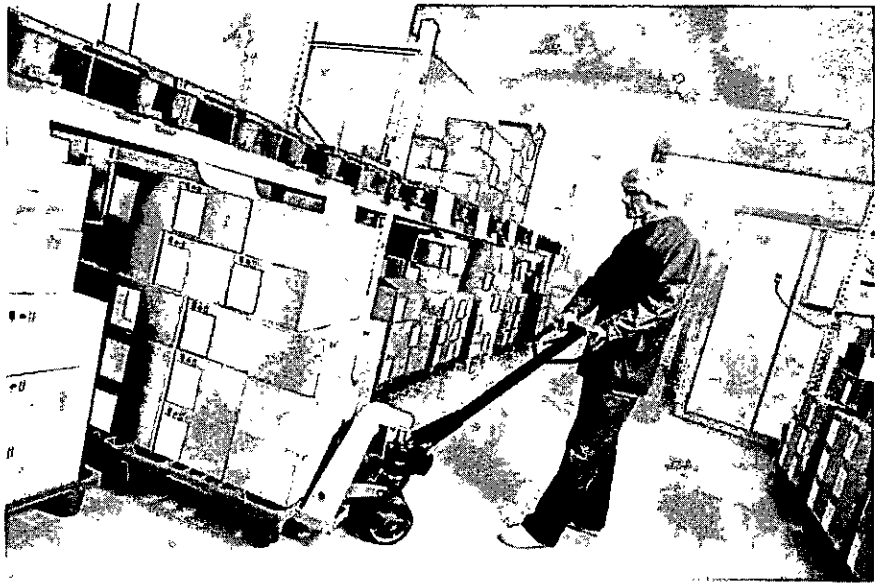
SOP Check



- **Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel.**
  - **Describes the required training, the frequency of training, and the process for evaluating the competency of personnel**

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Knowledge Check



Joey is a technician that usually helps to package up and transport CNSPs to the warehouse, but occasionally when the pharmacy is short staffed, he will pick up a shift that requires him to compound. He was trained initially.

What is the frequency in which he must re-complete competencies related to CNSPs and be re-evaluated/qualified?

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Knowledge Check



Joey is a technician that usually helps to package up and transport CNSPs to the warehouse, but occasionally when the pharmacy is short staffed, he will pick up a shift that ***requires him to compound***. He was trained initially.

What is the frequency in which he must re-complete competencies related to CNSPs and be re-evaluated/qualified?

Annually

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Thank you for watching.

Please proceed to the associated quiz and to your next assigned module.

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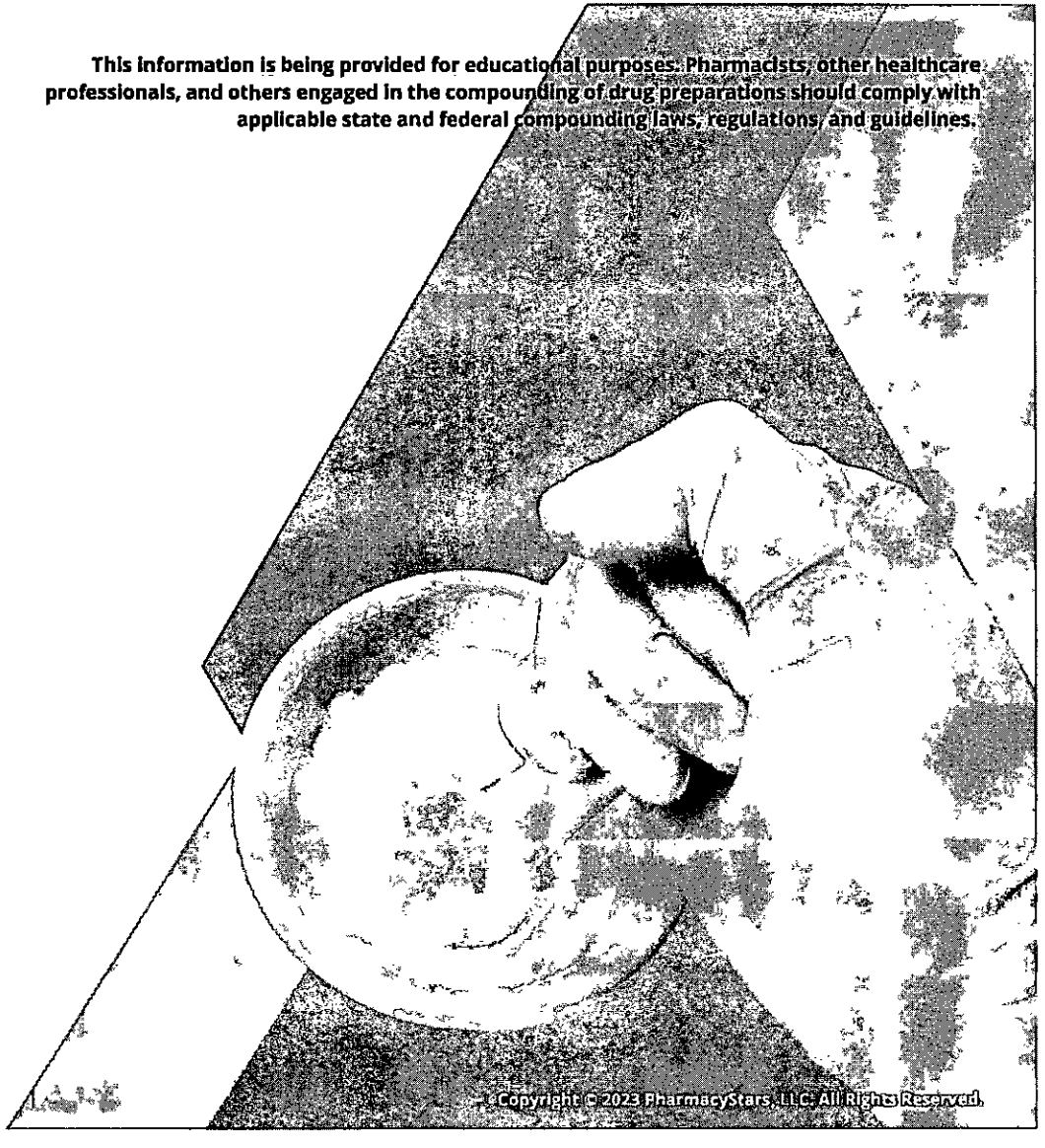
Pharmacy Stars

TRAINING MODULE

Module NS2

Compounding Compounded Non-Sterile Preparations (CNSPs)

This information is being provided for educational purposes. Pharmacists, other healthcare professionals, and others engaged in the compounding of drug preparations should comply with applicable state and federal compounding laws, regulations, and guidelines.



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Personal Hygiene, Garbing and Environmental Requirements for CNSPs

Compounding Compounded Non-Sterile Preparations (CNSPs) Series

(Module and Video 2 of 4)

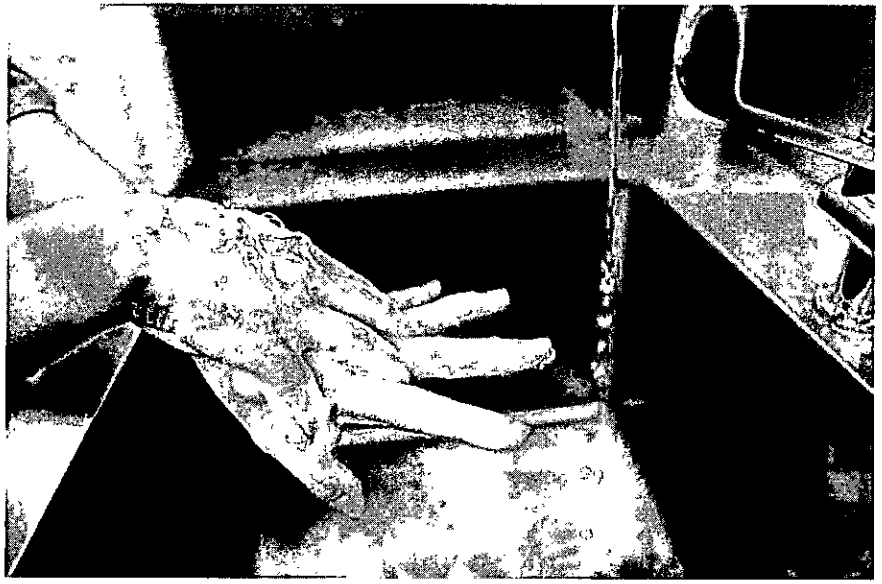
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Learning Objectives

Discuss	Review	Recall	Evaluate	Explain	Contrast
required steps that must be taken prior to entering a compounding area	the personal hygiene requirements for those preparing CNSPs	the required hand hygiene process for those preparing CNSPs	the environmental requirements for compounding areas where CNSPs occur	the requirements of water sources and what water should be used for what CNSP activity	the differences between cleaning and sanitizing

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Where we compound: Personal Hygiene and Garbing

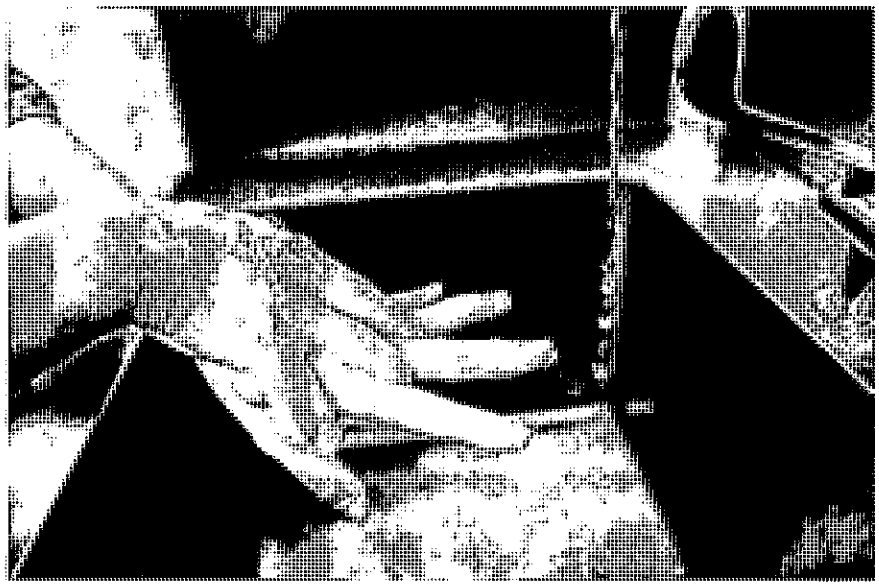


"Individuals entering the compounding area must maintain appropriate personal hygiene."

USP <795> (2023)

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Personal Hygiene and Garbing Compounding Personnel Responsbilities



Compounding Personnel

- Maintaining appropriate personal and hand hygiene
- Remove any items that are not easily cleanable and that might interfere with garbing
- Evaluate whether they have a personal risk of contaminating the compounding environment and the CNSP
  - Report these risks to the Designated Person

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Personal Hygiene and Garbing (High Risk Conditions)



Can you name some conditions that heighten the risk of contaminating the environment and CNSP?

- **Active respiratory infection**
- **Rashes**
- **Recent tattoos**
- **Oozing sores**
- **Conjunctivitis**

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Personal Hygiene and Garbing (High Risk Conditions)

Designated Person

- Evaluate whether these individuals should be excluded from working in compounding areas until their conditions have resolved



References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Personal Hygiene and Garbing (Non-Essential Items)



What are items that are "not easily cleanable and that might interfere with garbing?

- **Personal outer garments**
- **Hand wrist and other exposed jewelry**
- **Earbuds or headphoes**

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Personal Hygiene and Garbing (Non-Essential Items)

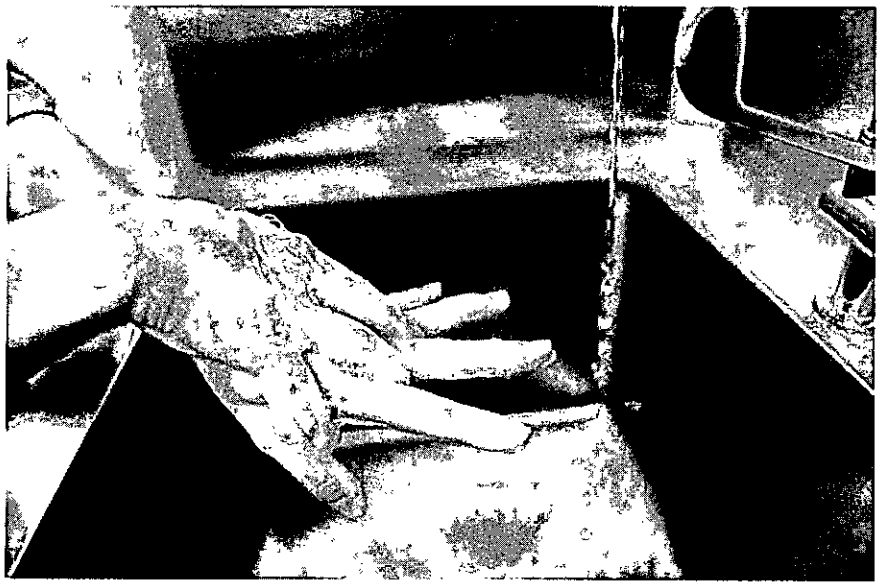
Designated Person

- Evaluate whether to permit accommodations of personal items that are not required for compounding in the compounding area.
  - These accommodations must not affect the quality of the environment or the CNSP
  - All accommodations should be documented.



References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Personal Hygiene and Garbing: Hand Hygiene

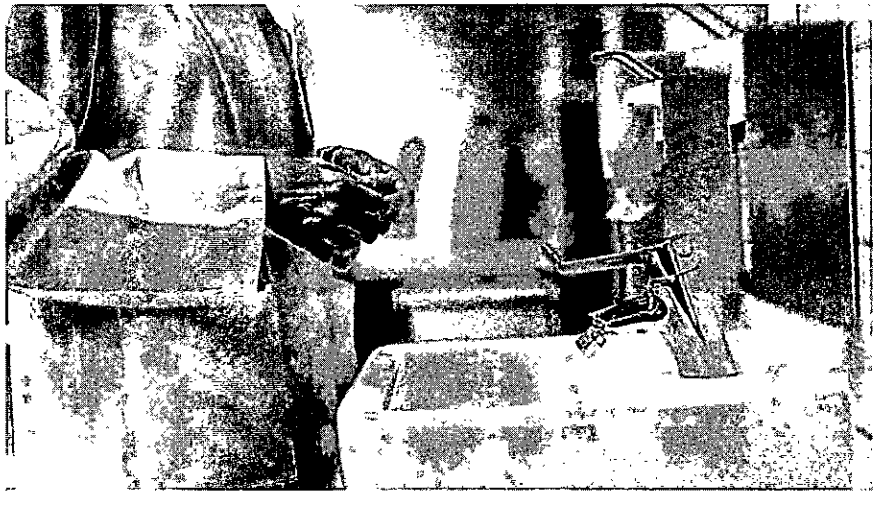


"Personnel **must** perform procedures necessary for appropriate hand hygiene when entering the compounding area to compound."

USP <795> (2023)

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Personal Hygiene and Garbing: Hand Hygiene



USP <795> Hand Hygiene Procedure

1. Wash hands with soap and water for at least 30 seconds.
2. Dry hands completely with disposable wipers.
3. Apply alcohol-based hand rub *(optional). If used, allow to dry.*
4. Don gloves.

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Garbing and Gloving

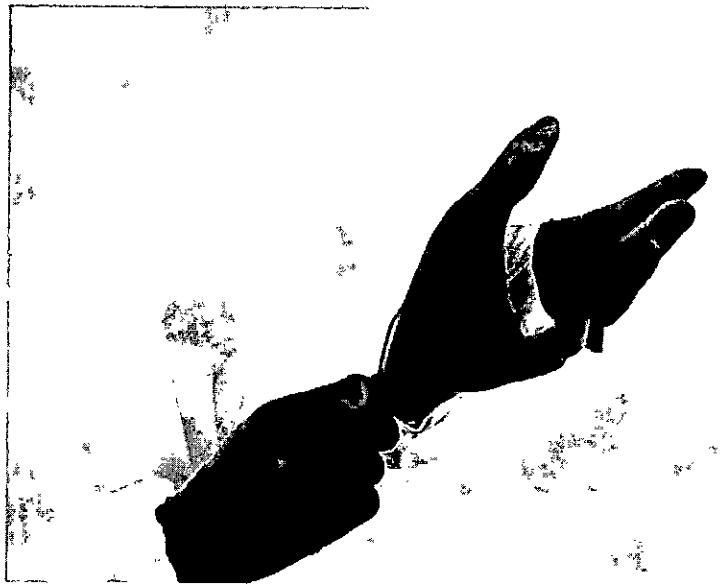


USP <795> Garb and Glove Requirements

1. Gloves must be worn for all compounding activities.
2. Shoe covers, head or hair covers, facial covers, masks and gowns may also be required (noted in your facility's SOPs).
3. Garbing must be appropriate for the type of compounding performed (and drugs that will be manipulated).
4. Garbing must protect personnel from chemical exposures.
5. Garbing must prevent the CNSP from becoming contaminated.
6. If compounding using HDs, additional requirements from USP <800> may also be required.

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Garbing and Gloving



When must garbing be replaced?

1. **Integrity Compromised**
   - Gloves: If they cannot be wiped/sanitized with IPA, should be replaced
   - Any garb: If there are holes, punctures or tears
2. **Visibly Soiled**
3. **Damaged**
4. **If there is a spill**

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Garbing and Gloving

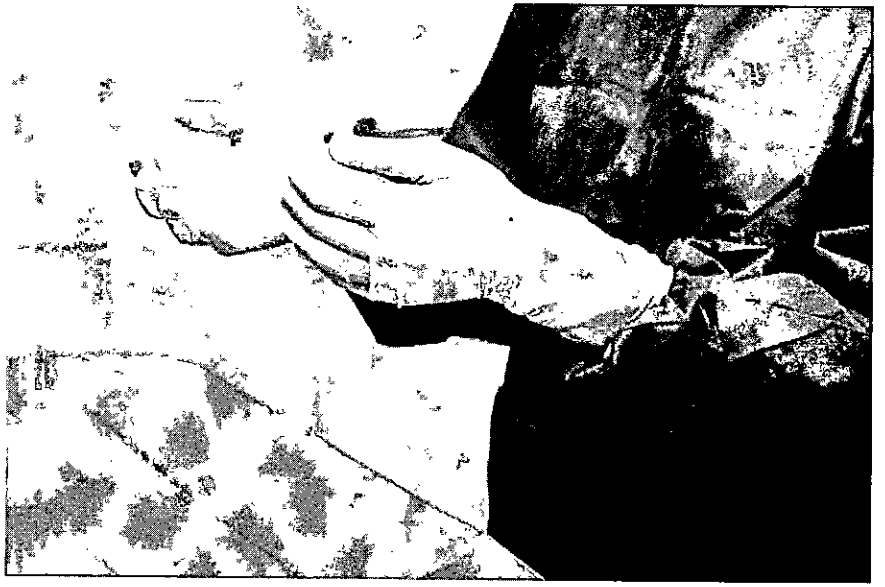
Garbing Reuse (CNSP Area)

1. Gloves MUST NOT be reused.
2. Gowns may be reused DURING THE SAME SHIFT if they remain in the compounding area.



References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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SOP Check



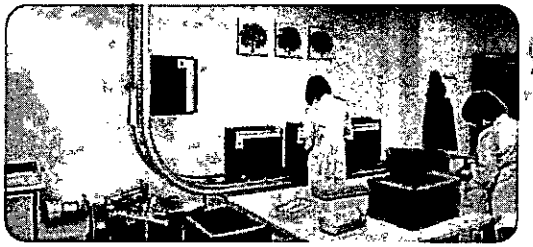
Does your Compounding SOP include the following?

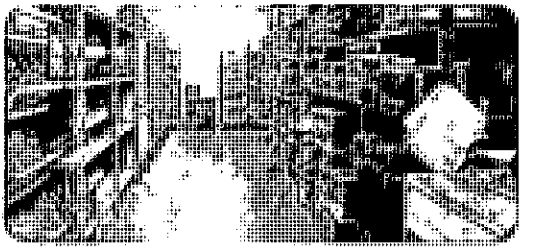
Garb and Glove SOP Requirements

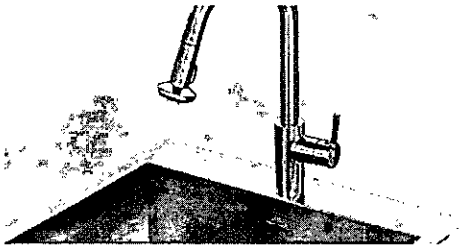
- How to Garb
- What other garb (besides gloves) must be worn
- Frequency of changing garbing
- Cleaning and sanitization of reusable garbing
  (e.g. goggles, respirators)

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Building and Facilities







Compounding Area

- Must be designated (segregated or separated) for compounding
- Restricted access to only trained compounding personnel

Storage Area

- Compounders, personnel, supplies, equipment, and components must be stored correctly
- Storage conditions must be according to manufacturer's specifications

Water Sources

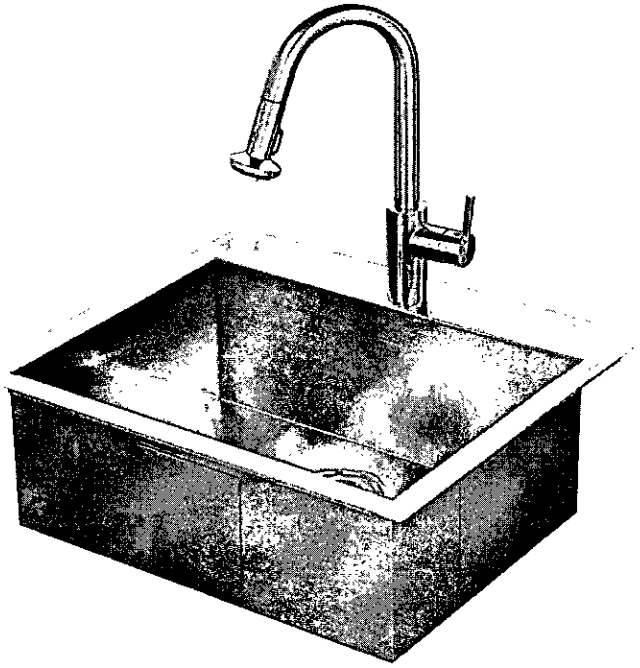
- Potable water is the minimum quality of water used in compounding
- Sterile water is required for preparation of sterile products

References:

US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.

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Building and Facilities: Sinks



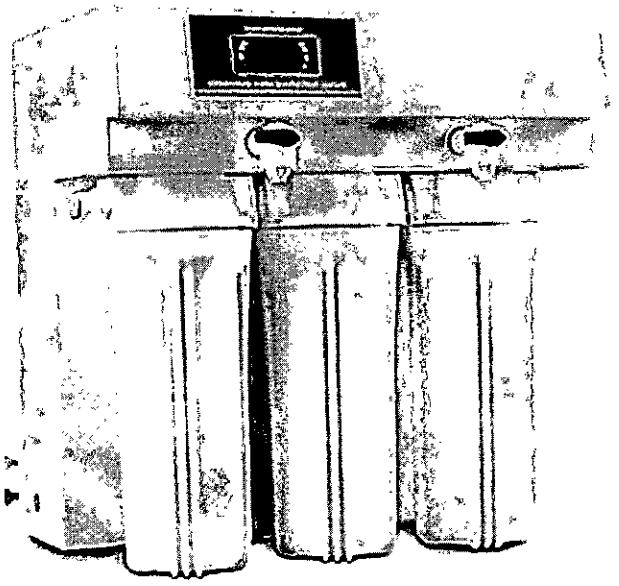


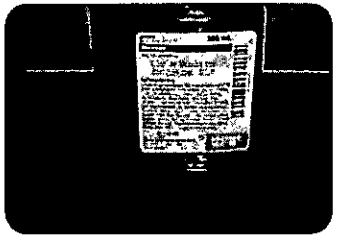
Sinks

- Must be cleaned if visibly soiled before use to clean equipment for CNSPs
- Must be emptied of all items not related to compounding

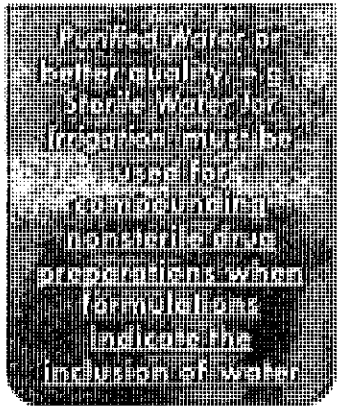
References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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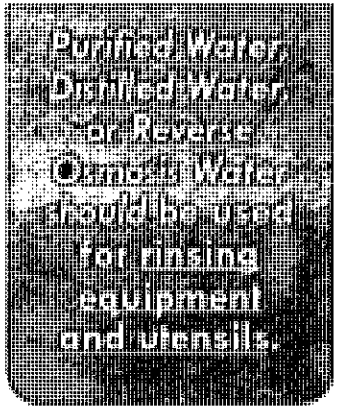
Building and Facilities: Water Sources







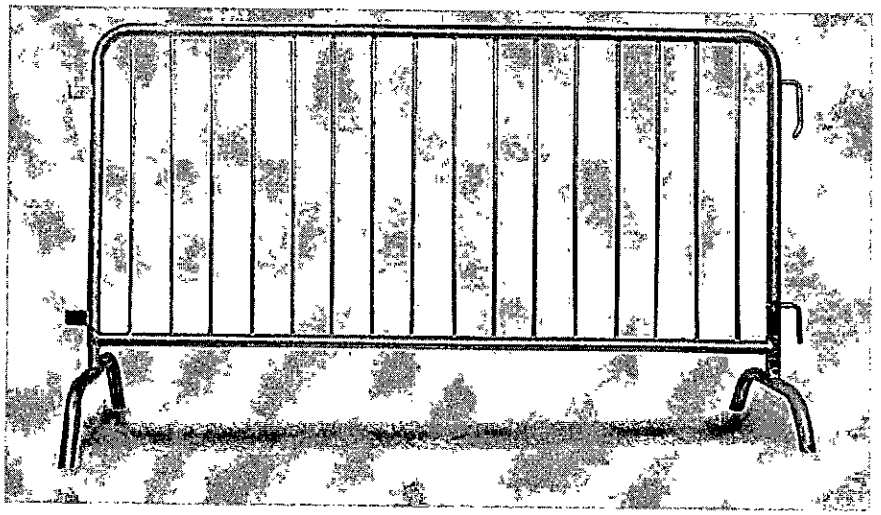




References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.

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SOP Check



The method of designation of the CNSP Compounding Area is described in the facility's SOP.

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Knowledge Check



T/F

Hand Sanitizer (e.g. alcohol based hand rub) may be used in place of hand washing if the sink is not easily accessible.

The use of alcohol-based hand rub may supplement hand washing prior to gloving, but alone is not sufficient.

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Cleaning and Sanitizing

Cleaning

- The process of (mechanical or chemical) *removing* substances (e.g., organic and inorganic material) from objects and surfaces
- Accomplished by manually or mechanically using water with detergents or enzymatic products.

Cleaning agent:

- An agent, usually containing a surfactant, used for the removal of substances from surfaces.

Goal

Remove

- Dirt
- Debris
- Microbes
- Residual drugs or chemicals

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Cleaning and Sanitizing

Sanitizing

- the process of *reducing* bioburden (number of microorganisms on a inanimate surface)
- accomplished by using a sanitizing agent

Examples of Sanitizing Agents

70% isopropyl alcohol

References:
US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Cleaning and Sanitizing

USP <795>[1] Minimum Frequency for Cleaning and Sanitizing Non-Sterile Compounding Area(s) – Surfaces

	Visibly Soiled, Known or Suspected Contamination	Beginning of shift	End of shift*	After Spills	Daily*	Quarterly (Every 3 months)
Work Surfaces	✓	✓	✓	✓	✓ (shift)	✓ (shift)
Floors	✓			✓	✓	✓ (daily)
Walls	✓			N/A		
Ceilings	✓			N/A		
Storage Shelving	✓			✓		✓

*on days when compounding occurs

What must be *cleaned* AND *sanitized* in the compounding area?

- **Work surfaces**
- **Floor**
- **Walls**
- **Ceilings**
- **Storage Shelving and contents**

References:
[1]US Pharmacopeia (2023). USP <795> Pharmaceutical Compounding - Non-Sterile Preparations.
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Thank you for watching.

Please proceed to the associated quiz and to your next assigned module.

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Logged Formula Worksheet

1/23/2026 2:34 PM

L52

Infinite Health Pharmacy Inc.
416 Clematis St, Ste B
West Palm Beach, FL 33401-5312
(833) 463-4679

C-IVERMECTIN 12MG TABS

Flavor:
Qty Made: 5500.000 EA
Date Made: 1/23/2026
Lot #: 52
Alternate Lot #:
Beyond Use Date: 7/22/2026
Pharmacist: Rebhandl, Thomas
Technician:

DEA Schedule: 0
Alternate ID:

Pricing calculations from the log

Estimated Price:	$425.79		
Ingredient Cost:	$394.32		
Additional Cost:	$0.00		
Time Cost:	$0.00	Minutes to Make:	0.00
Profit:	$31.47		

	Ingredient	DEA Schedule	Qty Used		QS (Balance)	Actual Cost & Date
1	Ivermectin USP (for Human Use) Lot: Exp. Date: NDC: 51927-5152-00 Barcode Checked: ☐	0	66.000	GM	☐	$346.50 1/20/2026
2	Glidetab FX Lot: Exp. Date: NDC: 72467-0223-65 Barcode Checked: ☐	0	759.000	GM	☑	$47.82 12/4/2025

Linked Prescriptions:

Rx Number	Rf	Date Filled	Date Written	Patient Name	Qty	Expiration Date

Log Instructions & Notes

Compounding Steps:
1. Verify component identity/lot/expiration and balance calibration.
2. Weigh ivermectin and Glidetab FX.
3. Sieve each powder through a metal strainer.
4. Blend via geometric dilution in mortar/pestle with trituration (60 sec between additions; 2 min final blend).
5. Sieve the final blend through a metal strainer.
6. Load blend into tablet press hopper and compress tablets per LFA RTP 118.
7. Weigh 10 tablets at startup and at defined intervals; document results and confirm within acceptance criteria.

Physical Description (Finished Tablets):
- Tablets should be:
  - Intact and uniform in appearance
  - Free from cracks, chips, capping, sticking, or lamination
  - Consistent color/finish throughout the batch
  - No visible powder segregation or mottling

Storage:
- Store in a tight, light-resistant container
- Controlled room temperature 20-25°C (USP Controlled Room Temperature)
- Protect from excessive heat and moisture

Final Container-Closure:
- Container: Tight, light-resistant Amber bottle
- Closure: Child-resistant cap

Equipment List
- Class A prescription balance
- Mortar and pestle
- Spatula(s)
- Powder funnel (optional)
- Metal strainer / sieve
- Weigh boats / weigh paper
- Tablet press
- Tablet tooling (die/punch set) appropriate for target tablet size
- Cleaning supplies (per equipment cleaning SOP)

L52

Infinite Health Pharmacy Inc.
416 Clematis St, Ste B
West Palm Beach, FL 33401-5312
(833) 463-4679

Reference Source
BUD Assignment (Tablets/Capsules):
- Up to 6 months, or the earliest expiration date of any ingredient, whichever is earlier for nonsterile solid oral dosage form
- USP <795> Pharmaceutical Compounding-Nonsterile Preparations (BUD guidelines)

Checked By: _____ Date: ____/____/_____

New Prescription

Issued By: Dieulune Honorat
Supervisor:
Location:
433 PLAZA REAL, STE 275
BOCA RATON, FL 33432
Phone: 8007581584

NPI#: 1851959415
DEA#:
XDEA#:
SPI#: 6780799642010
State License#: APRN11001175

Patient Name: [redacted]
Address: [redacted]
Date Of Birth: [redacted]

Prescriber Order Number: 1120775000070178413
RxReference Number:

PRESCRIPTION AS FOLLOWS

Written: 12/09/2025
Escript Expiration Date:

Medication NDC Prescribed:
NDC: 00102-0201-07

Medication Prescribed: Emergency Kit (Antibiotic)
Days Supply:

Quantity: 1.0000 Each (1.0000 Kit)
Refills: 0 (additional refills)

Directions: 1 kit(s) as needed , oral route Compound Ivermectin per protocol

Substitutions: Substitutions Allowed

Diagnosis/use: (not specified)
Diagnosis Codes:

DEA Schedule:

Note: NKDA

Sent: 12/19/25 1:17 PM
Received: 12/19/2025 1:22:27 PM
Printed 12/30/2025 12:42 PM

To: Infinite Health Pharmacy Inc.
Signed electronically by: Dieulune Honorat

Sender Message ID: 1120775000070178413
Signed on Date: 12/19/25 1:17 PM

New Prescription

Issued By: Patricia Keller
Supervisor:
Location:
433 PLAZA REAL, STE 275
BOCA RATON, FL 33432
Phone: 8007581584

NPI#: 1194046565
DEA#:
XDEA#:
SPI#: 6148736591029
State License#:

Patient Name: [redacted]
Address: [redacted]
Date Of Birth: [redacted]

Prescriber Order Number: 1120775000070190954 RxReference Number:

PRESCRIPTION AS FOLLOWS

Written: 12/19/2025 Escript Expiration Date:

Medication NDC Prescribed: NDC: 00102-0201-07

Medication Prescribed: Emergency Kit (Antibiotic) Days Supply:

Quantity: 1.0000 Each (1.0000 Kit) Refills: 0 (additional refills)

Directions: 1 kit(s) as needed , oral route Compound Ivermectin per protocol

Substitutions: Substitutions Allowed

Diagnosis/use: (not specified) Diagnosis Codes:

DEA Schedule:

Note: NKDA

Sent: 12/19/25 5:18 PM Received: 12/19/2025 5:22:49 PM Printed 12/30/2025 12:41 PM

To: Infinite Health Pharmacy Inc. Signed electronically by: Patricia Keller

Sender Message ID: 1120775000070190954 Signed on Date: 12/19/25 5:18 PM

Medical Emergency Kit

Medical Emergency Kit (BL)
med
Amoxicillin-Clavulanate 875-125mg Tablet
(28 tablets)
Take 1 tablet by mouth two times a day for 5 days,as directed
amox
Azithromycin 250mg Tablet
(12 tablets)
Take two tablets on day 1,then take one tablet by mouth daily on day 2-5,or as directed
Zpak2: Label: 2
Doxycycline Hyclate 100mg Capsule
(60 capsules)
Take one capsule by mouth two times a day for 7 days,or as directed
doxy
Metronidazole 500mg Tablet
(30 tablets)
Take 1 tablet by mouth two times a day for 7 days,or as directed
metro
Bactrim DS(Sulfamethoxazole-Tmp DS Tablet)
(28 tablet)
Take 1 tablet by mouth two times a day for 5 days,or as directed
Bactrim or sulf
C-Ivermectin 12mg Capsule
(25 capsule)
Take 1 capsule per 45 pounds (lbs) of body weight as directed by the medical guidebook.
C-iver : Manual price: $22.00
Fluconazole 150mg Tablet
(2 tablets)
Take one tablet by mouth once;repeat dose 3-7 days later if symptoms persist,or as directed
flue
Ondansetron HCl, 4 mg Tablet
(6 tablets)
Take one tablet by mouth every 4-8 hours as needed for nausea or vomiting, or as directed,do not exceed 16 mg per day
ond

Vendor Name	Website	Verified? (Y/N)	Type (API, Packaging, etc.)	Notes
Medisca	medisca.com	Y	API, Packaging	
PCCA	pccarx.com	Y	API, Packaging	
SpecialityRx	specializedrx.com	Y	API, Packaging	
Anda	anda.com	Y	Commerical products	DSCSA information retained 3T data for 6 years
Mckesson	mckesson.com	Y	Commerical products	DSCSA information retained 3T data for 6 years

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	1833352		**Inspection Information**
Legal Business Name:	Infinite Health Pharmacy, Inc	**Conference Call Date:**	12/23/2025
Doing Business As (DBA):	N/A	**Start Time: 24-hour format (13:00)**	15:00
Address:	416 Clematis St, Ste B	**End Time: 24-hour format (13:00)**	16:05
City:	West Palm Beach	**Onsite Inspection Date(s):**	12/30/2025
State:	Florida	**Start Time(s): 24-hour format (13:00)**	9:05
Zip Code:	33401	**End Time(s): 24-hour format (13:00)**	13:45
Telephone number:	561/621-1770	**Inspector Name(s):**	Ronnie Higgins, RPh
Toll free number:	833/463-4679	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	561/805-7138	**Observer Name/Affiliation (if applicable):**	N/A
Website:	N/A	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.

General Pharmacy - 15.00, 47.06, 47.07, 65.00, 65.02, 67.00, 67.01, 93.00

Nonsterile - 10.0, 10.3, 10.4, 28.0, 28.3, 28.4, 28.5, 28.7, 28.10, 29.0, 29.12, 29.13, 29.14, 58.0, 58.14, 58.15, 59.0, 59.1

Additional information on NABP's Inspection website.

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open Start Time: (24-hour format)	End Time: (24-hour format)	Closed (X)
Sunday			X
Monday	9:00	17:00	
Tuesday	9:00	17:00	
Wednesday	9:00	17:00	
Thursday	9:00	17:00	
Friday	9:00	17:00	
Saturday			X

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Thomas Rebhandl	infinitehealthrx@gmail.com	187705
Nonsterile Designated person(s)	Thomas Rebhandl	infinitehealthrx@gmail.com	187705
Sterile Designated person(s)	N/A	N/A	N/A
Hazardous Designated person(s)	N/A	N/A	N/A

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Thomas Rebhandl	PIC	Y
2	Jocelyn Freimuth	Pharmacist/Consultant	Y (TN)
3	Michael Raiff	Technician/Consultant	Y (TN)
4	Charelle Irang	Technician	Y
5	Otis James	Technician	Y
6	NiGarriyia Moore	Technician in Training	Y
7	Zachary Yong	Technician	Y
8	Vrxiela Barr	Pharmacy Clerk	N
9	Harry Bougard	Staff Pharmacist	Y
10			

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

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Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Florida Department of Health	Infinite Health Pharmacy, Inc	Pharmacy	PH32212 & 02/28/2027
Drug Enforcement Administration	Infinite Health Pharmacy, Inc	Pharmacy	FI8878893 & 11/30/2028

Inspector Notes: List states in which Non-Resident licenses are held The pharmacy is licensed in the following States: AZ, CO, IL, IN, IA, ME, MO, MT, NJ, NM, NC, ND, PA, RI, SD, WI and WY. It appears that the pharmacy shipped one prescription into the State of WA in November 2025 and the pharmacy does not hold a non-resident license in the state of Washington. Infinite Health Pharmacy changed their business model in October 2025. 99.9% of the purported prescriptions dispensed now are "Emergency Kits". The purported prescriptions are received as an e-script from the telemedicine company, The Wellness Company. The purported prescriptions received are for "Emergency Kit (antibiotic)", quantity of "1", and are "coded" to dispense '1 kit(s) as needed, oral route Compound Ivermectin per protocol.' The protocol for the "Emergency Kit (antbiotic)" contains 8 separate prescription drugs and are dispensed with 8 different prescription numbers. Most of the "Emergency Kits" contain 28 Amoxicillin-Clavulanate 875-125, 12 Azithromycin 250mg, 60 Doxycycline 100mg, 30 Metronidazole 500mg, 28Trimethoprim-Sulfamethoxazole 160-800, 25 Compounded Ivermectin 12mg Tablets, 2 Fluconazole 150mg, 8 Ondansetron 4mg and a Medical Emergency Kit Guidebook for Reference. These purported prescriptions are dispensed for future use to be determined by the patient.
The Ivermectin 12 mg tablets are compounded in batches of 10,000 tablets which is a 14 day supply. The pharmacy is compounding Ivermectin 12 mg tablets instead of the patient using the commercially available 3 mg tablet. The pharmacy is using an RTP 188 tablet press from LFA Machines.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01_GP_65.00	Copies of two purported prescriptions for 'Emergency Kit (antibiotic)' with PHI removed, quantity of '1', and are 'coded' to dispense '1 kit(s) as needed, oral route Compound Ivermectin per protocol' and a list of the contents of the kit per protocol.
Doc02_NS_20.2	COA for Ivermectin.
Doc03_NS_27.0	Master Formula and Compounding Record for Ivermectin 12mg Tablets.
Photo01_CPD_20.3	Pictures of Compounding Room along with Tablet Press and Capsule Machine.

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	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail	X	Central Fill/Processing/Shared Services	
Open to the Public	X	Nuclear Pharmacy	
Closed Door		Specialty Pharmacy	
Drive-through window		White bagging/ clear bagging	
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)		Wholesale Distributor	
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)		Provide prescription drugs for "Office Use" (eg distributes)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	X
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	
Telepharmacy		Sterile Compounding	
Internet Pharmacy		Sterile Hazardous Drug Compounding	

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients	X	CSPs for human patients	
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous		Category 1 CSPs	
Nonaqueous	X	Category 2 CSPs	
Specific types:		Category 3 CSPs	
Solid oral preparations	X	Types of CSPs:	
Liquid oral preparations		Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	
Topical preparations:		Blood-derived or other biological material (eg autologous serum)	
Nasal and sinus preparations:		Sterile injections/ sterile infusions	
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/ Pellets	
		Other (please list):	

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	Facility Size in Square Feet *(can be approximated)* and Number of PECs	Personnel	
Total Pharmacy size:	1,800	Total Pharmacists:	2
Nonsterile Compounding Room size:	200	Number of Compounding Pharmacists:	1
Nonsterile Compounding powder hoods number:	0	Total Student Interns:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	0	Total Technicians:	4
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	0	Number of Compounding Technicians:	1
Sterile Compounding Ante Room size:	0	Of technicians, how many are nationally certified?	2
Sterile Compounding Clean/Buffer Room size:	0	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number LAFW hoods/areas:	0	Total Other Unlicensed Personnel:	1
Sterile Compounding Number BSC hoods:	0	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	4:2
Sterile Compounding Number CAI/CACI hoods:	0	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs:	N/A
Negative Pressure Sterile HD Room size:	0		
Sterile HD Compounding Number of BSC hoods:	0		
Sterile HD Compounding Number of CACI hoods:	0		

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	N/A

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	800	Total Orders Distributed/day:	0
% Veterinary Prescriptions	0%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	Less than1%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	8%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	0%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):

Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)			
Alaska (AK)			
Arizona (AZ)	460	0	November 2025
Arkansas (AR)			
California (CA)			
Colorado (CO)	770	0	November 2025
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)	1,848	0	November 2025
Georgia (GA)			
Hawaii (HI)			
Idaho (ID)			
Illinois (IL)	938	0	November 2025
Indiana (IN)	135	0	November 2025
Iowa (IA)	0	0	November 2025
Kansas (KS)			
Kentucky (KY)			
Louisiana (LA)			
Maine (ME)	0	0	November 2025
Maryland (MD)			
Massachusetts (MA)			
Michigan (MI)			
Minnesota (MN)			
Mississippi (MS)			
Missouri (MO)	452	0	November 2025
Montana (MT)	378	0	November 2025

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States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)			
Nevada (NV)			
New Hampshire (NH)			
New Jersey (NJ)	117	0	November 2025
New Mexico (NM)	54	0	November 2025
New York (NY)			
North Carolina (NC)	655	0	November 2025
North Dakota (ND)	172	0	November 2025
Ohio (OH)			
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)	675	0	November 2025
Rhode Island (RI)	153	0	November 2025
South Carolina (SC)			
South Dakota (SD)	0	0	November 2025
Tennessee (TN)			
Texas (TX)			
Utah (UT)			
Vermont (VT)			
Virginia (VA)			
Washington (WA)	1	0	November 2025
West Virginia (WV)			
Wisconsin (WI)	309	0	November 2025
Wyoming (WY)	160	0	November 2025
Other:			

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Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Infinite Health Pharmacy, Inc
e-Profile ID: 1833352
Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	40 hours.
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	No	
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**	[redacted]	All personnel listed on the pharmacy information module were interviewed.

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Facility Name: Infinite Health Pharmacy, Inc

e-Profile ID: 1833352

Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Notes
Types of Practice Additional Questions If any part of a question is no, enter "No" and explain the observation.			
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	No	
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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Facility Name: Infinite Health Pharmacy, Inc

e-Profile ID: 1833352

Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Notes
General Operations and Licensure	**If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Unknown	Florida licenses and the DEA Certificate are posted as you enter the pharmacy. All posted licenses are current. Non-resident licenses are stored in a three-ring binder except for Washington. It appears the pharmacy shipped one prescription to Washington in November 2025 and does not hold a non-resident license in the state of Washington.
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	Last inspection by the State of Florida Department of Health was on 09/23/2024. Inspections are conducted on a random basis.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	No deficiencies noted.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	

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Facility Name: Infinite Health Pharmacy, Inc

e-Profile ID: 1833352

Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Notes
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	No	
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	All records both electronic and paper are maintained for a minimum of four years.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Infinite Health Pharmacy, Inc

e-Profile ID: 1833352

Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Notes
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	99.9% of prescriptions dispensed are e-scripts.
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	All e-scripts are maintained electronically.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	All dispensing records are maintained electronically in the Pioneer software system.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in herd copy).*	Yes	All dispensing records are maintained electronically in the Pioneer software system.
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	No records are stored offsite.
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	Addressed in P&Ps.

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Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Notes
Personnel	**If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Current licenses are posted in a locked cabinet on the wall as you enter the pharmacy.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	The PIC will conduct annual primary source verification.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	Four technicians to 2 pharmacists.
Facility and Security	**If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	ADT monitors the security system. The system consist of door contacts, glass breakage, motion detectors and in-house camera system.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	Yes	Schedule IIs are stored in a locked cabinet in the pharmacy. The pharmacy no longer dispenses controlled substances. All Schedule IIs will be sent to a reverse distributor.

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		Observation	Notes
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	This would be the responsibility of PIC Rebhandl to secure the drugs until the pharmacy could be secured.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	No destruction on site.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Pharma Logistics is utilized as the pharmacy's reverse distributor. Last returns were on 10/01/2025.
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	N/A	
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	The pharmacy has a private office that could be used for counseling.

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Facility Name: Infinite Health Pharmacy, Inc

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Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Notes
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	The temperature is recorded daily on the days the pharmacy is open. The temperature at time of inspection was 74 degrees F.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	No	Temperature is recorded daily when the pharmacy is open.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	No	The pharmacy would not be aware if an excursion occurred.
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	N/A	The pharmacy does not receive or dispense refrigerated drugs.
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	The pharmacy does not receive or dispense refrigerated drugs. Refrigerated drugs are in the process of being returned to a reverse distributor.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	N/A	

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Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Notes
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	The pharmacy does not receive, store, or dispense frozen drugs.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	No	
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	No	
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	No	The pharmacy would not be aware if an excursion occurred.
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	Yes	2 Kirby Lesters
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	

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		Observation	Notes
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	The pharmacy has a P&P that addresses sources.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	McKesson is primary and Anda is secondary. The pharmacy is only purchasing seven different products to dispense under the new business model.
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Yes	The pharmacy only purchases from NABP Drug Distributor Accredited Wholesalers.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	No	
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	No	

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		Observation	Notes
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	No	
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	The product would be quarantined and the manufacturer contacted.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom raported.*	No	None to date.
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	Yes	
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	No	The pharmacy no longer purchases or dispenses Schedule IIs.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	No	The pharmacy no longer purchases or dispenses Schedule IIs.

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Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Notes
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	A perpetual inventory is maintained in the Pioneer software system of all products and APIs.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports ere made.*	Yes	This pharmacy has not had a diversion but if one occurred the pharmacy would contact the local authorities, the Florida Board of Pharmacy and the DEA if a controlled substance was involved.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	N/A	The pharmacy no longer purchases or dispenses Schedule IIs.

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Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Notes
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	N/A	The pharmacy no longer purchases or dispenses Schedule IIs.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	Last controlled substance inventory was taken on 09/12/2024.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	Last PIC change inventory taken on 10/02/2025.
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	Every 90 days.

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		Observation	Notes
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?		Items that will expire in the next 180 days are pulled from the shelves.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	Yes	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	Yes	

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		Observation	Notes
Prescription Processing	**If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	All patient data is entered by a technician from the e-script and the electronic medical records. The pharmacist at PV2 is verifying the data. Data is updated if a new "Emergency Kit' is ordered or the patient contacts the pharmacy.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animel/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	N/A	The pharmacy does not dispense veterinary prescriptions.
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Unknown	99.9% of the purported prescriptions dispensed are e-scripts received from a telemedicine company, The Wellness Company. The purported prescriptions received are for "Emergency Kit (antibiotic)", quantity of "1", and are "coded" to dispense '1 kit(s) as needed, oral route Compound Ivermectin per protocol.' The protocol for the "Emergency Kit (antbiotic)" contains 8 separate prescription drugs and are dispensed with 8 different prescription numbers. Most of the "Emergency Kits" contain 28 Amoxicillin-Clavulanate 875-125, 12 Azithromycin 250mg, 60 Doxycycline 100mg, 30 Metronidazole 500mg, 28 Trimethoprim-Sulfamethoxazole 160-800, 25 Compounded Ivermectin 12mg Tablets, 2 Fluconazole 150mg, 8 Ondansetron 4mg and a Medical Emergency Kit Guidebook for Reference. These purported prescriptions are dispensed for future use to be determined by the patient (Doc01).
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	If a prescription was suspected to be fraudulent the prescriber would be contacted and if fraudulent the local authorities would be contacted.

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		Observation	Notes
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Unknown	99.9% of the purported prescriptions dispensed are e-scripts received from a telemedicine company, The Wellness Company. The purported prescriptions received are for "Emergency Kit (antibiotic)", quantity of "1", and are "coded" to dispense '1 kit(s) as needed, oral route Compound Ivermectin per protocol.' The protocol for the "Emergency Kit (antbiotic)" contains 8 separate prescription drugs and are dispensed with 8 different prescription numbers. Most of the "Emergency Kits" contain 28 Amoxicillin-Clavulanate 875-125, 12 Azithromycin 250mg, 60 Doxycycline 100mg, 30 Metronidazole 500mg, 28 Trimethoprim-Sulfamethoxazole 160-800, 25 Compounded Ivermectin 12mg Tablets, 2 Fluconazole 150mg, 8 Ondansetron 4mg and a Medical Emergency Kit Guidebook for Reference. These purported prescriptions are dispensed for future use to be determined by the patient (Doc01).
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Both
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	N/A	The pharmacy no longer dispenses controlled substances.
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	N/A	Data is verified by the pharmacist at the PV2 station.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Unknown	Reportedly, the DUR is conducted by the pharmacist at the PV2 station. However, the "Emergency Kits" dispensed contain multiple antibiotics and other prescription drugs (including ivermectin), intended for future use to be determined by the patient. The purported prescription drugs are dispensed for the patient to use in the future. No diagnoses codes were listed on the observed purported prescriptions and the pharmacy is relying on the patient to submit pertinent medical information to the telemedicine company. It is unclear if DUR is truly occurring with multiple antibiotics being dispensed at once (drug duplication). Refer to Doc01.

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		Observation	Notes
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Unknown	The pharmacy utilizes the electronic medical records that the patient has provided to the Wellness Company. The pharmacy has access only to the data provided by the patient. Furthermore, the pharmacy prepares "Emergency Kits" that were prescribed via telemedicine company purported prescription(s) which are "coded" to prepare per protocol. These "Emergency Kits" contain multiple antibiotics and other prescription drugs (including ivermectin), intended for future use to be determined by the patient. It is unclear that DUR is occurring as 99.9% of the pharmacies purported prescriptions are for antibiotic emergency kits and there would be drug duplication with issuing multiple antibiotics. Refer to Doc01.
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	Unknown	The pharmacy reports that they have access to the medical chart from the telemedicine company, which is information that comes from the patient. It is unclear is this is a complete medical review as the two prescriptions reviewed (see Doc01) was blank for medical conditions.
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	The pharmacy does a "Zero" reporting to all states that the pharmacy is licensed in.
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	N/A	The pharmacy no longer dispenses controlled substances under the new business model.
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	All overrides are performed by the pharmacist and documented in the Pioneer system. The pharmacists were documenting their multitude of overrides for drug duplication for the antibiotics in the "Emergency Kits" being dispensed.

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Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Infinite Health Pharmacy, Inc

e-Profile ID: 1833352

Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Notes
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	Medispan
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	N/A	The pharmacy does not dispense veterinary prescriptions.
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	Final verification is by the PV2 pharmacist and is documented in the Pioneer software system.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	As required by Florida Law and Rule.

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		Observation	Notes
70.00	**Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	Pioneer
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	Shred-It picks up every two weeks.
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	

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		Observation	Notes
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	

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Facility Name: Infinite Health Pharmacy, Inc

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		Observation	Notes
Patient Counseling and Communication If any part of a question is no, enter "No" and explain the observation.			
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	Either the pharmacist or the technician.
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
76.01	Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	Either the pharmacist or the technician.
77.00	Does the pharmacist provide counseling for <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	Yes	
77.01	Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	N/A	

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		Observation	Notes
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Pharmacy utilizes FedEx for deliveries. The patient is provided with a toll-free number plus a Guidebook for the Medical Emergency Kit.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	N/A	
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	N/A	Under the new business model, the pharmacy no longer dispense prescriptions that require a PPI.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	N/A	Under the new business model, the pharmacy no longer dispense prescriptions that require a MedGuide.
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	N/A	Under the new business model, the pharmacy no longer dispense prescriptions that are in a REMS program.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	If a prescription is picked up at the pharmacy, counseling is documented electronically and if delivered counseling is documented in the Pioneer system.

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		Observation	Notes
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	Yes	Calls are forwarded directly to the PIC's cell phone after hours.
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	

Quality Assurance/Quality Improvement Program

If any part of a question is no, enter "No" and explain the observation.

87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	PIC Rebhandl
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	Electronic

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		Observation	Notes
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Electronic. No QREs have occurred prior to this inspection.
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	

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		Observation	Notes
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	PIC Rebhandl performs analysis with each event.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	Yes	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	Quarterly meetings with staff.

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		Observation	Notes
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	ISMP
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	

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		Observation	Notes
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	No	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Infinite Health Pharmacy, Inc
e-Profile ID: 1833352
Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)		**Please note NABP did not review each SOP for alignment on USP <795>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes		11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. ***Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.***		Buildings and Facilities for Compounding Non-sterile Preparations 4.0 1.0	4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. ***Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."***		Personnel Training for Non-sterile Compounding 2.0 1.0	2, 11

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Nonsterile Compounding Inspection for USP <795>

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		Observation	Inspector Notes	USP Reference(s)
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. ***Inspector note: Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."***		Personal Hygiene and Garbing for Non-sterile Compounding 3.0 1.0	3.3, 11
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. ***Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."***		Components Used for Non-sterile Compounding 7.0 1.0	6.2, 11
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. ***Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."***		Buildings and Facilities for Compounding Non-sterile Preparations 4.0 1.0	4.2, 11

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Infinite Health Pharmacy, Inc
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Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Inspector Notes	USP Reference(s)
1.6	**Equipment**: The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). ***Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."***		Equipment for Non-sterile Compounding 6.0 1.0	6.1, 11
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. ***Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."***		Components Used for Non-sterile Compounding 7.0 1.0	6.2.5, 11
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. ***Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."***		Master Formulation Records for Non-sterile Compounded Preparations 8.0 1.0	7.1, 11

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Infinite Health Pharmacy, Inc
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Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Inspector Notes	USP Reference(s)
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. ***Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."***		Labeling of Non-sterile Compounded Preparations 11.0 1.0	9, 11
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel; adherence to procedures; and prevention and detection of errors and quality issues. ***Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."***		Inspection and Release of Non-sterile Compounded Preparations 12.0 1.0	11, 12 USP <1163>
1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. ***Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."***		Handling, Packaging and Transport on Non-sterile Preparations 13.0 1.0	1.1.3, 11, 12.1, 12.2, 12.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Infinite Health Pharmacy, Inc
e-Profile ID: 1833352
Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Inspector Notes	USP Reference(s)
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. ***Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."***		Handling, Packaging and Transport on Non-sterile Preparations 13.0 1.0	11, 13.1
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. ***Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."*** ***If the pharmacy does not transport CNSPs, inspector should answer statement as N/A.***		Handling, Packaging and Transport on Non-sterile Preparations 13.0 1.0	11, 13.2
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. ***Inspector note: Per USP, "The facility must have procedures in place to:*** ***- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)*** ***- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy*** ***- Investigate if other lots are affected and recall if necessary*** ***An SOP for recall of dispensed CNSPs must contain:*** ***- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall*** ***- Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution*** ***- Procedures to identify patients who have received the CNSP*** ***- Procedures for disposal and documentation of the recalled CNSP (and)*** ***- Procedures to investigate and document the reason for recall."***		Recall of Compounded Preparations 34.0 1.0	12.1

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		Observation	Inspector Notes	USP Reference(s)
	Designated Person(s) and Personnel Training Program **Inspector must complete the <795> Records Review module to complete this section.**			
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If no, go to compliance statements.***	Yes	The DP is the PIC who is the only compounding person.	1.1.4
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		1.1.4, 12
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***	Yes		1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes	The pharmacist/DP is the only person that compounds.	1.1.4, 2

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		Observation	Inspector Notes	USP Reference(s)
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes		1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	N/A	The pharmacist/DP is the only person that compounds.	1.1.4
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Yes		1.1.4, 11
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.	Yes		1.1.4
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If no, go to compliance statements.***	Yes	The DP is the PIC who is the only compounding person.	2, 14

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		Observation	Inspector Notes	USP Reference(s)
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes		2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	N/A	The pharmacist/DP is the only person that compounds.	2, 14
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** ***If questions 2.0-2.12 in the records review tab for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered no. For details, see the Records Review module.***	Yes		2, 14

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		Observation	Inspector Notes	USP Reference(s)
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel." Inspector should complete the <795> Records Review module question 3.0.***	N/A		2, 14
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***	N/A	The pharmacist/DP is the only person that compounds.	
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.	N/A		3

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		Observation	Inspector Notes	USP Reference(s)
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***	Yes		3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.	N/A	No accommodation has been issued.	3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.	Yes		3.2 Box 1
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***	Yes		3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***	Yes	The pharmacist garb with shoe covers, hair covers, face mask and gown. The pharmacist did not utilize a facial hair cover.	3.3
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.	Yes		3.3
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).	Yes		3.3
6.7	Gowns that are reused do not leave the compounding area.	Yes		3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).	Yes		3.3
6.9	Soiled garb is disposed of or sent for laundering.	Yes	All disposal garb.	3.3
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.	Yes		3.3
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?	N/A	No non-disposable garb.	3.3

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		Observation	Inspector Notes	USP Reference(s)
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.	Yes		4.1
8.2	The compounding area is well lit.	Yes		4.1
8.3	The compounding area is clean and sanitary.	Yes		4.1
8.4	The compounding area is orderly (eg, clutter free, no tripping hazards).	Yes		4.1
8.5	The compounding area is in a good state of repair.	Yes		4.1
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished CNSPs.	Yes		4.1

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		Observation	Inspector Notes	USP Reference(s)
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes		4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.	Yes		4.1
9.0	Is the compounding area free of carpet?	Yes		4.1
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	No		4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes	The temperature is recorded daily on days the pharmacy is open. The temperature at time of inspection was 71 degrees F.	4.2

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		Observation	Inspector Notes	USP Reference(s)
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."***	Yes	Daily temperature logs.	4.2
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.*** ***Monitoring devices are typically calibrated or replaced.***	No		4.2
10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."***	No	The pharmacy would not be aware of a temperature excursion. The temperature is not monitored 24/7.	4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2

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		Observation	Inspector Notes	USP Reference(s)
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.	Yes		4.2
11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***		The temperature at time of inspection was 71 degrees F.	4.2
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.	Yes		4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.	Yes		4.3
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***	No		4.3 USP <1231>

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		Observation	Inspector Notes	USP Reference(s)
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***		Clorox Disinfection Wipes and non-sterile IPA 70%	5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If no, go to compliance statements.***	Yes		5 Table 1
15.1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.	Yes		5 Table 1
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.	Yes		5 Table 1
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components.**	N/A	The pharmacy only compounds with Ivermectin from PCCA.	5 Table 1

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		Observation	Inspector Notes	USP Reference(s)
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.	Yes		5 Table 1
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***	Yes	The pharmacy only began compounding on 10/23/2025.	5 Table 1
15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.	Yes		5 Table 1
15.7	Storage shelving is cleaned and sanitized at least every three months.	Yes		5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
	Equipment and Components FDA defines manufacturer... as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes the activities of relabelers, repackers, and salvagers. When not modified by "domestic" or "foreign," the term includes both domestic manufacturers and foreign manufacturers.			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***	No	The pharmacy does not have any containment enclosure.	6.1
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If no, go to compliance statements.***	Yes	There are no certification reports.	6.1
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***	Yes		6.1

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		Observation	Inspector Notes	USP Reference(s)
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."*** ***If no, inspector should describe observations.***	Yes		6.1
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:*** ***- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;*** ***- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;*** ***- Under the work surface of a BSC is cleaned and sanitized at least monthly; and*** ***- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.*** ***If no, inspector should describe observations.***	Yes		6.1 Table 2

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Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Infinite Health Pharmacy, Inc
e-Profile ID: 1833352
Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Inspector Notes	USP Reference(s)
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***	Yes	The pharmacy utilizes a balance and a tablet press.	6.1
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***	Yes	The balance was calibrated on 12/29/2025.	6.1
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***	N/A		6.1
19.0	Does the pharmacy compounding CNSPs use APIs?	Yes		6.2

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20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*** ***If no, go to compliance statements.***	Yes	The pharmacy only compounds with Ivermectin from PCCA.	6.2.1
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***	Yes		6.2.1
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***	Yes	Doc02_NS20.2	6.2.1
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. Inspector should verify the pharmacy looks up the name of the manufacturer listed on the COA to determine if they are registered as an FDA drug establishment https://dps.fda.gov/decrs.***	Unknown	Only purchase Ivermectin from PCCA.	6.2.1

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		Observation	Inspector Notes	USP Reference(s)
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	N/A	Currently the pharmacy only compounds Ivermectin tablets.	6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***		N/A	6.2.1
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.2
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***	Yes		6.2.2
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	Yes		6.2.2, 14

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		Observation	Inspector Notes	USP Reference(s)
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations , 797 , 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***	N/A	All components have an expiration date.	6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		6.2.2
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.	Yes		6.2.2
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.3, 6.2.4

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		Observation	Inspector Notes	USP Reference(s)
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).	Yes		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	Yes		6.2.3
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.	Yes		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.	Yes		6.2.4
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***	No		6.2.4

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		Observation	Inspector Notes	USP Reference(s)
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).	Yes		6.2.5
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	Yes		6.2.5, 14
26.3	The pharmacy has a readily accessible spill kit in the compounding area.	Yes		6.2.5
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.	Yes		6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.5

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		Observation	Inspector Notes	USP Reference(s)
	Master Formulation Records (MFR) and Compounding Records (CR) **Inspector should review a minimum of five (5) MFRs and five (5) CRs.**			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If no, go to compliance statements.***	Yes	Pharmacy is only compounding Ivermectin 12mg tablets at the present time (Doc03).	7.1
27.1	An MFR is created for each unique formulation.	Yes		7.1 Box2
27.2	Any changes or alterations to the MFR are approved and documented.	Yes		7.1
27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***	Yes		7.1, 10.2 Table 4

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		Observation	Inspector Notes	USP Reference(s)
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***	No		7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	Yes		7.1
28.3	MFR includes the type of container–closure system(s).	No		7.1
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***	No		7.1

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		Observation	Inspector Notes	USP Reference(s)
28.5	MFR has a physical description of the final CNSP.	No		7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	Yes		7.1
28.7	MFR contains the reference source to support the assigned BUD.	No		7.1
28.8	Labeling requirements (eg, shake well) are described on the MFR.	N/A		7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	N/A		7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.	No		7.1
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***	No		7.2, 14
29.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.2, 14

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		Observation	Inspector Notes	USP Reference(s)
29.3	The CR includes the date (or date and time) the CNSP was prepared.	Yes		7.2, 14
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).	Yes		7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes		7.2, 14
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.	Yes		7.2, 14
29.8	The CR includes the weight or measurement of each component.	Yes		7.2, 14
29.9	The CR identifies the total quantity compounded.	Yes		7.2, 14
29.10	The CR lists the assigned BUD and storage requirements.	Yes		7.2, 14

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		Observation	Inspector Notes	USP Reference(s)
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.	Yes		7.2, 14
29.12	The CR has a physical description of the final CNSP.	No		7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	No		7.2, 14
29.14	The CR contains a MFR reference for the CNSP.	No		7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.	Yes		7.2, 8
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.	Yes		7.2, 12.1, 14
30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation. Inspector should describe their observations in the Inspector Notes.***	Yes	The pharmacist is the compounder.	2, 7.2, 8

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		Observation	Inspector Notes	USP Reference(s)
	Labeling			
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		9
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."***	Yes		9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).	Yes		9
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.	N/A	Ivermectin Tablets are stored at room temperature.	9
31.6	The label on the immediate container includes the BUD. ***If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***	Yes	Pharmacy uses "Discard by" as BUD.	9

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		Observation	Inspector Notes	USP Reference(s)
31.7	The label on the immediate container includes the dosage form.	Yes		9
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.	Yes		9
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***	Yes		9
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? ***Inspector note: Per USP, this is a recommendation.***	Yes		9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***	N/A		9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CNSP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.*** ***If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A.***	Yes		9

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		Observation	Inspector Notes	USP Reference(s)
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date."*** ***If no, go to compliance statements.***	Yes		10 USP <7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.	Yes		10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.	Yes	Pharmacy uses "Discard by" as BUD.	10.1
36.3	BUDs are assigned from the date (and time) of preparation.	Yes		10.1
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***	Yes		10.3

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36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		10.4
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If no, who establishes the maximum BUD for a MFR?***	Yes	As per USP <795>.	7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?	No		10.5

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40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If no, go to compliance statements.***	N/A		10.5
40.1	Pharmacy staff have access to the USP monograph for reference.	N/A		10.5
40.2	CNSPs are prepared in accordance with the USP monographs. ***If no, inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed.***	N/A		10.5
40.3	Components used by the compounder match those listed in the monograph. ***If no, describe the source of the component in monograph and the source that the pharmacy used.***	N/A		10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. ***If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.***	N/A		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	Yes	Ivermectin Tablets	10.4

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Infinite Health Pharmacy, Inc
e-Profile ID: 1833352
Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Inspector Notes	USP Reference(s)
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? ***Inspector note: This question is for the CNSPs compounded that are <u>not</u> following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.*** ***If no, go to compliance statements.*** ***If <u>all</u> CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.***	Yes		10.4
42.1	**Non-preserved, Aqueous Dosage Forms:** The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>

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		Observation	Inspector Notes	USP Reference(s)
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.*** ***If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>

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		Observation	Inspector Notes	USP Reference(s)
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?	No		10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If no, go to compliance statements.***	N/A		10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	N/A		10.5
44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.*** ***If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study.*** ***If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.***	N/A		10.5
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***	N/A		10.5
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4; have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***	Yes		1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***	Yes		12
45.2	The QA/QC programs address adherence to procedures.	Yes		12
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.	Yes		12
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***	Yes	No events. The process was reviewed with this Inspector.	12

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		Observation	Inspector Notes	USP Reference(s)
45.5	The QA/QC programs address appropriate investigations and corrective actions.	Yes		12
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?	No		12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.2
47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."***	Yes		12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.	Yes		12.2
47.4	Complaints are fully investigated.	Yes		12.2
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.	Yes		12.2
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***	Yes		12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 12.2
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.*** ***Review most recent recall and describe in the Inspector Notes.*** ***If the pharmacy has not had any recalls within the past two years, inspector should answer the question as No.***	No		12.1, 14

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		Observation	Inspector Notes	USP Reference(s)
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.1, 12.2, 12.3
49.1	The pharmacy has procedures to determine when recalls must be initiated.	Yes		12.1
49.2	The pharmacy documents the implementation of the recall.	Yes		12.1
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).	Yes		1.1.3, 12.1
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	Yes		12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***	Yes		12.1
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If no, go to compliance statements.***	Yes		13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).	Yes		13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).	Yes		13.1

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		Observation	Inspector Notes	USP Reference(s)
	Compounding Personnel Observations - *Inspector must observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with two creams or other drugs) as long as all observations can be viewed.*			
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).	Yes		3.1
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	N/A		3.1

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		Observation	Inspector Notes	USP Reference(s)
54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.2, Box 1
54.1	All personnel who enter the compounding area to compound performed hand hygiene.	Yes		3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3 Box 1
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3 Box 1
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***	Yes		3.2, 3.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1

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		Observation	Inspector Notes	USP Reference(s)
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***	N/A	Pharmacy only compounds with one component (Ivermectin).	3.3
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration.		Ivermectin Tablets 12 mg	
58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	No		2 Box 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.	Yes		3.1, 4.1
58.2	The compounding personnel started with a clean compounding area for CNSPs.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.	Yes		7, 7.1 Box 2
58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***	Yes		6.2 (6.2.1 - 6.2.5)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***	Yes		6.1 Table 2
58.8	The compounding personnel have knowledge of and access to any SDS.	Yes		6.2
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes		1.1.3
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***	Yes		7.1, 7.2 Box 2
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***	Yes		7.2, 14 Box 3

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58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***	Yes		14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If no, describe observations in Inspector Notes.***	No	Compounder weighs sample tablets but no description of final preparation on MFR.	7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.	No	No documentation of proper container closure system.	8.1 Box 2
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***	Yes		9
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***	Yes		7.2, 8, 14 Box 3
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
59.0	**Final CNSP check observation**: Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If no, go to compliance statements.***	No		8, 8.1, 9
59.1	CNSP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).	No	No description of the final preparation.	8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
59.3	CNSP label was verified against the prescription or medication order.	Yes		8, 8.1, 9
59.4	CNSP label was verified against the MFR.	Yes		8, 8.1, 9
59.5	CNSP label was verified against the CR.	Yes		8, 8.1, 9
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	Yes		8, 8.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Infinite Health Pharmacy, Inc
e-Profile ID: 1833352
Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Inspector Notes	USP Reference(s)
59.7	All checks and inspection that are performed are properly documented.	Yes		8.1, 14
59.8	CNSP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal	Yes		8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	N/A	Only compounds one preparation (Ivermectin 12mg tablets).	12
61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If no, go to compliance statements.***	Yes		5

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Infinite Health Pharmacy, Inc
e-Profile ID: 1833352
Inspection Date: 12/23/2025 & 12/30/2025

		Observation	Inspector Notes	USP Reference(s)
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	Yes		5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***	N/A	Only compounds one preparation (Ivermectin 12mg tablets).	5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).	Yes		6.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	Yes		5 Table 1

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Nonsterile <795> Employee File Records Review

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. *Do not record the employee name, list only their title or position.
From the drop-down List:
*Mark as "Yes" if the document is present in the records and the competency evaluation was conducted in compliance with USP <795> requirements.
*Mark as "No" if the document is present in the records but is not in compliance with USP <795> requirements.
*Mark as "Missing" if any part of the record is missing and explain in Notes column.
*Mark as "N/A" if the training does not apply (eg, long-term employee may not have initial training available). Document further in the Notes column.

		Employee Records #1	Employee Records #2	Employee Records #3	Employee Records #4	Employee Records #5	
	Employee Title	DP/PIC					Notes
1.0	The training program provides initial training, evaluation, and documentation on the core competencies listed below:						Only initial training on 10/15/2025
1.1	Compounding personnel are trained on facility SOPs.	Yes					
1.2	Compounding personnel are trained on USP <795> standards.	Yes					
1.3	The training record for hand hygiene is complete.	Yes					
1.4	The training record for garbing is complete.	Yes					
1.5	The training record for cleaning and sanitizing is complete.	Yes					
1.6	The training record for handling and transporting components and CNSPs is complete.	Yes					
1.7	The training record for measuring and mixing is complete.	Yes					
1.8	The training record for proper use of equipment is complete.	Yes					
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes					

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	Employee Title	DP/PIC					Notes
1.10	The training record for interpreting a Certification of Analysis (COA) is complete.	Yes					
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete.	Yes					
1.12	The training record for spill management is complete.	Yes					
2.0	The annual competency assessment was evaluated and documented on the following topics:						
2.1	Compounding personnel are re-trained on facility SOPs.	N/A					
2.2	Compounding personnel are re-trained on USP <795> standards.	N/A					
2.3	The annual competency assessment for hand hygiene is complete.	N/A					
2.4	The annual competency assessment for garbing is complete.	N/A					
2.5	The annual competency assessment for cleaning and sanitizing is complete.	N/A					
2.6	The annual competency assessment for handling and transporting components and CNSPs is complete.	N/A					
2.7	The annual competency assessment for measuring and mixing is complete.	N/A					
2.8	The annual competency assessment for proper use of equipment is complete.	N/A					
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	N/A					

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	Employee Title	DP/PIC					Notes
2.10	The annual competency assessment for interpreting a COA is complete.	N/A					
2.11	The annual competency assessment for how to read/interpret a SDS is complete.	N/A					
2.12	The annual competency assessment for spill management is complete.	N/A					
3.0	The designated person(s) has documented a (periodic) evaluation of their direct observations for compounding activities and documented any deficiencies in the record. *Inspector note: if there are not observations documented, the inspector should answer this question as N/A. Per USP, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*	N/A					

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Glossary & References	USP <795>
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as a bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added Substance	An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient.
Administration	The preparation of a nonsterile pharmacologic or other therapeutic agent for ingesting, inserting, applying, or otherwise providing a nonsterile medication in its final form to a single patient. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.
Alcohol-based hand rub	An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Assigned trainer	One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CNSPs.
Beyond-use date (BUD)	The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.
Biological Safety Cabinet (BSC)	A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
Bulk drug substance	See the entry for Active Pharmaceutical Ingredient.
Certificate of analysis (COA)	A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
Cleaning	The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleaning agent	An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Closed-system processing device	A device designed to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples include CVEs, BSCs, or single-use containment glove bags.

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Glossary & References	USP <795>
Component	Any ingredient used in the compounding of a preparation, including any API, added substance, or conventionally manufactured product.
Compounded nonsterile preparation (CNSP)	A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.
Compounding	The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.
Compounding area	An area that is specifically designated for nonsterile compounding.
Compounding personnel	Personnel trained to compound or oversee compounding of preparations.
Compounding record (CR)	Documents the compounding of each CNSP.
Container closure system	Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.
Containment glove bag	A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE)	A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
Conventionally manufactured product	A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Designated person(s)	One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs.
FDA	US Food and Drug Administration
Formulation	The specific qualitative and quantitative composition of the final CNSP.
Hazardous Drug (HD)	Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low dose in humans or animals; genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See <800>.
Label	The part of the labeling on the immediate container.
Labeling	All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container.

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Glossary & References	USP <795>
Master formulation record (MFR)	A detailed record of procedures that describes how the CNSP is to be prepared.
Monograph	A quality documentary standard within USP–NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Oversight	The review, monitoring, and supervision of actions taken by personnel; bearing responsibility for those actions; and being available if and when needed for consultation, even if not physically present.
Preservative	A substance added to inhibit microbial growth.
Purified water	The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). This source water may be purified using unit operations that include deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See <1231>, 3.1.1 Purified Water.)
Quality Assurance (QA)	A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
Quality Control (QC)	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CNSP.
Reconstitution	The process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.
Release inspection and testing	Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Sanitizing agent	An agent for reducing, on inanimate surfaces, the number of microorganisms (eg, 70% isopropyl alcohol).
SDS	Safety data sheet.
SOP	Standard operating procedure.
Specification	The tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.
Stability	The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Verify	To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Water activity (a_w)	A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Note that a_w is not water content.

To: Board of Pharmacy

RE: Thomas Rebhandl – Criminal Record Disclosure

I am writing to explain the details of the misdemeanor traffic offense arrest noted in my background screen report.

The incident took place on May 25, 2012, and resulted in case number 2012CT012635. The arrest arose out of a driving incident near my home in Palm Beach Gardens, Florida. At that time, I made the mistake of driving while under the influence of alcohol. I was pulled over and cited. Eventually, I was able to plead out of the case and was required to attend Driving Under the Influence School, pay a fine of $250, and complete 25 hours of required community service. The DUI charge was later reduced to reckless driving. The speeding charge was dismissed. Probation was completed successfully.

Please take into account that I learned my lesson and have not had any further incidents of driving under the influence of alcohol or drugs.

Should you have any further inquiries, please contact me:
Thomas Rebhandl
Cell: [redacted]
Email: [redacted]

Thank you for your time and consideration.
Respectfully,

/s/ Thomas Rebhandl

Thomas Rebhandl, PharmD

HASTON
(305) 12002643

[redacted]

FLORIDA DUI UNIFORM TRAFFIC CITATION 9125-XBI

PALM BEACH 06
PALM BEACH GARDENS
PBG 73 AGENCY

FRIDAY 05 25 2012 01:46
THOMAS

1900 N FEDERATION SMALL RD

R153820750890

ALTAIA (Block 13954), PALM BEACH GARDENS

05/27/2012 9125-XBI

3801 PGA [illegible] FL 33410

2012

COMPLAINT

WHEN PRESENTED TO VIOLATOR, THE FOLLOWING AMOUNT WAS ENTERED.
PAY A CIVIL PENALTY IN THE AMOUNT OF $ _____
CASE NO. _____ DOCKET NO. _____ PAGE NO. _____

DATE	COURT ACTION AND OTHER ORDERS
	BAIL FIXED AT $ _____ OR CASH DEPOSIT OF $ _____
	SIGNATURE OF PERSON GIVING BAIL
	SIGNATURE OF PERSON TAKING BAIL
	FINE IN THE AMOUNT OF $ _____ RECEIVED AS REQUIRED BY COURT SCHEDULE
	SIGNATURE OF CLERK
	CONTINUANCE TO _____ REASON _____
	CONTINUANCE TO _____ REASON _____
	BOND EXPIRED
	BOND FORFEITED
	VIOLATOR FAILED TO APPEAR-DRIVER LICENSE SUSPENDED
	VIOLATOR ARRAIGNED ON _____ (DATE)
	PLEA:
	FINDING:
	ADJUDICATION:
	SENTENCE: FINE _____ COST _____
	JAILED _____ DAYS
	DRIVER IMPROVEMENT SCHOOL
	OTHER
	DRIVER LICENSE SUSPENDED OR REVOKED FOR _____ DAYS
	RECOMMEND DRIVER LICENSE SUSPENSION FOR _____ DAYS
	RECOMMEND RE-TEST
	SIGNATURE OF JUDGE
	TESTIMONY - JUDGES NOTES (OR OTHER COURT ORDERS):
	APPEAL BOND OF $ _____
	VIOLATORS FINGERPRINT WHEN APPLICABLE

SHARON R. BOCK, CLERK
PALM BEACH COUNTY, FL
GUN CLUB BRANCH
2012 MAY 25 AM 9:51

SCANNED
MAY 29 2012

4BBB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: [redacted] ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: MEDBRIDGE PHARMACY

Physical Address: 10515 Balboa Blvd. Ste 125

City: Granada Hills State: CA Zip: 91344

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 747-600-9555 Toll Free # (NAC 639.708, NRS 639.23286): 888-719-2209

Fax: 747-600-8866 Contact Email: medbridgepharmacy@gmail.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): _____

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): _____

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Adrineh Keshish	NV Pharmacist Registration #: 24988
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): _____

Corporation/Organization Name: EliteMed Inc.

Mailing Address: 10515 Balboa Blvd. ste 125

City: Granada Hills, State: CA Zip: 91344

Telephone: 747-600-9555 Email: medbridgepharmacy@gmail.com

Contact Person Name: Adrineh keshish

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the owner/PIC (title) for MedBridge Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Adrineh Keshish

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

11/19/20

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Adrineh Keshish hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the owner/PIC (title) for MedBridge Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

_____
Signature

See attached

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

_____
Notary Public

CALIFORNIA JURAT WITH AFFIANT STATEMENT GOVERNMENT CODE § 8202

☒ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], not Notary)

1 _____
2 _____
3 _____
4 _____
5 _____
6 _____

Signature of Document Signer No. 1 *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of LOS ANGELES

SANDRA BONE-GONZALEZ
Notary Public - California
Los Angeles County
Commission # 2465103
My Comm. Expires Oct 2, 2027

Place Notary Seal and/or Stamp Above

Subscribed and sworn to (or affirmed) before me

on this 18th day of NOVEMBER 25
Date *Month* *Year*

by (1) ADRINEH KESHISH

(and (2) _____)

Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature _____
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: AFFIDAVIT FOR PHARMACY LICENSE

Document Date: NOVEMBER 18TH, 2025 Number of Pages: 1

Signer(s) Other Than Named Above: N/A

©2019 National Notary Association

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Adrineh Keshish

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

11/19/2025

Date

Board Use Only	Date Received: 2/23/26	Amount: $500 CHK 4102

BA20252248815

STATE OF CALIFORNIA
Office of the Secretary of State
STATEMENT OF INFORMATION
CORPORATION

California Secretary of State
1500 11th Street
Sacramento, California 95814
(916) 657-5448

For Office Use Only

-FILED-

File No.: BA20252248815
Date Filed: 11/18/2025

Entity Details

Corporation Name	ELITEMED, INC.
Entity No.	5710081
Formed In	CALIFORNIA

Street Address of Principal Office of Corporation

Principal Address	10515 BALBOA BLVD., STE. 125 GRANADA HILLS, CA 91344

Mailing Address of Corporation

Mailing Address	10515 BALBOA BLVD., STE. 125 GRANADA HILLS, CA 91344
Attention	

Street Address of California Office of Corporation

Street Address of California Office	10515 BALBOA BLVD., STE. 125 GRANADA HILLS, CA 91344

Officers

Officer Name	Officer Address	Position(s)
ADRINEH KESHISH	10515 BALBOA BLVD., STE. 125 GRANADA HILLS, CA 91344	Chief Executive Officer
EMILY SHAKHMALIAN	10515 BALBOA BLVD., STE. 125 GRANADA HILLS, CA 91344	Chief Financial Officer, Secretary

Additional Officers

Officer Name	Officer Address	Position	Stated Position
None Entered			

Directors

Director Name	Director Address
ADRINEH KESHISH	10515 BALBOA BLVD., STE. 125 GRANADA HILLS, CA 91344
EMILY SHAKHMALIAN	10515 BALBOA BLVD., STE. 125 GRANADA HILLS, CA 91344

The number of vacancies on Board of Directors is: 0

Agent for Service of Process

Agent Name	ADRINEH KESHISH
Agent Address	10515 BALBOA BLVD STE 125 GRANADA HILLS, CA 91344

Type of Business

Type of Business	PHARMACY

Email Notifications

Opt-in Email Notifications	No, I do NOT want to receive entity notifications via email. I prefer notifications by USPS mail.

B4177-7462 11/18/2025 4:41 PM Received by California Secretary of State

Labor Judgment

No Officer or Director of this Corporation has an outstanding final judgment issued by the Division of Labor Standards Enforcement or a court of law, for which no appeal therefrom is pending, for the violation of any wage order or provision of the Labor Code.

Electronic Signature

☒ By signing, I affirm that the information herein is true and correct and that I am authorized by California law to sign.

Adrineh Keshish	*11/18/2025*
Signature	Date

B4177-7463 11/18/2025 4:41 PM Received by California Secretary of State

California Secretary of State

Business Programs Division
1500 11th Street, Sacramento, CA 95814

ELITEMED, INC.
10515 BALBOA BLVD., STE. 125
GRANADA HILLS, CA 91344

Business Amendment Filing Approved

November 18, 2025

Entity Name: ELITEMED, INC.
Entity Type: Stock Corporation - CA - General
Entity No.: 5710081
Document Type: Statement of Information
Document No.: BA20252248815
File Date: 11/18/2025

The above referenced document has been approved and filed with the California Secretary of State. To access free copies of filed documents, go to **biz**fileOnline.sos.ca.gov and enter the entity name or entity number in the Search module.

What's Next?

The most up to date records may be obtained by searching for the Entity Name or Entity Number in the Search module at **biz**fileOnline.sos.ca.gov.

For further assistance, contact us at (916) 657-5448 or visit **biz**fileOnline.sos.ca.gov.

Thank you for using **biz**file California, the California Secretary of State's business portal for online filings, searches, business records, and additional resources.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler MedBridge Pharmacy

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 10515 Balboa Blvd ste 125

City Granada Hills State CA Zip 91344

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 747-600-9555 Website _____

Licensing Company Email medbridgepharmacy@gmail.com

Section 2: Personal Information

First Adrineh Middle _____ Last Keshish

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name Please see page 2 of 7 Personal History App.		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
MedBridge Pharmacy			09/23-present	
Business Address		**City**	**State**	**Zip**
10515 Balboa Blvd		Granada Hills	CA	91344
Phone	**Title**		**Number of Employed Hours**	
747-600-9555	Owner/PIC		4160	
Description of Duties				
PIC, full time pharmacist on duty				

Business Name			From - To (MM/YY – MM/YY)	
Avita Pharmacy			10/17-08/23	
Business Address		**City**	**State**	**Zip**
6801 Coldwater Canyon Ave		North Hollywood	CA	91605
Phone	**Title**		**Number of Employed Hours**	
(818) 301-6378	staff pharmacist		12,480	
Description of Duties				
full time staff pharmacist				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Adrineh Keshish, **certify that as the designated representative for**

MedBridge Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AK I am at least 21 years of age;
3. AK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Adrineh Keshish

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Adrineh Keshish

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/2025

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

See attached

Notary Public Signature

(Seal)

CALIFORNIA JURAT WITH AFFIANT STATEMENT **GOVERNMENT CODE § 8202**

☑ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], not Notary)

1 _____
2 _____
3 _____
4 _____
5 _____
6 _____

Signature of Document Signer No. 1 *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of LOS ANGELES

Subscribed and sworn to (or affirmed) before me

on this 18th day of NOVEMBER 20 25
Date *Month* *Year*

by (1) ADRIENN KESHISH

(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

SANDRA BONE-GONZALEZ
Notary Public - California
Los Angeles County
Commission # 2465103
My Comm. Expires Oct 2, 2027

Signature _____
Signature of Notary Public

Place Notary Seal and/or Stamp Above

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: DESIGNATED REPRESENTATIVE APPLICATION

Document Date: NOVEMBER 18th, 2025 Number of Pages: 1

Signer(s) Other Than Named Above: NA

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STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Retail Pharmacy Permit

LICENSE NO. PHY 59196

ISSUE DATE SEPTEMBER 13, 2023

MEDBRIDGE PHARMACY
10515 BALBOA BLVD #125
GRANADA HILLS CA 91344

The above is licensed with the State Board of Pharmacy as a Corporation.

CORPORATION
ADRINEH KESHISH

PHARMACIST IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

Renewal Certificate

Retail Pharmacy Permit

CALIFORNIA STATE BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

License No. PHY 59196
Receipt No. 51900725

Valid Until: 9/1/2026

MEDBRIDGE PHARMACY
10515 BALBOA BLVD #125
GRANADA HILLS, CA 91344

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.

This permit is valid only at the address shown

The official status of this license can be verified at www.pharmacy.ca.gov

---- NON-TRANSFERABLE ----- POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19) PHY

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

MedBridge Pharmacy
10515 Balboa Blvd.
Suite 125
Granada Hills, CA 91344

December 3, 2025

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: MEDBRIDGE PHARMACY

License Type: PHARMACY

License Number: PHY 59196

Status: ACTIVE

Issue Date: 09/13/2023

Expiration Date: 09/01/2026

Address of Record: 10515 BALBOA BLVD #125 GRANADA HILLS, CA 91344

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Ann Altamirano
Public Inquiry Analyst
(916) 518-3045
Pharmacy.PublicRecords@dca.ca.gov

MEDBRIDGE PHARMACY

LICENSE NUMBER: PHY 59196 **LICENSE TYPE:** PHARMACY (COMMUNITY)
LICENSE STATUS: CLEAR **EXPIRATION DATE:** SEPTEMBER 1, 2026
SECONDARY STATUS: N/A
CITY: GRANADA HILLS **STATE:** CALIFORNIA **COUNTY:** LOS ANGELES **ZIP:** 91344

Verified 3/2/26 2:25pm

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site MedBridge Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 10515 Balboa Blvd ste 125

City Granada Hills State CA Zip 91344

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 747-600-9555 Website _____

Licensing Company Email medbridgepharmacy@gmail.com

Section 2: Personal Information

First Adrineh Middle _____ Last Keshish

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
CALIFORNIA STATE UNIVERSITY NORTHRIDGE		01/05-06/08	
Address	**City**	**State**	**Zip**
18111 Nordhoff St, Northridge	Northridge	CA	91330
Diploma/Degree obtained, if any			
Bachelors of Science			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
01/16-present				
From - To (MM/YY – MM/YY)				
09/08-01/16				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
MedBridge Pharmacy			09/23- present
Business Address	**City**	**State**	**Zip**
10515 Balboa Blvd. ste 125	Granada Hills	Ca	91344
Phone	**Title**		
747-600-9555	Owner/PIC		
Description of Duties			
Full time Pharmacist, daily operations.			

Business Name			From - To (MM/YY – MM/YY)
Avita Pharmacy			10/17-08/23
Business Address	**City**	**State**	**Zip**
6801 coldwater Canyon Ave	North Hollywood	CA	91605
Phone	**Title**		
818-301-6378	staff pharmacist		
Description of Duties			
full time staff pharmacist.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Adrineh Keshish

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/18/2025

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

See attached

Notary Public Signature

(Seal)

CALIFORNIA JURAT WITH AFFIANT STATEMENT **GOVERNMENT CODE § 8202**

☒ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], not Notary)

1 _____
2 _____
3 _____
4 _____
5 _____
6 _____

Signature of Document Signer No. 1 *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of LOS ANGELES

SANDRA BONE-GONZALEZ
Notary Public - California
Los Angeles County
Commission # 2465103
My Comm. Expires Oct 2, 2027

Place Notary Seal and/or Stamp Above

Subscribed and sworn to (or affirmed) before me

on this 18TH day of NOVEMBER 20 25
Date *Month* *Year*

by (1) ADRINETH KESHISH

(and (2) _____);

Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature _____
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: PERSONAL HISTORY APPLICATION

Document Date: NOVEMBER 18TH 2025 Number of Pages: 1

Signer(s) Other Than Named Above: N/A

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Commingled Medication

Continued from page 4

to its original stocked location because the pharmacist affixed the wrong medication label to the bottle, despite scanning the returned medication. The pharmacy staff committed the error, and the available technology at the pharmacy was unable to prevent the dispensing of the incorrect medication. Moreover, the pharmacist could have identified the error by reviewing the medication with the patient at the time of consultation. This error underlines the importance of reviewing the medication personally with the patient, and pharmacies can encourage patients to agree to have the consultation.

It is of utmost importance for pharmacies to develop policies and procedures and to train their staff on the proper use of any technological solutions a pharmacy has incorporated into their practice. Pharmacists should continue to incorporate safe dispensing practices when verifying a prescription prior to furnishing prescription medications to a patient. By striking a balance between technology integration and ensuring pharmacists still exercise their professional judgment, pharmacies can continue to deliver exceptional customer care while prioritizing patient safety and well-being.

Inspection Results

Enforcement and Compounding Committee Releases Report on Inspections

California has 6,241 licensed pharmacies, and for the past five years the California State Board of Pharmacy has completed approximately 2,900 pharmacy inspections annually. The Enforcement and Compounding Committee released its 2022-2023 fiscal year (FY) report on inspections, and the Board continues to be on track to achieve their goal of inspecting all pharmacies every four years.

Reasons to inspect pharmacies included routine inspection, consumer complaint, probation, and annual compounding renewal inspections.

THE NUMBER OF PHARMACIES INSPECTED IN A FISCAL YEAR:

FY18/19	FY19/20	FY20/21	FY21/22	FY22/23
3,462	2,545	2,963 *2,817 in person/ 146 desk audits	2,938 *2862 in person/ 76 desk audits	3,045

The Board performed desk audits due to COVID restrictions in FY20/21 and FY 21/22

Most Board inspections were completed in pharmacies, which is the largest site licensing program. Sterile compounding pharmacies require mandated renewal inspections, which accounts for close to a third of the Board's total inspections.

Inspections by visit type:

- 922 - routine pharmacy inspection (PHY-PHE)
- 440 - consumer complaint
- 336 - pharmacy on probation
- 940 - Annual compounding renewal inspections
  - 56 new
  - 884 renewal

The remainder of Board inspections were made up of outsourcing inspections and a miscellaneous category. Outsourcing facilities do bulk compounding and may manufacture large batches. These are also mandated inspections, most of the licensed outsourcers are out of state.

See **Inspection Results**, Page 6

4CCC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☐ Controlled substances DEA #: FM1549849 ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: MRH Outpatient Pharmacy

Physical Address: 502 Jackson St Suite 1

City: Aberdeen State: MS Zip: 39730

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Toll Free # (NAC 639.708, NRS 639.23286): 833-877-2215

Fax: _____ Contact Email: _____

Website: https://monroeregionalhospital.com/

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Rose M. Blake

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20992

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Rose M. Blake	NV Pharmacist Registration #: 20992
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Boa Vida Hospital of Aberdeen, MS LLC

Business Name: Boa Vida Hospital of Aberdeen, MS LLC

Business Address: 500 S Chestnut Street

City: Aberdeen State: MS Zip: 39730

Telephone: 662-369-2455 Email: info@boavidahealthcare.com

Section 9: Statement of Responsibility- MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacy Director (title) for MRH Outpatient Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy:
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Rose M. Blake

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

5/15/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Rose M. Blake hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacy Director (title) for MRH Outpatient Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 15th day of May, 2025

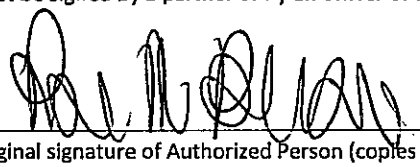
Notary Public

STATE OF MISSISSIPPI NOTARY PUBLIC ID# 22677 LISA D. TOMLIN Commission Expires Oct. 17, 2028 MONROE COUNTY

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rose M. Blake

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

5-15-25

Date

Board Use Only	Date Received: _____	Amount: 500.00/V# 19450

Michael Watson
SECRETARY OF STATE

Office of the Secretary of State
Jackson, Mississippi

Certificate of Good Standing

I, MICHAEL WATSON, Secretary of State of the State of Mississippi, and as such, the legal custodian of the records as required by The Mississippi Registration of Foreign Limited Liabilities Company Act to be filed in my office do hereby certify:

BOA VIDA HOSPITAL OF ABERDEEN, MS, LLC

Registered the 27th day of March, 2017

A Texas LIMITED LIABILITY COMPANY has filed the necessary documents in this office and has obtained a certificate of registration to do business in this state, under the provisions of The Mississippi Registration of Foreign Limited Liability Companies Act as shown by the records in this office.

I further certify that said Limited Liability Company has filed in this office an appointment of registration for service of process, with written acceptance endorsed thereon, and/or power of attorney, designating its agent and/or attorney for service of process in this State as:

InCorp Services, Inc.
302 Enterprise Dr. STE A
Oxford, MS 38655

I further certify that said Limited Liability Company has paid the fees for filing the above papers required by law as shown by the records of this office, and that said Limited Liability Company is in good standing to do business in Mississippi at this time.

Given under my hand and seal of office
the 13th day of March, 2025

Michael Watson

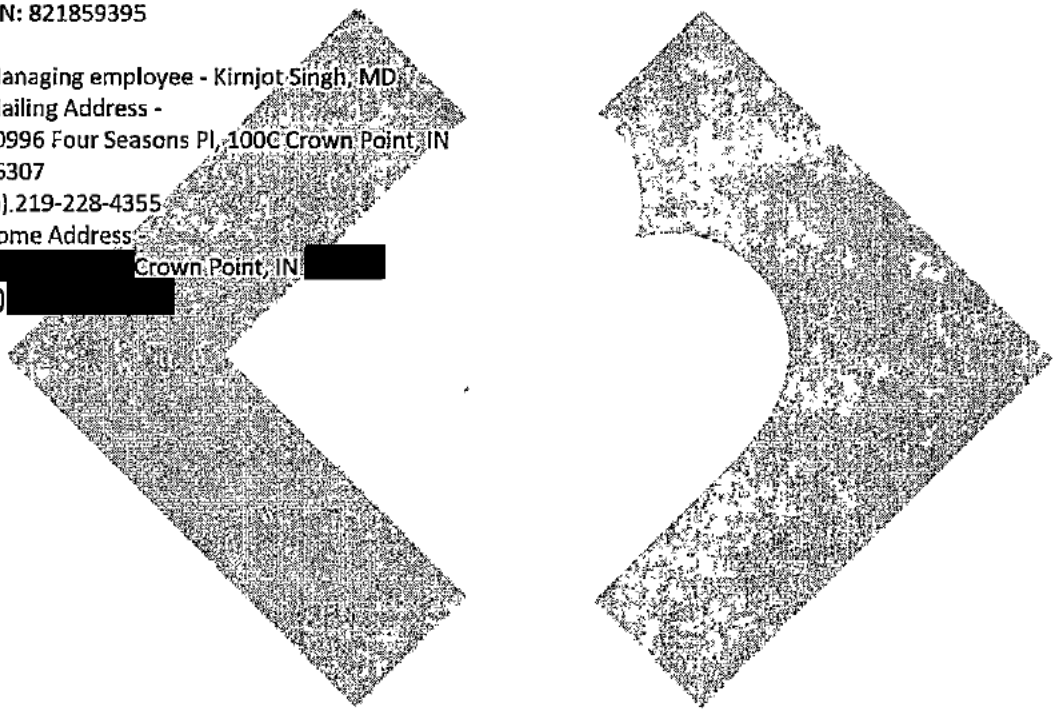
Certificate Number: CN25208516
Verify this certificate online at http://corp.sos.ms.gov/corpconv/verifycertificate.aspx

400 S Chestnut Street
Aberdeen, MS 37903
662-369-2455

MRH Hospital Corporate Structure

Corporate owner - BOA Vida Hospital of Aberdeen MS, LLC D/B/A Monroe Regional Hospital
100% Ownership
Address 400 S Chestnut St, Aberdeen, MS 39730
TIN: 821859395

Managing employee - Kirnjot Singh, MD
Mailing Address -
10996 Four Seasons Pl, 100C Crown Point, IN 46307
(o).219-228-4355
Home Address -
[redacted] Crown Point, IN [redacted]
(c) [redacted]



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler MRH Outpatient Pharmacy

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 502 Jackson St Suite 1

City Aberdeen State MS Zip 39730

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email pharmacy@monroeregionalhopsital.com

Section 2: Personal Information

First Rose Middle Marie Last Blake

Alias(es, nicknames, name changes, etc.) _____

Date of Birth 7-8-61 SSN or ITIN 426291549 Sex ☐ M ☒ F ☐ X

Mailing Address 3891 Lighthouse Lane

City Lakeland State TN Zip 38002

Telephone 901-482-1249 Email rosemarieblake@comcast.net

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Mississippi		08/1982-05/1989	
Address	City	State	Zip
201 Weir Hall	University	MS	38677
Diploma/Degree obtained, if any			
B.S. Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Shannon High School		08/1979-05-1982	
Address	City	State	Zip
218 East Cherry Street	Shannon	MS	38868
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10-2001 to present	[redacted]	Lakeland	TN	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
MRH Outpatient Pharmacy			03/2023 to present	
Business Address		**City**	**State**	**Zip**
502 Jackson St Suite 1		Aberdeen	MS	39730
Phone	**Title**		**Number of Employed Hours**	
662-510-4221	Pharmacy Director		800	
Description of Duties				
dispensing medication, counseling patients, MTM, inventory, managing of employees				

Business Name			From - To (MM/YY – MM/YY)	
,Methodist Healthcare System			02/1991 to present	
Business Address		**City**	**State**	**Zip**
1300 Wesley Drive		Memphis	TN	38116
Phone	**Title**		**Number of Employed Hours**	
901-516-3747	prn pharmacist		20000	
Description of Duties				
served in various capacities. Manager of outpatient pharmacy, clinical pharmacist, dispensing medication, counseling patients, MTM, inventory, managing of employees, IV room, accreditation team				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5-15-25
Date

I, Rose M. Blake, **certify that as the designated representative for**

_____,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RMB I am at least 21 years of age;
3. RMB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RMB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RMB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RMB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RMB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Rose M.Blake

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5-15-25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rose M. Blake

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5-15-25

Date

Please have this section completed in the presence of a Notary Public.

State of MS, ss. County of Monroe

I, Rose M Blake, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5-15-25

Date

Subscribed and Sworn to before me this 15th day of May 2025.

Notary Public Signature

STATE OF MISSISSIPPI NOTARY PUBLIC ID# 22677 LISA D. TOMLIN Commission Expires Oct. 17, 2028 MONROE COUNTY (Seal)

Mississippi Board of Pharmacy

Inspection Details

Name	Permit #	DEA #:	Assigned To
Monroe Regional Hospital	18431 [1.1]		
DBA	**CS #**	**DEA Expiration:**	
MRH Outpatient Pharmacy	CS-19365 - 01/05/2024 (Close)	**Inspection Date**	
Address	**Compounding #**	04/01/2024	
502 Jackson Street Suite 1 Aberdeen, MS 39730 Monroe	**Pharmacist In Charge** Kimberly K Patterson	**Inspection User** Seal, Sid	

Comments

Discussed forgeries

Community

	Answer	Question
1)	Satisfactory	Pharmacist on duty.
2)	Satisfactory	Pharmacy clean and orderly.
3)	Satisfactory	Prescriptions being properly filed. (Article XIII) (Any RX not maintained in a paper file must be printed and provided to an agent immediately)
4)	Satisfactory	Outdated drugs in stock.
5)	Satisfactory	Handling of outdated CS.
6)	Satisfactory	Adequate security of CS.
7)	Satisfactory	CS inventoried properly.
8)	Satisfactory	Ordering/Receiving CII drugs.
		Comments: Cardinal CSOS
9)	Satisfactory	CS prescriptions filled properly.
10)	Satisfactory	Dates on CS Prescriptions.
11)	Satisfactory	Addresses on CS Prescriptions.
12)	Satisfactory	Initials on CS Prescriptions.
13)	Satisfactory	DEA number on CS prescriptions.
14)	Satisfactory	Pharmacy only utilizes suppliers permitted by the Board.
		Comments: Cardinal
15)	Satisfactory	Pharmacy only utilizes Reverse Distributors permitted by the Board.
		Comments: Inmar

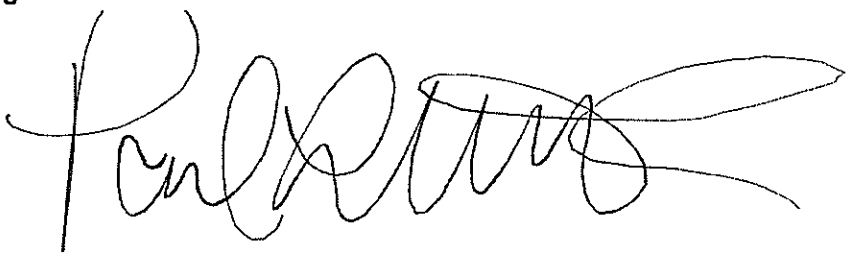
Community

	Answer	Question
16)	Not Applicable	Does the pharmacy provide medications to other pharmacies, physicians or facilities (such as an IEMK)? (Review invoices)
17)	Satisfactory	CS Invoice filed/retrievable.
18)	Satisfactory	CS hard copy printout.
		Comments: Printed weekly
19)	Satisfactory	Patient counseling.
20)	Not Applicable	Schedule V OTC sales.
21)	Satisfactory	Dispensed Rx labeling.
22)	Satisfactory	Technician compliance. (Ratio 3:1, Training/Certification)
23)	Not Applicable	Sterile compounding.
24)	Not Applicable	Non-Sterile compounding.

Person Providing Information

Full Name:
Paul White

Signature:



MISSISSIPPI BOARD OF PHARMACY

6311 Ridgewood Rd, Ste E401 Jackson, MS 39211 39211-2038/TELE: 601-899-8880/FAX: 601-899-8851

May 16, 2025

Nevada Board of Pharmacy
985 Damonte Ranch Parkway
Ste 206
Reno, NV 89521

STATE OF MISSISSIPPI
COUNTY OF HINDS

RE: CERTIFICATION OF RESIDENT PHARMACY PERMIT

MONROE REGIONAL HOSPITAL DBA: MRH OUTPATIENT PHARMACY
Issuance - May 24, 2022
License Number – 18431/1.1
502 Jackson Street
Ste 1
Aberdeen, MS 39730

I, Merrill Garner, Licensing Professional of the Mississippi Board of Pharmacy, certify that as official custodian of the records of the Board and pursuant to a request, do hereby certify that Monroe Regional Hospital dba: MRH Outpatient Pharmacy is currently licensed and in active status with an expiration date of December 31, 2025. There has not been any disciplinary action taken against this permit.

Witness my signature and the seal of the Mississippi Board of Pharmacy this the 16th day of May 2025.

Merrill Garner

Merrill Garner, Licensing Professional
Mississippi Board of Pharmacy

MISSISSIPPI

Board of Pharmacy

Permit #
18431 / 1.1

Pharmacy

Community - Independent

Monroe Regional Hospital
DBA MRH Outpatient Pharmacy
502 Jackson Street
Suite 1
Aberdeen, MS 39730
Monroe

This permit is not transferable or assignable.

Permit Holder:
Rose M Blake

Issued: 05/24/2022
Renewed: 03/05/2025
Expires: 12/31/2025

Executive Director

Mississippi Board of Pharmacy | 6360 I-55 North | Suite 400 | Jackson, MS 39211
Phone: 601-899-8880 | Fax: 601-899-8851

MISSISSIPPI BOARD OF PHARMACY

LICENSE VERIFICATION

The Mississippi Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, as well as performing hourly updates to the information represented. Therefore, the website is a secure and primary source of credential verification information, as authentic as a direct inquiry to the Board.

MRH Outpatient Pharmacy

Pharmacy

Permit Status:	Active	**Issued Date:**	05/24/2022	**Discipline on File:**	No
Permit #:	18431	**Effective Date:**	12/01/2025	**Discipline Status:**	No Discipline
Classification:	Community - Independent	**Expire Date:**	12/31/2027	**Address:**	502 Jackson Street Suite 1 Aberdeen, MS 39730
Manager Name:	Rose M Blake				

Controlled Substance Registration

Status:	Active	**Issued Date:**	05/24/2022
Number:	CS-19365	**Effective Date:**	12/01/2025
		Expire Date:	12/31/2026

Compounding Certificate

No compounding certificate found!

Public Records

No disciplinary documents were found!

Information loaded from this database is current as of 2/18/2026 4:44:56 PM

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FM1549849	01-31-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	12-21-2024

MRH OUTPATIENT PHARMACY
MONROE REGIONAL HOSPITAL
502 JACKSON ST
STE 1
ABERDEEN, MS 39730

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D C 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FM1549849	01-31-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	12-21-2024

MRH OUTPATIENT PHARMACY
MONROE REGIONAL HOSPITAL
502 JACKSON ST
STE 1
ABERDEEN, MS 39730

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended provide that the Attorney General may revoke or suspend a registration to manufacture, distribute dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: MRH Outpatient Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 502 Jackson St Suite 1

City: Aberdeen State: MS Zip: 39730

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Licensing Company Email: _____

Section 2: Personal Information

First: Kirnjot Middle: _____ Last: Singh

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Winfield State: IN Zip: [redacted]

Telephone: [redacted] Email: ksingh@boavidahealthcare.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
IU School of Medicine		1996 - 2001	
Address	**City**	**State**	**Zip**
340W 10th Street	Indianapolis	IN	46202
Diploma/Degree obtained, if any			
Ortho Surgery			

School Name		From - To (MM/YY – MM/YY)	
UTMB		1992 - 1996	
Address	**City**	**State**	**Zip**
301 University Blvd	Galveston	TX	77555
Diploma/Degree obtained, if any			
Medical			

School Name		From - To (MM/YY – MM/YY)	
University of Texas		1990 - 1992	
Address	**City**	**State**	**Zip**
110 Inner Campus Drive	Austin	TX	78712
Diploma/Degree obtained, if any			
BA			

School Name		From - To (MM/YY – MM/YY)	
HS for Health Professionals		1985 - 1988	
Address	**City**	**State**	**Zip**
2545 Pressler Street	Houston	TX	
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/05 - current	[redacted]	Crown Point	IN	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	X	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	X	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	X	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4,5,6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Monroe Regional Hospital - Multiple employee related litigations. All settled or ruled in our favor.

Kirnjot Singh, MD - License Issues

Original Signature (electronic, copies or stamps not accepted)

7/21/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kirnjot Singh

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/21/25

Date

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Lake

I, Kirnjot Singh, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/21/25

Date

Subscribed and Sworn to before me this 21st day of July 2025

Deana Przybyl

Notary Public Signature

DEANA PRZYBYL
My Commission Expires
August 26, 2028
Commission Number NP0637942
Porter County

(Seal)

Monroe Regional
Hospital

400 S. Chestnut St.
Aberdeen, MS 39370

August 4, 2025

RE: License Action Summary; Kirnjot Singh, MD

To Whom it May Concern:

In Feb 2007, the AG of Indiana instituted an investigation into an alleged boundary violation emanating from a single encounter with a former patient in Oct 2005. This culminated in the filing of a formal complaint by the AG's office in July 2007.

Upon the advice of counsel, I entered a settlement agreement, in October 2007, with the Indiana Attorney General's Office in response to the complaint filed by them in July 2007. The settlement agreement placed my IN license on probation, among other things, beginning in October 2007. This was officially removed in October 2008. As of October 2008, I have an unrestricted, clear IN medical license.

In June 2008, the NY medical board ordered my inactive NY medical license revoked based upon the IN action. This was upheld on appeal to the administrative review board in October 2008. I filed an unsuccessful Article 78 appeal in the Supreme Court of Albany, NY in the winter of 2008. I successfully petitioned three times to modify the discipline, since my IN License is unrestricted as of October 2008, resulting in the removal of the revocation, stayed revocation with certain conditions, and then finally all conditions. I had an unrestricted, clear NY medical license as of May 2019. In 2010, the Medicaid Inspector General issued a reprimand based on the actions of the NY medical board.

The IL Department of Professional Regulation ordered a retroactive probation in March 2009. The term of this probation was to be concurrent with the IN term. Therefore, as of October 2008, I had an unrestricted, clear IL medical license. Both of my IL and NY license are currently inactive.

Should you have any questions, please contact me.

Sincerely,

Kirnjot Singh, MD

4DDD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☐ New Pharmacy ☑ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 03634	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: Community	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: PGBB LLC DBA Specialty Care Rx

Physical Address: 200 E Katella Ave Ste A

City: Orange State: CA Zip: 92867

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 714-941-6177 Toll Free # (NAC 639.708, NRS 639.23286): 844-794-4844

Fax: 714-941-6178 Contact Email: ocinfo@myscrx.com

Website: www.myscrx.com

Nevada Business License # (if applicable) NV20232829989

Supervising/Managing Pharmacist Name (NRS 639.220): Hamid Javaheri

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24139

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Hamid Javaheri	NV Pharmacist Registration #: 24139
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A
Name: N/A	NV Pharmacist Registration #: N/A

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): N/A

Corporation Name: N/A

Mailing Address: N/A

City: N/A State: N/A Zip: N/A

Telephone: N/A Email: N/A

Contact Person Name: N/A

Date of SEC Registration: N/A | SEC Registration Number: N/A | Stock Exchange Symbol: N/A

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: CA

Parent Company (if any): BPJ LLC

Corporation/Organization Name: PGBB LLC

Mailing Address: 200 E Katella Ave Ste A

City: Orange State: CA Zip: 92867

Telephone: 714-941-6177 Email: ocinfo@myscrx.com

Contact Person Name: Blanca Monterroza

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: N/A

City: N/A State: N/A Zip: N/A

Telephone: N/A Email: N/A

Contact Person Name: N/A

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: N/A

Business Address: N/A

City: N/A State: N/A Zip: N/A

Telephone: N/A Email: N/A

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Managing Member (title) for PGBB LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Brenda Brown

Print Name of Authorized Person

Brenda Brown (Jan 16, 2026 16:48:17 CST)

Original signature of Authorized Person (copies or stamps not accepted)

01/16/2026

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Texas)
) ss.
Collin COUNTY)

I, Brenda Brown, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Managing Member. for PGBB LLC dba Specialty Care RX (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Brenda Brown., do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Brenda Brown
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
23 day of December, 2025.

NOTARY PUBLIC

BRYAN CULP BAKER
Notary Public, State of Texas
Comm. Expires 02-22-2026
Notary ID 133604919

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brenda Brown

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Brenda Brown (Jan 16, 2026 16:48:17 CST)

Original signature of Authorized Person (copies or stamps not accepted)

01/16/2026

Date

Board Use Only	Date Received: _____	Amount: 500.00 / #005246

Specialty Care Rx
Excellence is Our Specialty

200 E. Katella Ave, Suite A
Orange, CA 92867
T (714) 941-6177
www.myscrx.com

January 7, 2026

Dear Nevada Board of Pharmacy:

Please find below the list of the LLC members/officers for the enclosed ownership information.

BPJ LLC

Top 4 Members

1. Brenda Brown-30%
2. Jeffrey Griffith-10%
3. Bhav Patel-21% (CasaFusion LLC)
4. Yatin Patel-9% (CasaFusion LLC)

Other Members

1. Grace Duarte-10%
2. Brandon Walend-10%
3. Gilbert Ursulo-10%

Please let us know if you have any questions or need further information.

Thank you,

Specialty Care Rx
Excellence is Our Specialty
Specialty Care Infusion Center
Care for life

Chat with me on Teams

Blanca Monterroza
Director of Contracts and Regulatory Affairs, CPhT/PRS
Specialty Care Rx
(949) 506-1300 Ext.270
[redacted]
(866) 511-4654
bmonterroza@myscrx.com

We keep our patients at the center of everything we do!

Specialty Care Rx
Excellence is Our Specialty

200 E. Katella Ave, Suite A
Orange, CA 92867
T (714) 941-6177
www.myscrx.com

January 6, 2026

RE: Change of Ownership-PGBB LLC (License PH03634) and PBC LLC (License PH03749)

Dear Nevada Board of Pharmacy:

This is to further notify you of the change in ownership of our 2 locations specified above. The initial notification was given on December 12, 2025, when I spoke with Kristy at extension 131.

The change involves the current ownership being bought by a parent/holding company (BPJ LLC). However, the TIN, DBA and legal business name will not change. I have attached an organizational chart within the documents included and have summarized below the CHOW for your reference and convenience when reviewing our application.

Previous: Owner/License/DBA	**Change: New Parent Company**
PGBB LLC/ PH03634	BPJ LLC
Specialty Care Rx	All other information Same as previous

Previous: Owner/License/DBA	**Change: New Parent Company**
PBC LLC/ PH03749	BPJ LLC
Specialty Care Rx	All other information Same as previous

Please let me know if you have any questions or need further information to process the application.

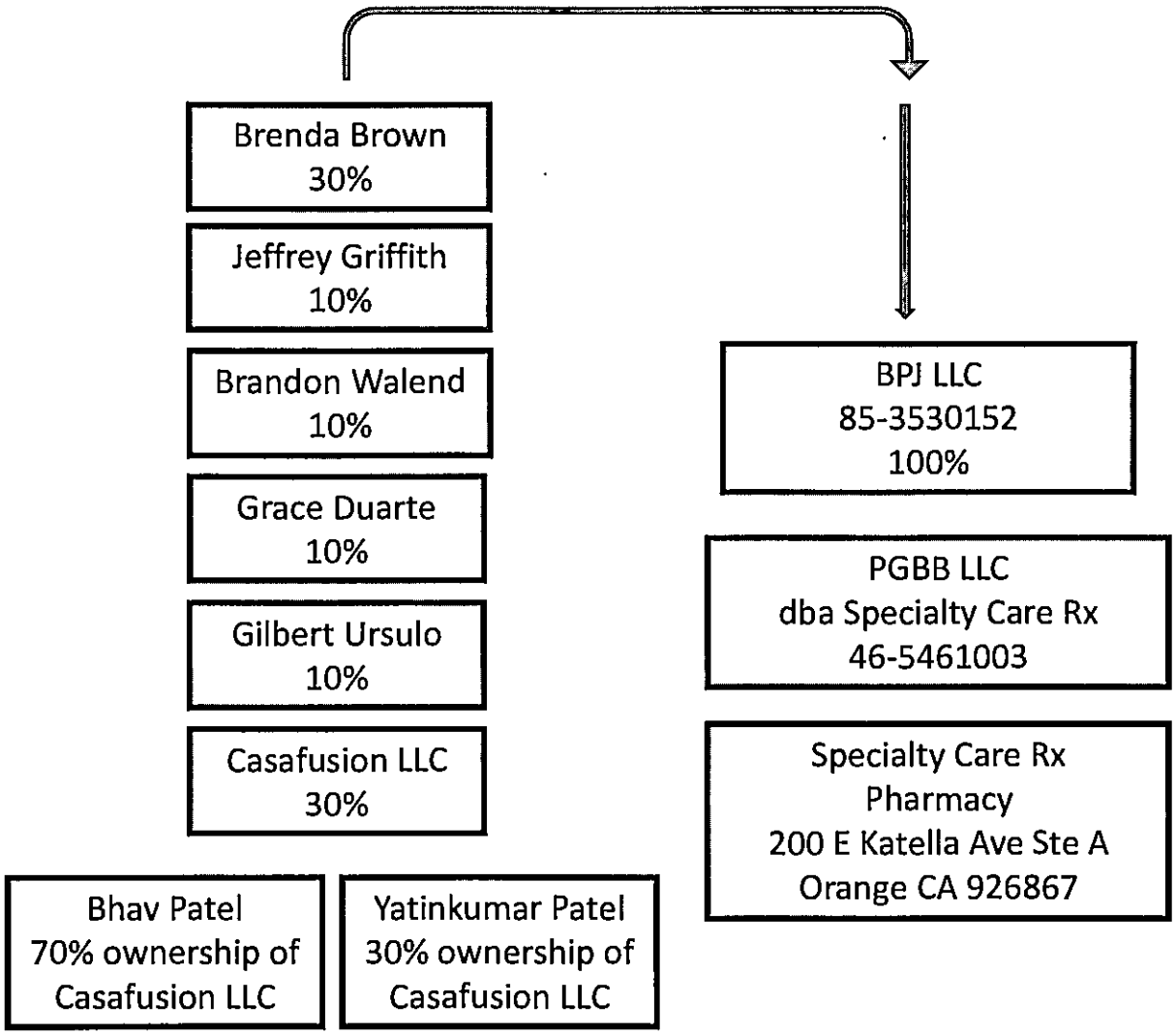
Thank you,

Specialty Care Rx
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Specialty Care Infusion Center
Care for life

Chat with me on Teams

Blanca Monterroza
Director of Contracts and Regulatory Affairs, CPhT/PRS
Specialty Care Rx
(949) 506-1300 Ext.270
[redacted]
(866) 511-4654
bmonterroza@myscrx.com

We keep our patients at the center of everything we do!


Brenda Brown
30%
Jeffrey Griffith
10%
Brandon Walend
10%
Grace Duarte
10%
Gilbert Ursulo
10%
Casafusion LLC
30%
Bhav Patel
70% ownership of
Casafusion LLC
Yatinkumar Patel
30% ownership of
Casafusion LLC
BPJ LLC
85-3530152
100%
PGBB LLC
dba Specialty Care Rx
46-5461003
Specialty Care Rx
Pharmacy
200 E Katella Ave Ste A
Orange CA 926867

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the reeords of the Nevada Secretary of State, at the date of this certificate, evidence **PGBB LLC** as a FOREIGN LIMITED-LIABILITY COMPANY duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 06/22/2023, and in good standing in this State.

I further certify that the above FOREIGN LIMITED-LIABILITY COMPANY has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 01/05/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202601056396890
You may verify this certificate
online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PGBB LLC DBA Specialty Care Rx

Pharmacy/Wholesaler License # (if applicable) PHY 59102

Physical Address 200 E Katella Ave Ste A

City Orange State CA Zip 92867

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 714-941-6177 Website www.myscrx.com

Licensing Company Email ocinfo@myscrx.com

Section 2: Personal Information

First Hamidreza Middle _____ Last Javaheri

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Tabriz University of Medical Science		10/87- 10/93	
Address	**City**	**State**	**Zip**
Golgasht Street	Tabriz	EAP	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Beheshti High School		10/83-3/87	
Address	**City**	**State**	**Zip**
Shohada Squaer, Moalem Blvd	Khomein	Markazi	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/22- present	[redacted]			
09/15-12/22				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Specialty Care Rx			10/23- Present
Business Address	**City**	**State**	**Zip**
200 E Katella	Orange	CA	92867
Phone	**Title**	**Number of Employed Hours**	
714-941-6177	Clinical Pharamcist	4000	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Specialty Care Pharamcy			04/18-10/23
Business Address	**City**	**State**	**Zip**
2140 Chapman Ave	Orange	CA	92868
Phone	**Title**	**Number of Employed Hours**	
714-941-6177	Pharmacy Technician	9000	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Hamidreza Javaheri, **certify that as the designated representative for**

Specialty Care Rx,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. HJ I am at least 21 years of age;
3. HJ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. HJ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. HJ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. HJ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. HJ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Hamidreza Javaheri

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/6/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hamidreza Javaheri

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/6/26

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Orange

I, Hamidreza Javaheri, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/6/26

Date

Subscribed and Sworn to before me this 6th day of January 2026

Notary Public Signature

SADHANA K. MALINE
Notary Public - California
Orange County
Commission # 2528013
My Comm. Expires Jul 24, 2029

(Seal)

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GAVIN NEWSOM, GOVERNOR

BE AWARE & TAKE CARE
Talk to your pharmacist!

CALIFORNIA
Board of Pharmacy

To: Specialty Care Pharmacy PHY 59102 **Fax:** ((714) 941 6178

Lora Ghaly (RPH74977) (PIC)

From: Michael Ajayi **Pages:** 8 **including cover sheet**

[redacted]

Phone: [redacted] **Date:** 03/11/2024

Re: Routine Inspection Report

x **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• **Comments: Attention PIC Ghaly. Sign and send back immediately.**

California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 3/5/2024 Inspector: Michael Ajayi

Firm: SPECIALTY CARE RX Phone: (714) 941-6177

Address: 200 KATELA AVE #A City: ORANGE Zip: 92867

Ownership: CORPORATION

Permit #: PHY59102 Permit Exp: 12/1/2024 DEA#: [redacted] DEA Exp: 3/31/2027

Date of Self Assessment Form: 12/11/2023 Other Permit #: N/A Date of DEA Inventory:

Hours M-F: 9AM-5PM Hours Saturday On Call Hours Sunday: On Call

PIC LORA S GHALY RPH74977 Administrator

KARIM A TOBGY RPH80786

RPH Consultant

Staff RPH Name:	License #:	Staff Name:	License #:
RAFIK RAMY R BOCTOR	RPH83587	ANN RAE E PABALINAS	TCH65292
HAMIDREZA JAVAHERI	RPH88462	GUSTAVO SOTO	CLERK

Inspector Remarks:

Routine Pharmacy Inspection Assisted by pharmacist in charge Lora Ghaly (RPH74977) Specialty Cared pharmacy moved to a new location in December 2023. Pharmacy dispenses an average of 7-9 patient and 45 prescriptions/day. 80% of them being refills and 20% new prescriptions. Pharmacy is licensed in 6 other states. With locations in Nebraska, Washington, Michigan, Nevada, Minnesota and Pennsylvania. Pharmacy dispenses IVIG, and factors.
Pharmacy get patients and prescriptions through referral from doctor's office. SCRX services patient in the orange county and Los Angeles area. 40% of the drugs are hand delivered by the drivers. FedEx shipments to Norcal patients.

- Notice to Consumers and Interpretive services posters posted
- DEA license; reviewed
- Zero control inventory
- Medication reconciliation: discussed zero count Pharmacy does not have control medications
- Drugs are package and shipped using the Temperature sensor monitor (Elitech) to confirm integrity
- Pharmacy operating software: CareTend ©: Intake and
- Community Pharmacy & Compounding Self-Assessments
- Biennial Controlled Substance Inventory reviewed, reviewed
- Medication reconciliation: reviewed
- Interpretive Services: Language Line Solution
- Identification badges & pharmacist to technician ratio observed
- Hot and cold running water and accessible restroom available
- Refrigerator and freezer-temperature logs observed DicksonOne ©
- Consultation- discussed patient information sheet with SCRX phone line and access to RPH for consultation
- Medication inventory & expired medications: Biennial inventory reviewed

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Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

- Educated PIC on the new laws
- Pharmacist signs for delivered medications
- Board's email subscription: PIC Ghaly is subscribed to the Board's email. Educated PIC to have all licensee subscribe to the Board's email.
- All pharmacists registered with CURES. PIC Ghaly is still registered . I discussed the new laws concerning CURES and 24 hour reviews.
- Quality assurance reporting
- Policies and procedures: QA for Medication Errors, Technician Job Description, Theft and Impairment, Immunizations, Temporary Absence of the Pharmacist-maintained on-line
- Two new infusion room not operational now. SCRX plans to hire nurses to work and administer drugs
- Wholesaler: McK, Special care distribution
- Reverse Distributor: McKesson, Reverse Distributor

The Script:

- Latest edition, August 2022 The Script is available at www.pharmacy.ca.gov.
- Topics include: Top citations FY 2021/2022, Article: Law forbids quotas for pharmacy duties, Pharmacy Well-Being Index, Article: ISMP can help reduce medication errors, Free webinar training available to pharmacists furnishing HIV PrEP/PEP, Updated 2022 pharmacy law webinar available to view online for CE credit, California Health Workforce Research Data Center News Update, Board re-elects officers, new members and retired members, Disciplinary actions for January – June 2022, and much more.

Monkey Pox Issues:

- **Waiver related to MPX Emergency: Dispensing Tecovirimat to ER Patients** – Effective 8/3/2022; Expires 90 days following the end of the declared emergency.
  - Waives BPC 4068(a)(1), 4068(a)(5), 4068(a)(6), BPC 4076.5 and 4427.2(a) under specific conditions.
- **Interim guidance: Intradermal administration of JYNNEOS smallpox and monkeypox vaccine recommended to extend scarce supplies.**
  - Allows properly trained pharmacists and intern pharmacists **only** to administer intradermal doses of JYNNEOS pursuant to Business and Professions Code section 4052.8.

Covid- 19 Issues:

- CDPH issues Joint Statement on Authorization of Updated Moderna and Pfizer-BioNTech Boosters.
- Updated COVID-19 boosters: Most Californians are now eligible for an updated Moderna or Pfizer-BioNTech booster and will be able to strengthen their protection against COVID-19. Both boosters are bivalent, which means they are pulling double duty by increasing immunity against the original coronavirus strain while also protecting against the newer Omicron variants. The updated boosters are a safe way to maintain protection and reduce the most severe outcomes of COVID-19.
- To be eligible, individuals must have completed their primary series dose(s) at least two months prior to receiving an updated booster. Individuals are eligible to receive the updated booster regardless of previous booster doses received.
- The updated bivalent boosters will now replace the existing monovalent booster vaccines for individuals 12 years of age and older. Children ages 5-11 can still boost their immunity with the monovalent boosters.

Community Pharmacy Staffing – BPC 4113.5, CCR 1714.3:

- A community pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located, is made available to assist the pharmacist at all times.
- Pharmacies not required to comply are listed in BPC 4113.5(b).
- Actions against the pharmacy will not be taken if they meet both of the criteria listed in BPC 4113.5(d).

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Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

- For pharmacies subject to BPC section 4113.5. CCR section 1714.3 requires that when the pharmacy is open to the public and the pharmacist is working without another pharmacy employee currently working, the pharmacy must make another person who is an employee of the establishment within which the pharmacy is located available to assist the pharmacist. The pharmacy must:
  - Designate the name(s) of one or more persons who will be available to assist the pharmacist.
  - Ensure each designated person is able, at a minimum, to perform the duties of non-licensed pharmacy personnel as specified in CCR 1793.3.
  - Ensure each designated person qualifies to have access to controlled substances by conducting a background check on each person that is consistent with federal requirements for pharmacy employees with such access.
  - Ensure a designated person responds and is able to assist the pharmacist within 5 minutes after the pharmacist's request. Pharmacists must request the assistance.
- Maintain policies and procedures on: (1) how the pharmacist on duty will be able to identify the designated person(s) as available to assist them, and the required criteria and training for the designated person(s); , (2) the process for the pharmacist to request assistance and to document the response time between the request and arrival of the designated person at the pharmacy; and (3) maintained in the pharmacy premises in a readily retrievable format.
- All impacted employees must read and sign a copy of the policies and procedures.

Recently approved changes in existing regulations or new regulations:

This section details recent changes to regulations or new regulations and only provides a summary. You can and should review the full text of these rules at Laws and Regulations - California State Board of Pharmacy.

- **CCR 1746.4 – Pharmacists initiating and administering vaccines (Effective 1/25/2022).** Based on the recent changes, at the request of a patient, a pharmacist must notify each patient's primary care provider of any vaccine administered to the patient or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider, and must take place within 14 days of the administration of any vaccine.
- **CCR 1704- Providing addresses (Effective 4/1/2022).** Each applicant or person holding a certificate, license, permit, registration, or exemption to practice who has an electronic mail address must provide to the Board that electronic mail address and must maintain a current electronic mail address, if any, with the Board and, within 30 days, must notify the Board of any change of electronic mail address, giving both the old and new electronic mail address.
- **CCR 1715.6 – Reporting drug loss (Effective 4/1/2022).** The owner must submit to the Board a report specifying the identity, amount, and strength of each controlled substance lost, and date of discovery of the loss, for all losses that have made the report necessary. The report must be submitted within 30 days after the date of discovery of the following:
  - Any loss of controlled substances in one of the following categories that causes the aggregate amount of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed: (a) 99 dosage units for tablets/capsules/other oral medications; (b) 10 dosage units for single-dose injectable medications/lozenges/oral, buccal and sublingual film/suppositories/patches; (c) 2 or more multi-dose vials/infusion bags/other containers for injectable multi-dose medications administered by continuous intravenous infusion, or any other multi-dose unit not described.
  - Any loss of a controlled substance, regardless of the amount, attributed to employee theft in addition to the requirements of BPC 4104.
  - Any significant loss as determined by the PIC, including but not limited to losses deemed significant relative to the dispensing volume of the pharmacy.
- **CCR 1717.5 – Automatic Refill Programs. (Effective 7/1/2022)**

  To have an automatic refill program, a pharmacy:

  - Must have written policies and procedures describing the program and how it will comply with the rule requirements.
  - Must, before a patient enrolls, provide a written or electronic notice summarizing the program to the patient or patient's agent that, at minimum, includes instructions on how to withdraw a prescription medication from the refill

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

program or how to disenroll entirely from the program.

- Must ensure that a patient or patient's agent enrolls by written, online, or electronic informed consent to participate in the program for each new prescription when there is a change in prescription medication/strength/dosage form/direction for use.
- Must obtain from the patient or patient's agent annual renewal of each prescription in the program no later than 12 months after the prescription is enrolled in the program.
- Must keep a copy of the written or electronic informed consent to enroll on file for one year from date of dispensing, maintain the documentation of the withdraw/disenrollment instructions received for one year and any notice sent to a patient or patient's agent, or notification of withdrawal/disenrollment received from patients, or their agents must be maintained for a minimum of one year.
- Must complete drug regimen review for each prescription refilled through the program at the time of refill.
- Must provide a written or electronic notification to the patient/patient's agent confirming each time a prescription medication is being refilled through the program.
- The patient/patient's agent must at any time be able to withdraw a specific prescription medication from the auto-refill program or disenroll entirely from the program, and the pharmacy must provide confirmation of the withdrawal or disenrollment from the program to the patient or their agent.
- The pharmacy must provide a full refund if the patient did not want the refill, regardless of the reason, or the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the refilled prescription medication.
- Notifications must be available in alternate languages as required by state or federal law.
- Does not apply to licensed health facilities defined by HSC 1250.
- Pharmacies refilling prescription for inmates of an adult correctional facility or juvenile detention facility need not comply with this rule if the facility has written policies and procedures describing how a patient may request a medication be automatically refilled and how a patient may refuse the medication.

- **CCR 1715 – Self-Assessment of a pharmacy by the PIC. (Effective 10/1/2022)**
  - Revised and adopted 1/2022 version of the Community/Hospital Outpatient Pharmacy (17M-13) and the Hospital Pharmacy Self-Assessments are available on the board's website.
  - For each "no" response, the PIC must provide a written corrective action or action plan to come into compliance with the law, must initial each page with original handwritten initials on the self-assessment, certify on the final page he/she completed the self-assessment and certify a timeframe within which any deficiency identified will be corrected.
  - The pharmacy owner or hospital administrator must also certify the final page of the self-assessment
- **CCR 1708.1 – Notification of Temporary Closure. (Effective 10/1/2022)**
  - A permit holder (except for correctional pharmacies) must notify the board of any temporary closure of a facility as soon as any closure exceeds three (3) consecutive calendar days.
  - Closure dates will be public information.
  - A temporary closure does not include a routine closures (including weekends or state and federal holidays) unless that closure exceeds four (4) consecutive calendar days.
- **CCR 1715.65 – Inventory Activities and Inventory Reconciliation Reports of Controlled Substances. (Effective 1/1/2023)**
  - Every pharmacy and every clinic (BPC 4180, 4190) must perform periodic inventory activities and prepare inventory reconciliation reports to detect and prevent the loss of "federal" controlled substances.
  - Inventory reconciliation reports must be prepared on the following ongoing basis:
    (1) For federal Schedule II controlled substances, at least once every three months.
    (2) For products containing the following substances in the following strengths per tablet/capsule/other unit/specified volume, at least once every twelve months: Alprazolam 1mg/unit, Alprazolam 2mg/unit, Tramadol 50mg/unit, Promethazine/Codeine 6.25mg/10mg per 5ml.
    (3) For any controlled substance not listed above, an inventory reconciliation report must be prepared for identified

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controlled substances lost no later than three months after discovery of the reportable loss. A report is completed if the loss is discovered either by inventory activities required above or in any other manner. The report must cover the period from the last physical count of that controlled substance before the loss was discovered through the date of discovery. A reportable loss is specified in CCR 1715.6 or any pattern of losses identified by the PIC defined by policies and procedures. A reportable loss must require an inventory reconciliation report for each pattern of loss identified. Inventory activities for each controlled substance not covered in (1) and (2) must be performed at least once every two years from the performance of the last inventory activities.

- Defines "inventory activities" to mean inventory and all other functions sufficient to identify loss of controlled substances. The functions sufficient to identify loss outside of the inventory reconciliation process must be identified within the pharmacy's policies and procedures.
- The PIC or consulting pharmacist of a clinic must review all inventory activities performed and inventory reconciliation reports prepared and establish and maintain secure methods to prevent losses of federal controlled substances.
- **Inventory reconciliation report must include:** (1) physical count, not an estimate, a biennial inventory required by federal law may serve as one of the mandated inventories, and an individual who performs the inventory must sign and date the inventory or report; (2) a review of all acquisition and disposition of each federal controlled substance covered by the report since the last inventory reconciliation report; (3) a comparison of (1) and (2) to determine any variances; (4) identification of all records used to compile the report, maintained in the pharmacy or clinic for three years;
- Requires reporting to the board identified losses and known causes within 30 days of discovery unless the cause of the loss is theft, diversion or self-use which requires reporting within 14 days as required by BPC 4104. If the cause of the loss is not identified, further investigation must be undertaken to identify the cause and actions necessary to prevent additional losses.
- The inventory reconciliation report must be dated and signed by the PIC or professional director of a clinic (BPC 4180, 4190) and individual(s) who performed the inventory. A required signatory may use digital or electronic signature or biometric identifier in lieu of a physical signature if, in addition, the signatory physically signs a printed statement confirming the accuracy of the inventory report.
- A new PIC must complete an inventory reconciliation report within 30 days of becoming the PIC. When possible, the outgoing PIC should also complete an inventory reconciliation report.
- Inpatient hospital pharmacies must prepare an inventory reconciliation report(s) on a quarterly basis. The report(s) must include controlled substances stored within the pharmacy, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control. If an inpatient hospital pharmacy or licensed correctional pharmacy uses an ADDS, inventory in the ADDS may be accounted for using means other than a physical count.

Did you know...

- The Board created a Standard of Care Ad Hoc Committee to review, as directed by the Legislature in its sunset bill, whether movement to a standard of care enforcement model is both appropriate and feasible. The meetings can be viewed online by webcast and WebEx on www.pharmacy.ca.gov. The next meetings are scheduled for 10/25/2022 and 2/1/2023.
- The Board also created a Medication Error Reduction and Workforce Ad Hoc Committee to review approaches on reducing medication errors, including a review of pharmacy workforce issues, and staffing and whether such issues contribute to medication errors. The meeting can be viewed online by webcast and Webex on www.pharmacy.ca.gov. The next meetings are scheduled for 9/14/2022, 11/16/2022, 1/24/2023, 3/8/2023, and 6/7/2023.
- These Board and Committee meetings are occurring virtually through WebEx and the Board welcomes comments. If you want to have your voices heard on these issues, please plan on attending one or more of these meetings.

-CCR 1746.3/ BPC 4052.01 Protocol for pharmacists furnishing Naloxone
-SB159 Pre and Post exposure to HIV drugs: Increased access to once daily therapy. Pharmacist ability to furnish 30-60 days therapy.
-AB528 Controlled Substances; CURES database report to include CV
-CURES reporting updated to 24 hours (HSC11165 effective 01/01/2021
-Serial number for controlled forms updated 01'01/2021

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INSPECTION REPORT

Compounding of drug preparations (AB973/BOPC4126.8)
Medication list for high risk Hospitalized patients (BPC4118.5)
Scripts publications on the Board website
Opioid warning label-risk of overdose or addiction "caution opioid. Risk of Overdose and addiction,"(BPC4076.7/SB1109)
Correction issued CCR 1714. Large amount of dust build up on the shelves and refrigerator.

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

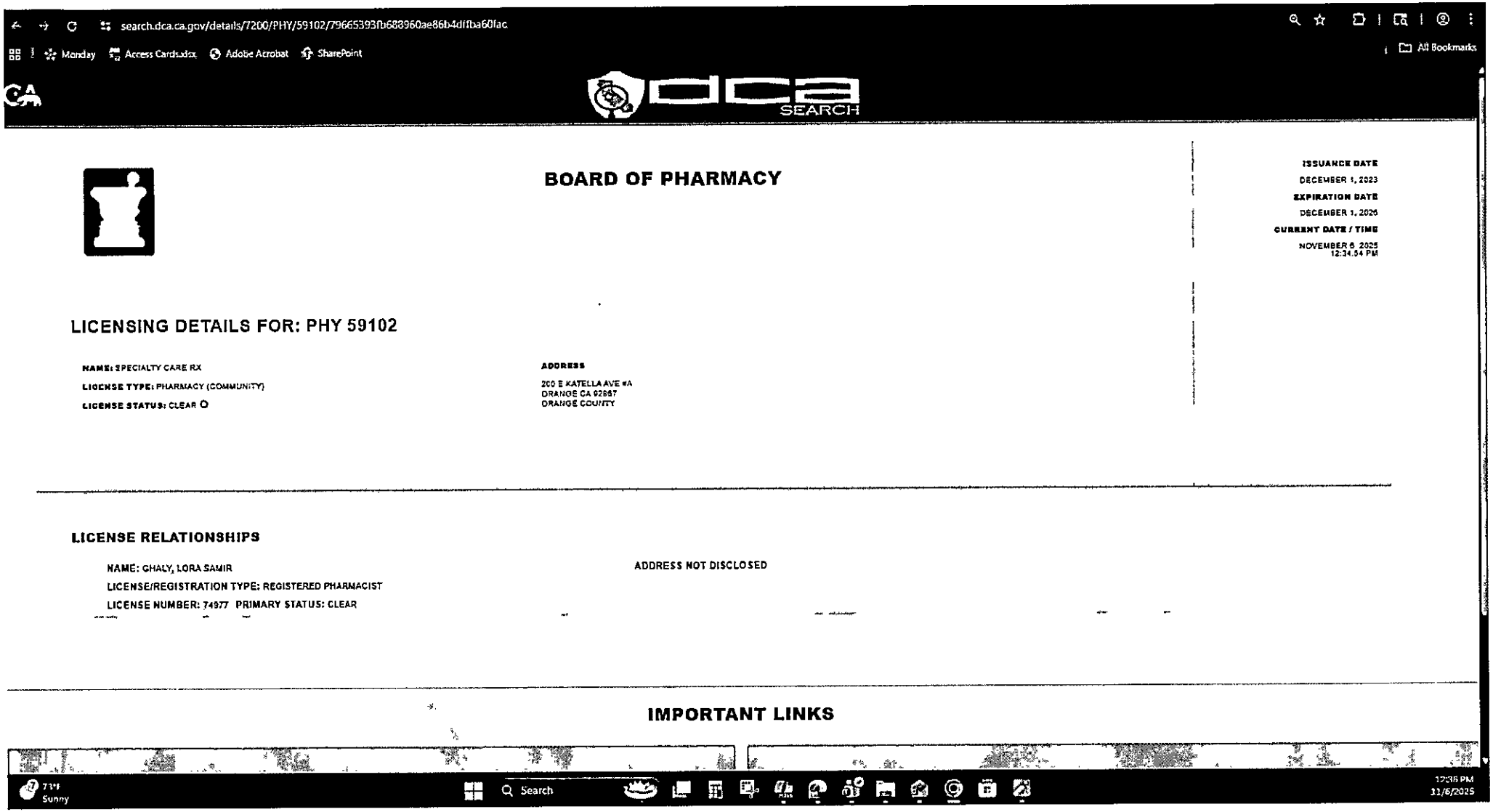
Pharmacist (sign) _____
Pharmacist (print) Lora Ghaly

Inspector (sign) _____
Inspector (print) MICHAEL AJAYI

Owner(sign) _____
Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:


search.dca.ca.gov/details/7200/PHY/59102/79665393fb688960ae86b4dffba60fac
Monday
Access Cards.xdcx
Adobe Acrobat
SharePoint
All Bookmarks
dca SEARCH
BOARD OF PHARMACY
ISSUANCE DATE
DECEMBER 1, 2023
EXPIRATION DATE
DECEMBER 1, 2025
CURRENT DATE / TIME
NOVEMBER 6, 2025
12:34:54 PM
LICENSING DETAILS FOR: PHY 59102
NAME: SPECIALTY CARE RX
LICENSE TYPE: PHARMACY (COMMUNITY)
LICENSE STATUS: CLEAR
ADDRESS
200 E KATELLA AVE #A
ORANGE CA 92867
ORANGE COUNTY
LICENSE RELATIONSHIPS
NAME: GHALY, LORA SAMIR
LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST
LICENSE NUMBER: 74977 PRIMARY STATUS: CLEAR
ADDRESS NOT DISCLOSED
IMPORTANT LINKS
71°F
Sunny
Search
12:35 PM
11/6/2025

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PGBB LLC DBA Specialty Care Rx

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 200 E Katella Ave

City Orange State CA Zip 92867

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 714-941-6177 Website www.myscrx.com

Licensing Company Email ocinfo@myscrx.com

Section 2: Personal Information

First Jeffrey Middle Scott Last Griffith

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern California		9/1989 - 12-1991	
Address	City	State	Zip
	Los Angeles	CA	
Diploma/Degree obtained, if any			
BA Communications, Business, Spanish			

School Name		From - To (MM/YY – MM/YY)	
Pasadena City College		9-1987-6-1989	
Address	City	State	Zip
	Pasadena	CA	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Glendale CC		9-1986-6-1987	
Address	City	State	Zip
	Glendale	CA	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
07/25- Present				
From - To (MM/YY – MM/YY)				
12/17-07/25				
From - To (MM/YY – MM/YY)				
09/01-12/17				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
BMR Partners / Specialty Care RX			10/16 - Present
Business Address	**City**	**State**	**Zip**
200 E. Katella Ave , Suite C	Orange	CA	92867
Phone	**Title**		
760 525-3545	Partner / Chief Business Development Officer		
Description of Duties			
SR. Leadership, Partner, Chief Business Development Officer			

Business Name			From - To (MM/YY – MM/YY)
Baxter / Baxalta / Shire			01/2001-10/2016
Business Address	**City**	**State**	**Zip**
	Round Lake	IL	60015
Phone	**Title**		
Description of Duties			
Sales Manager			

Business Name			From - To (MM/YY – MM/YY)
JHHG Enterprises			01/23- 12/25
Business Address	**City**	**State**	**Zip**
4701 Borden Ct	Carlsbad	CA	92010
Phone	**Title**		
760 525-3545	CEO		
Description of Duties			
Consultant			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey Griffith

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/05/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Jeffrey Griffith, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01-05-2026

Date

Subscribed and Sworn to before me this 6 day of JANUARY 2026.

Notary Public Signature

Aubrey Caramanica
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 23-9921-01
My Appt. Expires February 6, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PGBB LLC DBA Specialty Care Rx

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 200 E Katella Ave

City Orange State CA Zip 92867

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 714-941-6177 Website www.myscrx.com

Licensing Company Email ocinfo@myscrx.com

Section 2: Personal Information

First YATINKUMAR Middle AMRUTLAL Last PATEL

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520; NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
WESTERN UNIVERSITY OF HEALTH SCIENCE		08/2006- 12/2008	
Address	**City**	**State**	**Zip**
309 E. Second St.	Pomona	CA	91766
Diploma/Degree obtained, if any			
Pharm.D.			

School Name		From - To (MM/YY – MM/YY)	
University of New south Wales		Jan/2004- Dec/2004	
Address	**City**	**State**	**Zip**
UNSW, Level 3, Mathews Building F23, Gate 11, Botany Street,	Kensington, Sydney	NSW	2033
Diploma/Degree obtained, if any			
Msc. in Biopharmaceuticals			

School Name		From - To (MM/YY – MM/YY)	
Hemchandracharya North Gujarat University		08/1999-04/2003	
Address	**City**	**State**	**Zip**
V45M+RP2, chamunda society	Patan	Gujarat	384265
Diploma/Degree obtained, if any			
Bachelor in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Saurabh High School		08/1997-04/1999	
Address	**City**	**State**	**Zip**
Near Bhavsar Hostel, New Vadaj,	Ahmedabad	Gujarat	380013
Diploma/Degree obtained, if any			
High School Graduate			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
05/2013- Current				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Specialty Care RX			02-2025- current	
Business Address		**City**	**State**	**Zip**
21450 Golden Spring Drive, Suite 110		Diamond Bar	CA	91789
Phone	**Title**			
818-848-8112	Pharmacist-in-charge			

Description of Duties

responsible for pharmacist and pharmacist-in-charge role. Responsible to overall pharmacy compliance for all regulatory agencies such as Board of Pharmacy, CMS, ACHC, FDA, DEA.

Business Name			From - To (MM/YY – MM/YY)	
JBGG LLC			04/24-Current	
Business Address		**City**	**State**	**Zip**
801 S Rancho Drive, Suite D1-B		Las Vegas	NV	89106
Phone	**Title**			
702-825-4900	Member			

Description of Duties

Assist in consulting operation whenever called upon by board

Business Name			From - To (MM/YY – MM/YY)	
RPh Partners, Inc			03/25-Current	
Business Address		**City**	**State**	**Zip**
4295 Jurupa St, Ste 102		Ontario	CA	91761
Phone	**Title**			
909-443-7294	shareholder			

Description of Duties

Assist in Consulting operations whenever called upon by board

Business Name			From - To (MM/YY – MM/YY)	
Casafusion LLC			08/24- Current	
Business Address		**City**	**State**	**Zip**
8 Rock Bluff Dr		Pomona	CA	91766
Phone	**Title**			
323-215-5965	Shareholder			

Description of Duties

Owner- Regular management and operation of business

Business Name			From - To (MM/YY – MM/YY)	
I4H pharmacy			12/2023-12/2024	
Business Address		**City**	**State**	**Zip**
11705 Slate Ave STE 100		Riverside	CA	92505
Phone	**Title**			
951-499-4911	Clinical Pharmacist			

Description of Duties

Responsible for Pharmacist duties for managing patients in home infusion setting as well as ambulatory infusion suites. Manage pharmacy operations, including inventory control, record-keeping, and compliance.

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Prime Therapeutics			03/2023-12/2023	
Business Address		City	State	Zip
2900 Ames Crossing Road, Suite 200		Eagan	MN	55121
Phone	Title			
800-858-0723	Prior Authorization Pharmacist			
Description of Duties				
Positions in this function performed various duties related to the prior authorization of prescription orders and specialty medical utilization management.				

Business Name			From - To (MM/YY – MM/YY)	
OptumRx and Optum Infusion Services			05/2018- 07/2022	
Business Address		City	State	Zip
4900 Rivergrade Rd		Irwindale	CA	91706
Phone	Title			
866-827-0972	Pharmacist-in-charge, Prior Authorization Pharmacist			
Description of Duties				
Provided clinical and pharmacist oversight for factor and non-factor therapies, including prophylaxis, on-demand treatment, and preoperative management. Responsible as Pharmacist-in-charge				

Business Name			From - To (MM/YY – MM/YY)	
A & J Family Pharmacy, Inc			06/2015- Current	
Business Address		City	State	Zip
8 Rock Bluff Rd		Pomona	Ca	91766
Phone	Title			
323-215-5965	Shareholder			
Description of Duties				
Responsible for business operation and other related matters				

Business Name			From - To (MM/YY – MM/YY)	
Coram Healthcare			10/2017-05/2018	
Business Address		City	State	Zip
4355 E Lowell St		Ontario	CA	91761
Phone	Title			
909-605-0010	Pharmacist			
Description of Duties				
Pharmacist responsibilities for Branch service patient with acute and chronic therapy				

Business Name			From - To (MM/YY – MM/YY)	
Modern Health Pharmacy			11/2011-09/2017	
Business Address		City	State	Zip
110 E Huntington Dr		Monrovia	CA	91016
Phone	Title			
626-932-1600	Infusion Services Manager/ IV pharmacist			
Description of Duties				
Operational responsibilities for Infusion services for skilled nursing patients such as: overseeing staff scheduling, record keeping, competency tracking and assigning competencies, personal observation of compounding staff				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Yatinkumar Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/24/2025

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Yatinkumar Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/24/2025

Date

Subscribed and Sworn to before me this 24th day of December 2025

Notary Public Signature

RITA PATEL
COMM. #2392359
Notary Public - California
LOS ANGELES COUNTY
My Comm. Exp. Feb. 8, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PGBB LLC DBA Specialty Care Rx

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 200 E Katella Ave

City Orange State CA Zip 92867

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 714-941-6177 Website www.myscrx.com

Licensing Company Email ocinfo@myscrx.com

Section 2: Personal Information

First Bhav Middle Girish Last Patel

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of California, Los Angeles		09/16-06/21	
Address	**City**	**State**	**Zip**
580 Portola Plaza	Los Angeles	CA	90095
Diploma/Degree obtained, if any			
BS, MS			

School Name		From - To (MM/YY – MM/YY)	
La Salle High School		09/12-06/16	
Address	**City**	**State**	**Zip**
3880 E Sierra Madre Blvd	Pasadena	CA	91107
Diploma/Degree obtained, if any			
GED			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/23-Current	[redacted]			
07/22-07/23				
09/21-07/22				
06/19-09/21				
09/17-06/19				
01/03-09/17				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Casafusion LLC			08/24-Current
Business Address	**City**	**State**	**Zip**
8 Rock Bluff Drive	Pomona	CA	91766
Phone	**Title**		
323-399-5958	Shareholder		
Description of Duties			
Owner - regular management duties			

Business Name			From - To (MM/YY – MM/YY)
IVIGRx LLC			09/24-Current
Business Address	**City**	**State**	**Zip**
21450 Golden Springs Drive, Suite 110	Diamond Bar	CA	91789
Phone	**Title**		
818-848-8112	Advisor		
Description of Duties			
Help with running the pharmacy branch from a finance/ops perspective.			

Business Name			From - To (MM/YY – MM/YY)
KB Real Estate Enterprise			05/24-Current
Business Address	**City**	**State**	**Zip**
330 Mount Olive Drive	Bradbury	CA	91008
Phone	**Title**		
323-399-5958	Owner		
Description of Duties			
Manage a real estate rental company for Single Family Homes			

Business Name			From - To (MM/YY – MM/YY)
BA Hospitality Consulting			11/23-Current
Business Address	**City**	**State**	**Zip**
330 Mount Olive Drive	Bradbury	CA	91008
Phone	**Title**		
847-208-0878	Shareholder		
Description of Duties			
Assist hotel owners with managing & running their business (silent partner).			

Business Name			From - To (MM/YY – MM/YY)
Shilo Inn Mammoth Lakes			01/23-Current
Business Address	**City**	**State**	**Zip**
2963 Main St	Mammoth Lakes	CA	93546
Phone	**Title**		
760-965-0544	Minority Shareholder		
Description of Duties			
Minority shareholder in Hotel property, assisting in renovations.			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Healing Soul LLC			10/22-Current
Business Address	**City**	**State**	**Zip**
40550 Del Luz Murrieta Rd	Fallbrook	CA	92028
Phone	**Title**		
323-399-5958	Shareholder		
Description of Duties			
Minority Shareholder for vineyard operations. Consult on farming operations.			

Business Name			From - To (MM/YY – MM/YY)
JGBB LLC			04/24-Current
Business Address	**City**	**State**	**Zip**
801 S Rancho Drive Suite D1-B	Las Vegas	NV	89106
Phone	**Title**		
702-825-4900	Member		
Description of Duties			
Assist in consulting operations whenever called upon by board.			

Business Name			From - To (MM/YY – MM/YY)
RPH Inc			2/25-Current
Business Address	**City**	**State**	**Zip**
4295 JURUPA ST STE 102	Ontario	CA	91761
Phone	**Title**		
909-443-7294	Shareholder		
Description of Duties			
Assist in consulting operations whenever called upon by leadership.			

Business Name			From - To (MM/YY – MM/YY)
Northrop Grumman			09/21-09/24
Business Address	**City**	**State**	**Zip**
1 Space Park	Redondo Beach	CA	90278
Phone	**Title**		
	FTL Systems Engineer		
Description of Duties			
Program/Project Manager on Aerospace Projects			

Business Name			From - To (MM/YY – MM/YY)
Falcon Exodynamics			11/20-06/21
Business Address	**City**	**State**	**Zip**
1730 E. Holly Ave.	El Segundo	CA	90245
Phone	**Title**		
	Mechanical Engineer		
Description of Duties			
Research & Development engineer for satellites.			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Quartus Engineering			06/19-09/19
Business Address	**City**	**State**	**Zip**
9689 Towne Centre Dr	~~El Segundo~~ San Diego	CA	92121
Phone	**Title**		
	Analysis Intern		
Description of Duties			
Engineering intern at consulting firm.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bhav, Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/24/25

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Bhav Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/24/25

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

See Attached

(Seal)

JURAT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 24th day of Dec,

2025 by Bhav Patel,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

RITA PATEL
COMM. #2392359
Notary Public - California
LOS ANGELES COUNTY
My Comm. Exp. Feb. 8, 2026

Signature _____ (Seal)

OPTIONAL INFORMATION

DESCRIPTION OF THE ATTACHED DOCUMENT

_____
(Title or description of attached document)

_____
(Title or description of attached document continued)

Number of Pages _____ Document Date _____

_____
Additional information

INSTRUCTIONS

The wording of all Jurats completed in California after January 1, 2015 must be in the form as set forth within this Jurat. There are no exceptions. If a Jurat to be completed does not follow this form, the notary must correct the verbiage by using a jurat stamp containing the correct wording or attaching a seperate jurat form such as this one with does contain the proper wording. In addition, the notary must require an oath or affirmation from the document signer regarding the truthfulness of the contents of the document. The document must be signed AFTER the oath or affirmation. If the document was previously signed, it must be re-signed in front of the notary public during the jurat process.

- State and county information must be the state and county where the document signer(s) personally appeared before the notary public.
- Date of notarization must be the date the signer(s) personally appeared which must also be the same date the jurat process is completed.
- Print the name(s) of the document signer(s) who personally appear at the time of notarization.
- Signature of the notary public must match the signature on file with the office of the county clerk.
- The notary seal impression must be clear and photographically reproducible. Impression must not cover text or lines. If seal impression smudges, re-seal if a sufficient area permits, otherwise complete a different jurat form.
  - ❖ Additional information is not required but could help to ensure this jurat is not misused or attached to a different document.
  - ❖ Indicate title or type of attached document, number of pages and date.
- Securely attach this document to the signed document with a staple.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PGBB LLC DBA Specialty Care Rx

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PHY 59102

Physical Address 200 E Katella Ave Ste A

City Orange State CA Zip 92867

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 714-941-6177 Website www.myscrx.com

Licensing Company Email ocinfo@myscrx.com

Section 2: Personal Information

First Brenda Middle Aurora Last Brown

Alias(es, nicknames, name changes, etc.) Brenda A Martinez

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
FIDM		09/1994- 06/ 1996	
Address	**City**	**State**	**Zip**
919 S Grand Ave	Los Angeles	CA	90015
Diploma/Degree obtained, If any			
Fashion Merch. Mktg			

School Name		From - To (MM/YY – MM/YY)	
John F. Kennedy HS		09/1991- 06/1994	
Address	**City**	**State**	**Zip**
11254 Gothic Ave	Granada Hills	CA	91344
Diploma/Degree obtained, If any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2025- Present	[redacted]			
04/2024- 04/2025				
04/2017- 04/2024				
04/2014- 04/2017				
04/2012- 04/2014				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
PGBB LLC DBA Specialty Care Rx			01/2014- Present
Business Address	**City**	**State**	**Zip**
200 E Katella Ave	Orange	CA	92867
Phone	**Title**		
714-941-6177	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
RPH			07/2015- Present
Business Address	**City**	**State**	**Zip**
4295 E Jurupa St 102	Ontario	CA	91761
Phone	**Title**		
909-687-7064	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
SanFer Inc			01/2000- 04/2018
Business Address	**City**	**State**	**Zip**
15257 Parthenia St	North Hills	CA	91343
Phone	**Title**		
818-893-9971	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
IVIGRX LLC DBA Specialty Care Rx			01/2024- Present
Business Address	**City**	**State**	**Zip**
21450 Golden Springs Dr Suite 110	Diamond Bar	CA	91789
Phone	**Title**		
818-848-8112	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
PBC LLC DBA Specialty Care Rx			01/2017- Present
Business Address	**City**	**State**	**Zip**
801 S Rancho Dr Ste D1A	Las Vegas	NV	89106
Phone	**Title**		
702-790-4404	Officer		
Description of Duties			
Management			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Specialty Care Rx LLC			01/2021- Present
Business Address	**City**	**State**	**Zip**
150 Collins St	Memphis	TN	38112
Phone	**Title**		
901-560-3580	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
PBJ Partners LLC DBA Specialty Care Rx			01/2023- Present
Business Address	**City**	**State**	**Zip**
5736 Citrus Blvd Ste 103	New Orleans	LA	70123
Phone	**Title**		
504-340-5221	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
Excel Rx Consulting LLC DBA Specialty Care Rx			01/2021- Present
Business Address	**City**	**State**	**Zip**
6200 Chase Oaks Blvd Ste 102A	Plano	CA	75023
Phone	**Title**		
469-257-4200	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
JGBB LLC DBA Specialty Care Infusion Center			01/2018- Present
Business Address	**City**	**State**	**Zip**
801 S Rancho Dr Ste D1B	Las Vegas	NV	89106
Phone	**Title**		
702-825-4900	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brenda Brown

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/23/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Collin

I, Brenda A. Brown, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/23/2025

Date

Subscribed and Sworn to before me this 23 day of December 2025

Notary Public Signature

BRYAN CULP BAKER
Notary Public, State of Texas
Comm. Expires 02-22-2026
Notary ID 133604919

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PGBB LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH03634

Physical Address 200 E. KATELLA AVE SUITE A

City ORANGE State CA Zip 92867

Mailing Address (if different from physical address) SAME AS ABOVE

City _____ State _____ Zip _____

Telephone 714-941-6177 Website WWW.MYSCRX.COM

Licensing Company Email OCINFO@MYSCRX.COM

Section 2: Personal Information

First GRACE Middle G Last DUARTE

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	10/24 - Present	[redacted]		
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Specialty Care Rx			05/17	Present
Business Address		City	State	Zip
200 E. Katella Ave		Orange	Ca	92867
Phone	Title			
714 941-6177	VP of Business Development			
Description of Duties				
Sales and managing people.				

Business Name			From - To (MM/YY – MM/YY)	
Brothers Health Care			2014	5/2017
Business Address		City	State	Zip
2175 Sampson Ave		Corona	Ca	92879
Phone	Title			
951 808-5434	Account manager.			
Description of Duties				
Sales				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Grace Galvan Duarte
Print Name (First, Last)

Grace G Duarte
Original Signature (electronic, copies or stamps not accepted)

03/11/2026
Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Grace G Duarte
Original Signature

03/11/2026
Date

Subscribed and Sworn to before me this _____ day of _____.

_____
Notary Public Signature

SEE ATTACHED

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Riverside

Subscribed and sworn to (or affirmed) before me on this 11th day of March, 20 26, by Grace Galvan Duarte,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

I. SERRATO
COMM. # 2478112
NOTARY PUBLIC - CALIFORNIA
RIVERSIDE COUNTY
COMM. EXPIRES JAN. 1, 2028

(Seal)

Signature

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PGBB LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH03634

Physical Address 200 E. KATELLA AVE SUITE A

City ORANGE State CA Zip 92867

Mailing Address (if different from physical address) SAME AS ABOVE

City _____ State _____ Zip _____

Telephone 714-941-6177 Website WWW.MYSCRX.COM

Licensing Company Email OCINFO@MYSCRX.COM

Section 2: Personal Information

First BRANDON Middle D Last WALEND

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
San Gorgonio High		09/88 -06/91	
Address	**City**	**State**	**Zip**
2299 Pacific St	San Bernardino	CA	92404
Diploma/Degree obtained, If any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2024 -present	[redacted]			
04/2018-04/2024				
02/2012-5/2018				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
IVIGRX LLC	12/13/2024-CURRENT

Business Address	City	State	Zip
21450 GOLDEN SPRINGS DR SUITE 110	DIAMOND BAR	CA	91789

Phone	Title
818-848-8112	MEMBER

Description of Duties

MEMBER OF LLC

Business Name	From - To (MM/YY – MM/YY)
PGBB LLC	4/2012-CURRENT

Business Address	City	State	Zip
200 E. KATELLA AVE. SUITE A ORANGE, CA 92867			

Phone	Title
714-941-617	MEMBER

Description of Duties

MEMBER OF LLC

Business Name	From - To (MM/YY – MM/YY)
PBJ PARTNERS LLC	08/2023-CURRENT

Business Address	City	State	Zip
5736 Citrus Blvd Suite 103	NEW ORLEANS	LA	70123

Phone	Title
504-340-5221	MEMBER

Description of Duties

MEMBER OF LLC

Business Name	From - To (MM/YY – MM/YY)
PBC LLC	JAN 2017-CURRENT

Business Address	City	State	Zip
801 S. RANCHO DR. STE D1-A	LAS VEGAS	NV	89106

Phone	Title
702-790-4404	MEMBER

Description of Duties

MEMBER OF LLC

Business Name	From - To (MM/YY – MM/YY)
SPECIALTY CARE RX LLC	04/21-CURRENT

Business Address	City	State	Zip
150 COLLINS ST	MEMPHIS	TN	38112

Phone	Title
901-560-3580	MEMBER

Description of Duties

MEMBER OF LLC

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
EXCEL RX CONSULTING LLC			04/21-CURRENT
Business Address	**City**	**State**	**Zip**
6200 CHASE OAKS BLVD SUITE 102A	PLANO	TX	75023
Phone	**Title**		
469-257-4200	MEMBER		
Description of Duties			
MEMBER OF LLC			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brandon Walend

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3-9-2026

Date

Please have this section completed in the presence of a Notary Public.

State of CA, ss. County of San Bernardino

I, Brandon Walend, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3-9-2026

Date

Subscribed and Sworn to before me this 9th day of March.

Notary Public Signature

Please see attached Notary Certificate

(Seal)

CALIFORNIA JURAT **GOVERNMENT CODE § 8202**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of San Bernardino

Subscribed and sworn to (or affirmed) before me on this 9th (Date) day of March (Month), 2026 (Year), by

(1) Brandon D. Waterd

(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

TEHYA BOGGS
COMM. #2502389
Notary Public - California
Santa Barbara County
My Comm. Expires Oct. 19, 2028

Place Notary Seal and/or Stamp Above

Signature _____
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Personal History Application

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PGBB LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH03634

Physical Address 200 E. KATELLA AVE SUITE A

City ORANGE State CA Zip 92867

Mailing Address (if different from physical address) SAME AS ABOVE

City _____ State _____ Zip _____

Telephone 714-941-6177 Website WWW.MYSCRX.COM

Licensing Company Email OCINFO@MYSCRX.COM

Section 2: Personal Information

First GILBERT Middle J Last URSULO

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Bonita High School		9/1990 - 6/1994	
Address	**City**	**State**	**Zip**
3102 D Street	LaVerne	CA	91750
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Santiago Canyon College		9/1999-6/2002	
Address	**City**	**State**	**Zip**
8045 E. Chapman Ave	Orange	CA	92869
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2/2025 - present	[redacted]			
12/2012-2/2025				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
IVIGRx, LLC			12/13/2024-Current
Business Address	**City**	**State**	**Zip**
21450 Golden Springs Dr, Suite 110	Diamond Bar	CA	91789
Phone	**Title**		
818-848-8112	Member		
Description of Duties			
Member of LLC			

Business Name			From - To (MM/YY – MM/YY)
PGBB, LLC			4/2012-Current
Business Address	**City**	**State**	**Zip**
200 E. Katella Ave Suite A	Orange	CA	92867
Phone	**Title**		
714-941-6177	Member		
Description of Duties			
Member of LLC			

Business Name			From - To (MM/YY – MM/YY)
PBJ Partners, LLC			8/2023-Current
Business Address	**City**	**State**	**Zip**
5736 Citrus Blvd, Suite 103	New Orleans	LA	70123
Phone	**Title**		
504-340-5221	Member		
Description of Duties			
Member of LLC			

Business Name			From - To (MM/YY – MM/YY)
PBC, LLC			1/2017-Current
Business Address	**City**	**State**	**Zip**
801 S. Rancho Dr, Suite D1-A	Las Vegas	NV	89106
Phone	**Title**		
702-790-4404	Member		
Description of Duties			
Member of LLC			

Business Name			From - To (MM/YY – MM/YY)
Specialty Care Rx, LLC			4/2021-Current
Business Address	**City**	**State**	**Zip**
150 Collins St	Memphis	TN	38112
Phone	**Title**		
901-560-3580	Member		
Description of Duties			
Member of LLC			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Excel Rx Cunsulting, LLC			4/2021-Current	
Business Address		**City**	**State**	**Zip**
6200 Chase Oaks Blvd, Suite 102A		Plano	TX	75023
Phone	**Title**			
469-257-4200	Member			
Description of Duties				
Member of LLC				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gilbert Ursulo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/11/2026

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of ORANGE

I, Gilbert Ursulo, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

03/11/2026

Date

Subscribed and Sworn to before me this 11 day of MARCH. 2026

Notary Public Signature

MOHAMAD T. YOUNES
COMM. # 2443016
NOTARY PUBLIC-CALIFORNIA
ORANGE COUNTY
MY COMM. EXP. APRIL 1, 2027
(Seal)

A NOTARY PUBLIC OR OTHER OFFICER COMPLETING THIS CERTIFICATE VERIFIES ONLY THE IDENTITY OF THE INDIVIDUAL WHO SIGNED THE DOCUMENT TO WHICH THIS CERTIFICATE IS ATTACHED, AND NOT THE TRUTHFULNESS, ACCURACY, OR VALIDITY OF THAT DOCUMENT.

4EEE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 04425	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Mail Order and Compounding	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☒ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Spectrum Solutions Rx, LLC

Physical Address: 12278 S Lone Peak Pky, Suite 106

City: Draper State: UT Zip: 84020

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 385-279-4420 Toll Free # (NAC 639.708, NRS 639.23286): 888-500-4711

Fax: 385-855-1221 Contact Email: pharmacy@genesiscompounding.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Tyler Gunderson

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22571

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Tyler Gunderson	NV Pharmacist Registration #: 22571
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Utah

Parent Company (if any): Genesis Compounding LLC

Corporation/Organization Name: Genesis Compounding LLC /Spectrum Solutions TN, LLC

Mailing Address: 12278 S Lone Peak Pky, Suite 106

City: Draper State: UT Zip: 84020

Telephone: 888-500-4711 Email: pharmacy@genesiscompounding.com

Contact Person Name: Ryan Davies

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner (title) for Spectrum Solutions Rx, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Ryan Davies

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2/4/2026

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Ryan Davies hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner (title) for Spectrum Solutions Rx, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 5 day of FEBRUARY, 2026

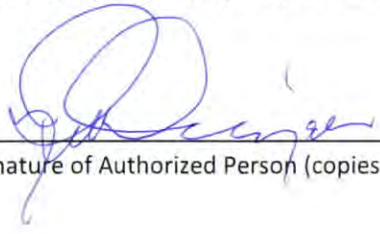
Notary Public

DANIEL SPRINGER
Notary Public - State of Utah
Comm. No. 723389
My Commission Expires on
Mar 3, 2026

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ryan Davies

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

02/04/2026

Date

Board Use Only	Date Received: 2/9/26	Amount: $500-ck 1059

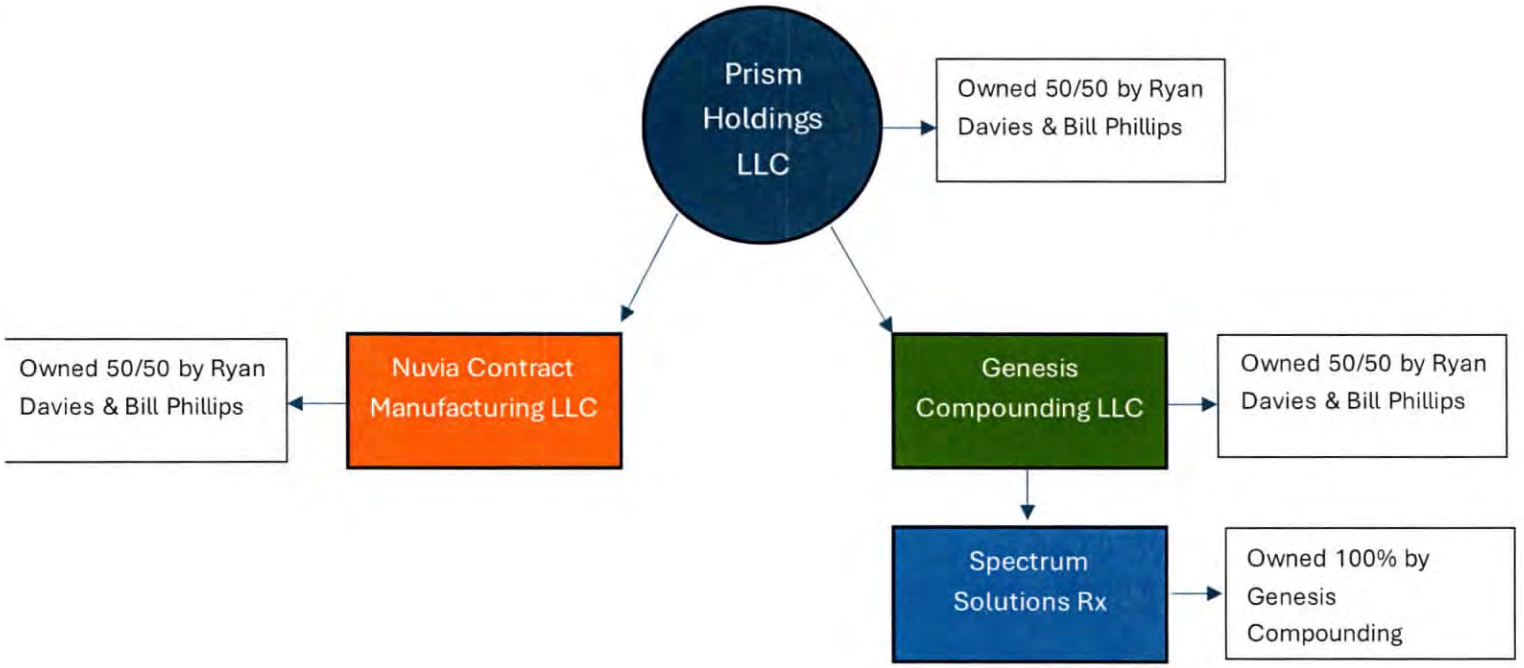
Spectrum Solutions Rx, LLC

William Phillips, Owner 50%

[redacted]

Ryan David Davies, Owner 50%

[redacted]


Prism Holdings LLC
Owned 50/50 by Ryan Davies & Bill Phillips
Nuvia Contract Manufacturing LLC
Owned 50/50 by Ryan Davies & Bill Phillips
Genesis Compounding LLC
Owned 50/50 by Ryan Davies & Bill Phillips
Spectrum Solutions Rx
Owned 100% by Genesis Compounding

SPENCER J. COX
Governor

DEIDRE M. HENDERSON
Lieutenant Governor

UTAH DEPARTMENT OF COMMERCE
Division of Corporations and Commercial Code

MARGARET W. BUSSE
Executive Director

G. SCOTT WHITTAKER
Division Director

February 04, 2026

CERTIFICATE OF EXISTENCE

Registration Number:	12614903-0161
Business Name:	SPECTRUM SOLUTIONS RX, LLC
Principal Office Address:	12278 S LONE PEAK PARKWAY, SUITE 106, DRAPER, UT 84020
Registered Date:	12/17/2021
Entity Type:	FOREIGN LIMITED LIABILITY COMPANY
Current Status:	ACTIVE - CURRENT

The Division of Corporations and Commercial Code of the State of Utah, custodian of the records of business registrations, certifies that the business entity on this certificate is authorized to transact business and was duly registered under the laws of the State of Utah. The Division also certifies that this entity has paid all fees and penalties owed to this state; its most recent annual report has been filed by the Division unless the status above is delinquent; and, that Articles of Dissolution have not been filed.

Scott Whittaker

G. Scott Whittaker
Director
Division of Corporations and Commercial Code

Certificate Number: 202602041620477
Enter the certificate number at https://businessregistration.utah.gov/ to verify this certification.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Spectrum Solutions Rx, LLC

Pharmacy/Wholesaler License # (if applicable) PH04425

Physical Address 12278 S Lone Peak Pky, Suite 106

City Draper State UT Zip 84020

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email pharmacy@genesiscompounding.com

Section 2: Personal Information

First Adrienne Middle O Last Murray

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Utah		1989 - 1996	
Address	**City**	**State**	**Zip**
201 Presidents Circle	Salt Lake City	UT	84112,
Diploma/Degree obtained, if any			
Doctor of Pharmacy (PharmD)			

School Name		From - To (MM/YY – MM/YY)	
Brighton High School		1985-1989	
Address	**City**	**State**	**Zip**
2220 Bengal Blvd	Cottonwood Heights,	UT	84121
Diploma/Degree obtained, if any			
Graduate			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1998 - present	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Spectrum Solutions Rx, LLC			7/1/24 - present
Business Address	**City**	**State**	**Zip**
12278 S Lone Peak Pkwy, Suite 106	Draper	UT	84020
Phone	**Title**	**Number of Employed Hours**	
8885004711	Pharmacist in Charge	3200	

Description of Duties

Serve as Pharmacist-in-Charge for a closed-door, mail-order, non-resident pharmacy with nationwide operations. Evaluate and maintain licensure, reporting, and operational compliance across all U.S. jurisdictions (50 states + DC).

Business Name			From - To (MM/YY – MM/YY)
University of Utah Health Care			1997-2008
Business Address	**City**	**State**	**Zip**
1525 West 2100 South	Salt Lake City	UT	84119
Phone	**Title**	**Number of Employed Hours**	
8012139950	Clinical Pharmacist	10,000+	

Description of Duties

Clinical Pharmacist partnering with internal medicine providers and managing patients across a large Anticoagulation Clinic under a collaborative practice agreement.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Adrienne O Murray, **certify that as the designated representative for**

Spectrum Solutions Rx, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AOM I am at least 21 years of age;
3. AOM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AOM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AOM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AOM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AOM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Adrienne Murray

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-5-2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Adrienne Murray

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-5-2026

Date

Please have this section completed in the presence of a Notary Public.

State of UTAH, ss. County of SALT LAKE

I, DANIEL SPRINGER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2-5-2026

Date

Subscribed and Sworn to before me this 5 day of FEB 2026.

Notary Public Signature

DANIEL SPRINGER
Notary Public - State of Utah
Comm. No. 723389
My Commission Expires on
Mar 3, 2026

(Seal)

UTAH DEPARTMENT OF COMMERCE
Division of Professional Licensing

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Online: DOPL.utah.gov
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NON-STERILE COMPOUNDING

INSPECTION

☐ Opening ☑ Random

INFORMATION

Pharmacy Name: Spectrum Solutions Rx, LLC Date: 9/5/24

Pharmacy License Number: 12615417-1703 Expiration Date: 9/30/25

Controlled Substance License Number: 12615417-8913 Expiration Date: 9/30/25

DEA Registration Number: pending Expiration Date:

Pharmacist-in-Charge (PIC): Adrienne O Murray

Pharmacist-in-Charge License Number: 153930-1701 Expiration Date: 9/30/25

Compounding Facilities engaged in simple, moderate or complex non-sterile or any level of sterile compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met:(a)Shall follow USP-NF Chapter 795, compounding of non-sterile preparations, and USP-NF Chapter 797 if compounding sterile preparations [UAC R156-17b-614a (3)]

GENERAL OPERATIONS AND INFORMATION

	Yes	No	
1	☑	☐	Compounders shall acquire and maintain knowledge and skills in all areas (e.g., dosage form, patient population, and medical specialty) for which they compound. [USP-NF Chapter 795—*Categories of Compounding*]

Which categories of compounding does the facility perform?

2	☐	☑	**Simple**- Making a preparation that has a *United States Pharmacopeia (USP)* compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability date for that formulation with appropriate BUDs; or reconstitution or manipulation commercial products that may require the addition of one or more ingredients as directed by the manufacturer. Examples include *Captopril Oral Solution*, and *Indomethacin Topical Gel*, and *Potassium Bromide Oral Solution, Veterinary*. [USP-NF Chapter 795—*Categories of Compounding—Description of Categories*]
	☑	☐	**Moderate**- Making a preparation that requires special calculations or procedure (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units; or making a preparation for which stability data for that specific formulation are not available. Examples include *Morphine Sulfate Suppositories,* diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known. [USP-NF Chapter 795—*Categories of Compounding—Description of Categories*]
	☐	☑	**Complex**- Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects. [USP-NF Chapter 795—*Categories of Compounding—Description of Categories*]
3	☑	☐	The preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device is in accordance with a licensed practitioner's prescription, medication order, or initiative based upon the practitioner/patient/pharmacist/compounder relationship in the normal course of professional practice[USP-NF Chapter 795—*Definitions—Compounding]*
4	☐	☑	Does the facility compound nonsterile prescriptions which are then delivered to a practitioner for administration to the patient in the office, clinic or facility?

	Yes	No	
5	☐	☑	A pharmacy licensed under this chapter may, subject to rules established by the Division, repackage or compound a prescription drug for sale to a practitioner if: the prescription drug: does not include a compounded drug; or includes a compounded drug; and is not a controlled substance; the pharmacy labels the prescription drug "for office use only"; the practitioner administers the drug to a patient in the practitioner's office or facility; and except in accordance with Title 58, Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, the practitioner does not dispense the drug to the patient. [UCA 58-17b-624(1)(a)(i)(ii)(A)(B)(b)(c)(d)] Pursuant to Section 58-17b-624, a pharmacy may repackage or compound a prescription drug for sale to a practitioner for office use provided that it is in compliance with all applicable federal and state laws and regulations regarding the practice of pharmacy, including, but not limited to the Food, Drug, and Cosmetic Act, 21 U.S.C A § 301 et seq. [R156-17b-624]
6	☐	☑	Does the facility distribute non-sterile compounded preparations to hospitals, clinics, or surgery centers?
7	☐	☑	Does the facility have a sales force that distributes samples containing active ingredients? List on separate sheet.
8	☐	☑	Does the facility provide non-sterile compounded preparations to other pharmacies for dispensing?
9	☑	☐	What does the facility compound?

☐ Tablets ☑ Liquids ☐ Troches ☐ Ointments
☐ Capsules ☐ Lozenges ☐ Creams ☐ Suppositories
☐ Patches ☑ Sprays ☐ Powders ☐ Oral Pastes
☐ Transdermals ☐ _____ ☐ _____ ☐ _____

10	☐	☑	Does the facility compound vitamins or nutritional supplements? If so, list on separate sheet.
11	☐	☑	Does the facility compound investigational drugs? If so, list on separate sheet.
12	☑	☐	The facility does not prepare a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner. [UCA 58-17b-502 (13)]
13	☐	☑	Does the facility perform compounding with hazardous drugs?
14	☐	☑	Does the facility segregate hazardous drugs from normal compounding stock?
15	☑	☐	MSDSs shall be readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facilities premises. Employees should be instructed on how to retrieve and interpret needed information. [USP-NF Chapter 795—*Compounding Documentation—Material Safety Data Sheets File*]
16	☑	☐	Does the facility make non-sterile compounded preparations using bulk powder active pharmaceutical ingredients?
17	☑	☐	All significant procedures performed in the compounding area should be covered by written standard operating procedure (SOPs). Implementing SOPs establishes procedural consistency and also provides a reference for orientation and training of personnel. To ensure accountability, accuracy, quality, safety and uniformity in compounding procedures should be developed for the following: [USP-NF Chapter 795—*Compounding Documentation—Standard Operating Procedures*]

☑ Facility ☑ Equipment ☑ Personnel
☑ Packaging ☑ Storage ☑ Preparation

18	☑	☐	A *United States Pharmacopeia (USP), National Formulary (NF), or Food Chemical Codex (FCC)* substance is the recommended source of all ingredients for compounding all preparations. [USP-NF Chapter 795—*Component Selection, Handling, and Storage(1)*]
19	☑	☐	Bulk active ingredients must be procured from a facility registered with the federal Food and Drug Administration and must not be listed on the federal Food and Drug Administration list of drug products withdrawn or removed from the market for reasons of safety or effectiveness. [R156-17b-614a (3)(c)(i)(ii)]

20 ☑ ☐ Bulk containers are labeled with appropriate Occupational Safety and Health Administration (OSHA) hazard communication labels (see OSHA.gov), and Material Safety Data Sheets (MSDSs) are available to compounding personnel for all drugs and chemicals used in compounding. [USP-NF Chapter 795—*Responsibilities of the Compounder—General Principles of Compounding (3)*]

BEYOND USE DATING

21 ☑ ☐ All components used in the compounding of preparations must be store as directed by the manufacturer or according to *USP*, *NF*, or *FCC* monograph requirements, in a clean area, and under appropriation temperatures and humidity conditions (controlled room temperature, refrigerator, or freezer). [USP-NF Chapter 795—*Component Selection, Handling, and Storage (11)*]

22 ☑ ☐ For components that do not have expiration dates assigned by the manufacture or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the component (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Labeling, Expiration Date and Beyond-Use Date)* based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions. [USP-NF Chapter 795—*Component Selection, Handling, and Storage(6)*]

23 ☑ ☐ If the component has been transferred to a different container, that container shall be identified with the component name, lot or control number, transfer date, and expiration date and shall provide integrity that is equivalent to or better than that of the original container. [USP-NF Chapter 795—*Component Selection, Handling, and Storage(5)*]

24 ☑ ☐ The compounder shall ensure that the container and container closures used in packaging compounded preparations meet *USP* requirements (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Containers; Containers—Glass* <660>; *Containers—Plastics*<661>; *Containers—Performance Testing* <671>; Chapter <681>; Chapter <1136>; *Packaging Practice—Repackaging a Single Solid Oral Drug Product into a Unit-Dose Container*<1146>); and when available, compounding monographs. Compounders are not expected to perform the tests described in these chapters but should be knowledgeable about the stands described in them. [USP-NF Chapter 795—*Packaging and Drug Preparation Containers*]

25 ☑ ☐ The containers and closures shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the older stock is used first. The containers and container closures shall be stored in such a way as to permit inspection and cleaning of the storage area. [USP-NF Chapter 795—*Packaging and Drug Preparation Containers*]

26 ☑ ☐ The BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded. [USP-NF Chapter 795—*Stability Criteria and Beyond-Use Dating*]

27 ☑ ☐ The beyond use date assigned shall be based on currently available drug stability information and sterility considerations or appropriate in-house or contract service stability testing. [R156-17b-614a (3)(g)]

28 ☑ ☐ Sources of drug stability information shall include the following: [R156-17b-614a (3)(g)(i)(A)(B)(C)]
☑ References can be found in "Trissel's Handbook on Injectable Drugs", 17th Edition, October 31, 2012 ☑ Manufacturer recommendations ☑ Reliable, published research

29 These maximum BUDs (shown below) are recommended for non-sterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation. They are packaged in tight, light resistant containers and stored at controlled room temperature. The BUD shall not be later than the expiration date on the container of any component. [USP-NF Chapter 795—*Stability Criteria and Beyond-Use Dating—General Guidelines for Assigning Beyond-Use Dates*]

☑ ☐ BUDs for Nonaqueous Formulations—The BUD is not later that the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.

☑ ☐ BUDs for Water-Containing Oral Formulations—The BUD is not later than 14 days when stored at controlled cold temperatures.

☑ ☐ BUDs for Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations—The BUD is not later than 30 days.

ENVIRONMENT

30 ☑ ☐ Compounding facilities shall have an adequate space that is specifically designated for compounding of prescriptions. This space shall provide the orderly placement of equipment and materials to prevent mixups among ingredients, containers, labels, in-process materials and finished preparations and is designed, arranged and used to prevent adventitious cross-contamination. [USP-NF Chapter 795—*Compounding Facilities*]

31 ☑ ☐ Areas used for sterile preparations shall be separated and distinct from the nonsterile compounding area (see Chapter <797>, *Environmental Quality and Control*). [USP-NF Chapter 795—*Compounding Facilities*]

32 ☑ ☐ Compounding is done in an appropriately clean and sanitized area dedicated to this activity (see section *Compounding Facilities*). [USP-NF Chapter 795—*Compounding Process—Criteria When Compounding Each Drug Preparation (4)*]

33 ☑ ☐ Only one preparation is compounded at one time in a specific workspace. [USP-NF Chapter 795—Compounding Process—*Criteria When Compounding Each Drug Preparation (5)*]

34 ☑ ☐ The entire compounding and storage area should be well lighted. [USP-NF Chapter 795—*Compounding Facilities*]

35 ☑ ☐ Heating, ventilation, and air conditioning systems shall be controlled to avoid decomposition and contamination of chemicals (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Storage Temperature and Humidity;* and the manufacturers' labeled storage conditions). [USP-NF Chapter 795—*Compounding Facilities*]

36 ☑ ☐ Potable water shall be supplied for hand washing and equipment washing. *Purified Water* (see *Purified Water* monograph) shall be used for compounding nonsterile preparations when formulations indicate the inclusion of water. *Purified Water* should be used for rinsing equipment and utensils. [USP-NF Chapter 795—*Compounding Facilities*]

37 ☐ ☐ n/a Hazardous drugs shall be stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other personnel. [USP-NF Chapter 795—*Compounding Facilities*]

38 ☐ ☐ n/a Disposal of all hazardous drugs wastes shall comply with all applicable federal and state regulations. All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedure to protect themselves and prevent contamination. [USP-NF Chapter 795—*Compounding Facilities*]

TRAINING

39 ☑ ☐ Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties. Such training should be documented. Compounding personnel should be evaluated annually. [USP-NF Chapter 795—*Responsibilities of the Compounder—General Principles of Compounding (1), Training*]

40 ☑ ☐ All employees involved in pharmaceutical compounding shall read and become familiar with the chapter (USP-NF Chapter 795). They should also become familiar with the contents of the *USP Pharmacists' Pharmacopoeia* and other relevant publications, including how to read and interpret MSDS. [USP-NF Chapter 795—*Training*]

41 ☑ ☐ All employees shall read and become familiar with each of the procedures related to compounding, including those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage, and dispensing. [USP-NF Chapter 795—Training]

COMPOUNDING EQUIPMENT

42 ☑ ☐ All equipment used in compounding is clean, properly maintained, and used appropriately. [USP-NF Chapter 795—Responsibilities of the Compounder—General Principles of Compounding (4)]

43 ☑ ☐ Equipment shall be stored to protect it from contamination and shall be located to facilitate its use, maintenance and cleaning. Automated, mechanical, electronic, and other types of equipment used in compounding or testing of compounded preparations shall be routinely inspected, calibrated as necessary, and checked to ensure proper performance. Immediately before compounding operations, the equipment shall be inspected by the compounder to determine its suitability for use. After use, the equipment shall be appropriately cleaned. [USP-NF Chapter 795—Compounding Equipment]

DOCUMENTATION

44 ☑ ☐ A master worksheet shall be developed and approved by a pharmacist for each batch of sterile or non-sterile pharmaceuticals to be prepared. Once approved, a duplicate of the master worksheet shall be used as the preparation worksheet from which each batch is prepared an on which all document for that batch occurs. The master worksheet may be stored electronically and shall contain at a minimum: [UAC R156-17b-614a (3)(d)(i)(ii)(iii)(iv)(v)(vi)(vii)(viii)(A-D)(ix)(A-D)(x)(xi)(xii)(xiii)]

- ☑ Official or assigned name
- ☑ Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients
- ☑ Equipment needed to prepare the preparation
- ☑ Container used in dispensing
- ☑ Quality control procedures and expected results
- ☑ Description of final preparation
- ☑ Strength
- ☑ Description of all ingredients and their quantities
- ☑ Mixing instructions, which shall include: order of mixing, mixing temperature or other environmental controls, duration of mixing, and other factors pertinent to the replication of the preparation as compounded
- ☑ Packaging and storage requirements
- ☑ Dosage form of the preparation
- ☑ Compatibility and stability information, including references when available
- ☑ Sample labeling information, which shall contain, in addition to legally required information: generic name and quantity or concentration of each active ingredient, assigned beyond use date, storage conditions, and prescription or control number, whichever is applicable

45 ☑ ☐ A preparation worksheet for each batch of sterile or non-sterile pharmaceuticals shall document the following: [UAC R156-17b-614a (3)(e)(i)(ii)(iii)(iv)(v)(vi)(vii)(viii)(ix)(x)(xi)(xii)(A-D)(xiii)(A,B,C,D)(I-III)(xiv)(xv)(xvi)]

- ☑ Official or assigned name
- ☑ Names and quantities of all components
- ☑ Name of the person who prepared the preparation
- ☑ Date of the preparation
- ☑ Proof of duplicate labeling information, which shall: be kept at the pharmacy, be immediately retrievable; include an audit trail for any altered form, and be reproduced in: the original format that was dispensed, and electronic version, or a scanned electronic version
- ☑ Strength and dosage of the preparation
- ☑ Sources, lot numbers, and expiration dates of components
- ☑ Name of the compounder who approved the preparation
- ☑ Assigned control number, if for anticipation of use or prescription number, if patient specific, whichever is applicable
- ☑ Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver
- ☑ Description of final preparation
- ☑ Master Formulation Record reference for the preparation
- ☑ Total quantity compounded
- ☑ Name of the person who performed the quality control procedures
- ☑ Duplicate label as described in the Master Formulation Record means the sample labeling information that is dispensed on the final product given to the patient and shall at minimum contain: active ingredients, beyond-use-date, storage conditions, and lot number
- ☑ Results of quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids)

46 ☑ ☐ Compounding records including the master worksheet, preparation worksheet, and prescription files, including refill information shall be maintained for a minimum of five years and be immediately retrievable in written or electronic format. [UAC R156-17b-612 (4)]

47 ☑ ☐ There shall a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities that follow USP-NF Chapters 795 and 797 standards. [R156-17b-614a (3)(h)]

COMPOUNDING PROCEDURES

48 ☑ ☐ Only authorized personnel are allowed in the immediate vicinity of the compounding operations. [USP-NF Chapter 795—Responsibilities of the Compounder—General Principles of Compounding(6)]

49 ☑ ☐ Personnel engaged in compounding maintain good hand hygiene and wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, face masks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for preventions of drug contamination. [USP-NF Chapter 795—Compounding Process—Criteria When Compounding Each Drug Preparation (8)]

50 ☑ ☐ Critical processes (including but not limited to weighing, measuring, and mixing) are verified by the compounder to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation. [USP-NF 795—Compounding Process—Criteria When Compounding Each Drug Preparation]

PRESCRIPTION LABELING

51 ☑ ☐ All prescription labels for compounded sterile and non-sterile medications when dispensed to the ultimate user or Agent shall bear at a minimum in addition what is required in Section 58-17b-602 the following: [UAC R156-17b-614a (3)(h)(i)(ii)(iii)]

- ☑ generic name and quantity or concentration of each active ingredient. In the instance of a sterile preparation for parenteral use, labeling shall include the name and base solution for infusion preparation;
- ☑ assigned compounding record or lot number;
- ☑ "This is a compounded preparation" or similar language.

PATIENT COUNSELING AND COMMUNICATION

52 ☑ ☐ At the time of dispensing the prescription, the patient or the patient's agent shall be counseled about proper use, storage, handling, and disposal of the compounded preparation. The patient or the patient's agent shall also be instructed to report any adverse event and to observe and report to the compounder any changes in the physical characteristics of the compounded preparation (see Chapter <1191>, *Responsibility of the Pharmacist*). The compounder shall investigate and document any reported problem with a compounded preparation and shall take corrective action. [USP-NF Chapter 795—*Patient Counseling*]

VETERINARY COMPOUNDING

53 ☐ ☑ Does the facility compound for veterinary use?

54 ☐ ☑ If compounding for both humans and animals, are the API's or other components that are labeled for veterinary use only are segregated or marked in such way to prevent them from being used for human compounding?

55 ☐ ☑ The pharmacist shall be knowledgeable about the individual species' limitation in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used in compounded preparations. For this reason, compounders making preparations for animals should use, when possible, formulations specifically developed for animal patients. If such formulations are not available, the compounder shall conduct a literature review to determine whether a specific component of the formula is toxic to the target species. [USP-NF Chapter 795—Compounding For Animal Patients]

COMMENTS (Use an additional sheet if necessary)

Assisted by PIC Adrienne Murray.

Pharmacy compounds allergen extract sprays and sublingual drops at this time.

SOPs are compliant for non-sterile compounding.

The pharmacy does not compound with hazardous drugs.

Training records are compliant.

Master and Compounding Formulation Records are compliant.

Prescription labels for compounds are compliant.

Pharmacy does not compound for animal use.

☑ By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."

Signature of Responsible Party: _____ Date of Signature: 9/5/24

Signature of Division Investigator: _____ Date of Signature: 9/5/24

UTAH DEPARTMENT OF COMMERCE
Division of Professional Licensing

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CLASS A
RETAIL
PHARMACY

INSPECTION

☐ Opening ☑ Random

INFORMATION

Pharmacy Name: Spectrum Solutions Rx, LLC Date: 9/5/24

License Number: 126154 17-1703 Exp Date: 9/30/25

C.S. License Number: 12615417-8913 Exp Date: 9/30/25

DEA Registration: pending Exp Date:

Pharmacy FEIN Number (Tax ID): 87-4414158

Pharmacy Email: pharmacy@spectrumsolution.com

Pharmacy Phone Number: 888-500-4711 Fax: 385-885-1221

Pharmacy Toll Free Number: 888-500-4711

Affiliated Websites: n/a

Pharmacy Hours: Monday-Friday: 7-3:30 Saturday: 8-12 Sunday: n/a

Pharmacy Address: 12278 S Lone Peak Pkwy Ste 106

City: Draper State: UT Zip: 84020

Pharmacist In Charge (PIC): Adrienne O Murray

PIC License Number: 153930-1701 Expiration Date: 9/30/25

Personnel

List ALL pharmacists, interns, pharmacy technicians and techs-in-training (attach a separate sheet, if necessary):

Name: Nancy Morales	License # 10511154-1717	Exp: 09/30/2025
Name: Adam Myers	License # 14101576-1701	Exp: 09/30/2025
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
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Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:

CLASS A RETAIL PHARMACY INSPECTION

Name: License # Exp:

Name: License # Exp:

Name: License # Exp:

Name: License # Exp:

Name: License # Exp:

Name: License # Exp:

Name: License # Exp:

INSPECTION

	YES	NO	
1	☐	☑	The facility shall maintain a current list of licensed employees involved in the practice of the pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable. The list may be maintained in paper or electronic form. [UAC R156-17b-614a (5)(a)(i-vi)(b)]
2	☑	☐	Notification has been provided to the Division in regards to the unique email address used for self audits or pharmacy alerts. The pharmacy will notify the division of any change in the email address within seven days of the change. [UAC R156-17b-603 (2) and (3) (t) (i-ii)]
3	☑	☐	Notification has been provided to the Division in regards to the assignment of the PIC at the above stated pharmacy. The Division is notified of a change in PIC within 30 days of the change. [UAC R156-17b-603 (3) (s)]
4	☐	☐	If the facility has a pharmacy technician training program, the program and curriculum of education and training, meets standards established by Division rule made in collaboration with the Board. [UAC R156-17b-303a (3)] ☑ N/A
5	☑	☐	A pharmacy technician trainee shall practice only under the direct supervision of a pharmacist, and in a ratio not to exceed one pharmacy technician trainee to one pharmacist or two pharmacy technician trainees to one pharmacist, if a licensed pharmacy technician or intern is working during the same shift. [UAC R156-17b-601(4)(a)(i-ii)]
6	☑	☐	A licensed pharmacy technician shall practice under the general supervision of a licensed pharmacist. [UCA 58-17b-102 (57)]
7	☑	☐	A pharmacy technician may administer vaccines and emergency medications pursuant to delegation by a pharmacist... And is under "direct", on-site supervision by the delegating pharmacist as defined in R156-1-102a(4)(a); [UAC R156-17b-601 (3)(b)]
8	☑	☐	The operating standards for a Pharmacist acting as a preceptor includes meeting the following criteria by providing direct, on-site supervision to no more than two pharmacy interns during a working shift. [UAC R156-17b-606(3)(a)]
9	☑	☐	In accordance with Subsecton 58-17b-102(72)(b) all supportive personnel shall be under the supervision of a licensed pharmacist or DMP. The licensed pharmacist or DMP shall be present in the area where the person being supervised is performing services and shall be immediately available to assist the person being supervised in the serivces being performed expect for the delivery of pre-filled prescriptions as provided in Subsection (1)(g) above. [UAC R156-17b-607 (3)]
10	☑	☐	In accordance with Subsection 58-17b-102(72)(a), supportive personnel may assist in any tasks not related to drug preparation or processing, including: [UAC R156-17b-607 (1)(a-g)]

- ☑ stock ordering and restocking;
- ☐ cashiering;
- ☐ billing;

☐ filing;
☐ receiving a written prescription and delivering it to the pharmacist, pharmacy intern, pharmacy technician, pharmacy technician trainee, DMP, or DMP designee;
☐ housekeeping;
☑ delivering a pre-filled prescription to a patient.

11 ☑ ☐ The pharmacist-in-charge (PIC) is responsible for assuring that no pharmacy or pharmacist operates the pharmacy or allows operation of the pharmacy with a ratio of pharmacist to pharmacy personnel which, under the circumstances of the particular practice setting, results in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare. [UAC R156-17b-603 (3) (r)]

12 ☑ ☐ All individuals employed in a pharmacy facility having any contact with the public or patients receiving services from that pharmacy facility does wear on their person a clearly visible and readable identification showing the individual's name and position. [UCA 58-17b-603 (1)]

13 ☑ ☐ When communicating by any means, written, verbal, or electronic, pharmacy personnel do identify themselves as to licensure classification. [UCA 58-17b-603 (2)]

14 ☑ ☐ The facility or parent company shall maintain a record for not less than five years of the initials or identification codes that identify each dispensing pharmacist by name. The initials or identification code shall be unique to ensure that each pharmacist can be identified; therefore identical initials or identification codes shall not be used. [UAC R156-17b-614a (8)]

15 ☑ ☐ The facility does have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel: [UAC R156-17b-614a (4) (a-k)]

- ☑ UCA 58-1 (DOPL Licensing Act)
- ☑ UAC R156-1 (General Rules of DOPL)
- ☑ UCA 58-17b (Pharmacy Practice Act)
- ☑ UAC R156-17b(Pharmacy Practice Act Rules)
- ☑ UCA 58-37 (Controlled Substance Act)
- ☑ UAC R156-37(Controlled Substance Act Rules)
- ☑ UCA 58-37f (Controlled Substance Database Act)
- ☑ UAC R156-37f (Controlled Substance Database Act Rule)
- ☑ Code of Federal Regulations Title 21 parts 1300 to end
- ☑ FDA Approved Drug Product(Orange Book)
- ☑ General Drug References

16 ☑ ☐ The facility is well lighted, ventilated, clean and sanitary. [UAC R156-17b-614a (1) (a)]

17 ☑ ☐ If transferring a drug from a manufacturer's or distributor's original container to another container, the dispensing area, shall have a sink with hot and cold culinary water separate and apart from restroom facilities. All required equipment shall be clean and in good operating condition. [UAC R156-17b-614a (1) (b)]

18 ☑ ☐ The facility is equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory. [UAC R156-17b-614a (1) (c)]

19 ☑ ☐ The facility is equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility. [UAC R156-17b-614a (1) (e)]

20 ☑ ☐ All out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals and in correlation to the beyond use date imprinted on the label. [UAC R156-17b-605(1)]

21 ☑ ☐ The facility is stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare. [UAC R156-17b-614a (1) (f)]

22 ☑ ☐ If dispensing controlled substances, the facility is equipped with a security system to permit detection of entry at all times when the facility is closed, and provide notice of unauthorized entry to an individual, and be equipped with a lock on any entrances to the facility where drugs are stored. [UAC R156-17b-614a (1)(g)(i-ii)(h)(i-ii)]

23 ☑ ☐ If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling, the pharmacy's perimeter walls shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy. [UAC R156-17b-614a (15)] ☐ N/A

24 ☑ ☐ Only a licensed Utah pharmacist or authorized pharmacy personnel does have access to the pharmacy when the pharmacy is closed. [UAC R156-17b-614a (7)]

25 ☑ ☐ A pharmacy shall not dispense a prescription drug or device to a patient unless a pharmacist is physically present and immediately available in the facility. [UAC R156- 17b-614a (6)]

26 ☑ ☐ The temperature of the pharmacy is maintained within a range compatible with the proper storage of the drugs. [UAC R156-17b-614a (3)]

27 ☑ ☐ The temperature of the refrigerator and freezer is maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing. The pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain the log for three years. [UAC R156-17b-614a (3)]

28 ☑ ☐ For the purpose of promoting therapeutic appropriateness, a pharmacist shall at the time of dispensing a prescription, or a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant conditions, situations or items, such as: [UAC R156-17b-611 (2) (a-g)]

- ☑ Inappropriate drug utilization
- ☑ Therapeutic duplications
- ☑ Drug-disease contraindications
- ☑ Drug-drug interactions
- ☑ Incorrect drug dosage
- ☑ Incorrect duration of drug treatment
- ☑ Drug-allergy interactions
- ☑ Clinical abuse or misuse

29 ☑ ☐ Facility does have a counseling area to allow for confidential patient counseling. [UAC R156-17b-614a (1)(i)]

30 ☑ ☐ Every pharmacy shall verbally offer to counsel a patient or a patient's agent in a personal face-to-face discussion regarding each prescription drug dispensed. If the patient or patient's agent delivers the prescription in person to the pharmacist or pharmacy intern; or receives the drug in person at the time it is dispensed at the facility. [UCA 58-17b-613 (1)]

31 ☑ ☐ A pharmacist or pharmacy intern that receives a prescription from a patient by means other than personal delivery, and that dispenses prescription drugs to the patient by means other than personal delivery shall provide patient counseling to a patient regarding each prescription drug the pharmacy dispenses and provide each patient with a toll-free telephone number by which the patient can contact the pharmacist or pharmacy intern at the pharmacy for counseling. [UCA 58-17b-613(2)]

32 ☑ ☐ If a prescription drug order is delivered to the patient or the patient's agent at the patient's or other designated location, the following is applicable: [UCA R156-17b-610(6)(a-c)

- ☑ the pharmacy shall provide the information specified in R156-17b-610(3) be delivered with the dispensed prescription in writing.

☑ if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."

☑ written information provided in Subsection (b) of this section shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information.

33 ☑ ☐ The offer to counsel is documented and said documentation shall be available to the Division. These records must be maintained for a period of five years and be available for inspection within 7-10 business days. [UAC R156-17b-610 (4)]

34 ☑ ☐ A pharmacy may only deliver a prescription drug to a patient or patient's agent in person at the pharmacy or via the United States Postal Service, a licensed common carrier, or supportive personnel, if the pharmacy takes reasonable precautions to ensure the prescription drug is delivered to the patient or patient's agent or returned to the pharmacy. [UCA 58-17b-602(9)(a)(b)(i-ii)]

35 ☑ ☐ A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient shall, under the direction of the PIC, or other responsible employee: [UAC R156-17b-608(1)(a-e)(2)(a-c)]

☑ Use adequate storage or shipping containers and shipping processes to ensure drug stability and potency. The shipping processes shall include the use of appropriate packing material and devices, according to the recommendations of the manufacturer or the United States Pharmacopeia Chapter 1079, in order to ensure that the drug is kept at appropriate storage temperatures throughout the delivery process to maintain the integrity of the medication.

☑ Use shipping containers that are sealed in a manner to detect evidence of opening or tampering.

☑ Develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures shall address when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment. In these instances, the pharmacy shall make provisions for the replacement of the drug.

☑ Provide for an electronic, telephonic, or written communication mechanism for a pharmacy to offer counseling to the patient as defined in section 58-17b-613; and provide documentation of such counseling.

☑ Provide information to the patient indicating what the patient should do if the integrity of the package or drug was compromised during shipment.

36 ☑ ☐ Each drug dispensed from the pharmacy does have a label securely affixed to the container indicating the required minimum information, including: [UCA 58-17b-602 (5) (a) (i-viii)]

- ☑ name, address, & phone number of pharmacy
- ☑ filling date or last dispensing date
- ☑ name of the prescriber
- ☑ trade, generic or chemical name
- *(Unless Otherwise Indicated by Prescriber)*
- ☑ serial number of prescription
- ☑ name of the patient or auimal owner/species
- ☑ directions for use & cautionary statements
- ☑ amount dispensed & strength of dosage form
- ☑ beyond use date

37 ☑ ☐ Unless otherwise requested, child-resistant containers are used for dispensing medications to patients. [UAC R156-17b-502(6) & 16 CFR 1700.14]

38 ☑ ☐ Controlled substances are not accepted back for destruction unless allowed for by state and federal law. [UAC R156-37-606 (1-2) & 21 CFR 1307.21]

39 ☐ ☑ The registered pharmacy only processes electronically signed prescriptions for controlled substances under the following conditions: the pharmacy uses a pharmacy application that meets all the applicable requirements; the prescription is otherwise in conformity with the requirements of the Code of Federal Regulations; and Certification Authority (CA) has been obtained. The electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form and at no time may the prescription be converted to another form *(i.e. facsimile)* for transmission. [CFR, Title 21, Chapter 11, Section 1311, UAC R156-17b-613 (1)]

40 ☑ ☐ Prescription files, including refill information, is maintained for a minimum of five years and should be immediately retrievable in written or electronic format. [UAC R156-17b-612 (4)]

41 ☑ ☐ Prescription records may be maintained electronically so long as the original of each prescription, including telephone prescriptions, is maintained in a physical file and contains all of the information required by federal and state law; and an automated data processing system is used for the storage and immediate retrieval of refill information for prescription orders.
[UAC R156-37-602 (4) (a-b)]

42 ☐ ☐ All records relating to Schedule II controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years.
[UAC R156-37-602(3) (5)]
n/a

43 ☐ ☐ All records relating to Schedule III, IV, V controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years.
[UAC R156-37-602(3) (6)]
n/a

44 ☐ ☐ Requirement for annual controlled substances inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs and drugs in automated pharmacy systems.
[UAC R156-17b-605 (4)]
n/a

45 ☐ ☐ Requirements for taking the initial controlled substances inventory shall include the following: all pharmacies shall take an inventory on the opening day of business. Such inventory shall include all controlled substances including any out-of-date drugs and drugs in automated pharmacy systems. In the event a pharmacy commences business with no controlled substances on hand, the pharmacy shall record this fact as the initial inventory. An inventory reporting no Schedule I and II controlled substances shall be listed separately from an inventory reporting no Schedule III, IV, and V controlled substances. The initial inventory shall serve as the pharmacy's inventory until the next completed inventory as specified in Subsection (4) of this section. [UAC R156-17b-605 (3) (a-c)] ☐ N/A
n/a

46 ☐ ☐ General Requirements for inventory of a pharmacy shall include: [UAC R156-17b-605 (2)(a)(b)(c)(f)(g)(h)(k)(l)]
n/a

☐ the PIC shall be responsible for taking all required inventories, but may delegate the performance of the inventory to another person or persons;

☐ the inventory records shall be maintained for a period of five years and be readily available for inspection

☐ the inventory records shall be filed separately from all other records

☐ the inventory may be taken either as the opening of the business or the close of business on the inventory date;

☐ the person taking the inventory and the PIC shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken. The signature of the PIC and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory.

☐ the inventory of Schedule I and II controlled substances shall be listed separately from the inventory of Schedule III, IV and V controlled substances;

☐ if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventories, the perpetual inventory shall be reconciled on the date of the inventory.

n/a 47 ☐ ☐ All pharmacies shall maintain a perpetual inventory of all Schedule II controlled substances that shall be reconciled according to facility policy. [UAC R156-17b-605(6)]

n/a 48 ☐ ☐ The pharmacy does reconcile its controlled substance inventory to account for shortages of controlled substances. [UAC R156-17b-603 (3) (k) & R156-37-502(4)]

49 ☑ ☐ Any facility who experiences any theft, including diversion, or significant loss of controlled substances shall immediately file the appropriate forms with the Drug Enforcement Administration, with a copy to the Division directed to the attention of the Investigation Bureau Division; and report the incident to the local law enforcement agency. [UAC R156-37-602 (2)]

n/a 50 ☐ ☐ Pharmacists or other responsible individuals do verify that the suppliers' invoices of controlled substances, listed on the invoices were actually received by clearly recording their initials and the actual date of receipt of the controlled substances. [UAC R156-17b-614a (11)]

n/a 51 ☐ ☐ The facility shall maintain a record of suppliers' credit memos for controlled substances. [UAC R156-17b-614a (12)]

n/a 52 ☐ ☐ The facility does maintain a copy 3 of DEA order form (form 222) which has been properly dated, initialed, and filed and all copies of each unaccepted or defective order form and any attached statements or other documents. [UAC R156-17b-614a(9)(a-c)]

53 ☑ ☐ The Division shall implement on a statewide basis, including non-resident pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to submit information: real-time submission of the information required to be submitted under this part of the controlled substance database; and 24-hour daily or next business day, whichever is later, batch submission of the information required to be submitted under this part to the controlled substance database. [UCA 58-37f-203(1)(a)(i,ii)]

54 ☑ ☐ In accordance with 58-37f-203(6), the pharmacist-in-charge and the pharmacist identified in Subsections 58-37f-203(2) and (3) shall provide the following data fields to the Division: the state that issued identification, type of identification used, identification number used and first and last name of individual picking up dispensed drug. [UCA R156-37f-203 (4) (bb-ff)]

55 ☐ ☑ The pharmacy maintains emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMT's, ambulances)? If the answer is "yes", note name(s) of facilities or entities.

56 ☐ ☑ The pharmacy maintains automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home? If the answer is "yes", note type and location.

57 ☐ ☑ The pharmacy utilizes an Automated Pharmacy System? If the answer is "yes" to this question, a automation questionnaire must be completed. [UAC R156-17b-620]

58 ☐ ☑ The facility is engaged in hazardous drug compounding as defined by USP-NF Chapter 800. If you answer "yes" to this question, a compounding questionnaire must be completed.

59 ☑ ☐ The facility is engaged in simple, medium, or complex compounding activities as defined by USP 35 Chapter 795. If you answer "yes" to this question, a compounding questionnaire must be completed. [(UAC R156-17b-614a (2)]

60 ☐ ☑ The facility is engaged in low, medium, or high risk *sterile* compounding as defined by USP 35 Chapter 797. If you answer "yes" to this question, a compounding questionnaire must be completed. [UAC R156-17b-614a (2)]

COMMENTS

Assisted by PIC Adrienne Murray.

*Pharmacy had pharmacy licenses posted. Pharmacy did not have a readily available, current list of licensed pharmacy employees. The list is to have licensee names, numbers, expiration dates, and license types.

The pharmacy uses supportive personnel for shipping and inventory.

All prescriptions are shipped from pharmacy to patient. Shipping SOPs and statements are in compliance.

Prescription labels are compliant.

The pharmacy recently obtained a controlled substance license. The DEA registration is pending. Pharmacy has 120 days to obtain a DEA registration. Pharmacy is to follow up once received via email. tdrebing@utah.gov.

Pharmacy does not have any controlled substances.

Pharmacy is working on submitting to the CSDB.

A non-sterile compounding inspection was conducted.

☑ By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."

Signature of Responsible Party: [signature] Date: 9/5/24

Name of Responsible Party (Print): Adrienne Murray

Signature of Division Investigator: [signature] Date: 9/5/24

Name of Division Investigator (Print): Travis Drebing

Revised 8/2023

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LICENSE

SPECTRUM SOLUTIONS RX, LLC

EFFECTIVE 01/26/2026

EXPIRATION 07/26/2026

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

14266761-1703 Pharmacy - Class A
14266761-8913 Dispensing Controlled Substance License

Compounding Non-Sterile

DBA:

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

SPECTRUM SOLUTIONS RX, LLC
12278 S LONE PEAK PKWY, STE 106
DRAPER UT 84020

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE
DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING
ACTIVE LICENSE

EFFECTIVE DATE: **01/26/2026**

EXPIRATION DATE: **07/26/2026**

ISSUED TO: **SPECTRUM SOLUTIONS RX, LLC**
12278 S Lone Peak Pkwy, Ste 106
Draper UT 84020

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

14266761-1703 Pharmacy - Class A
14266761-8913 Dispensing Controlled Substance License
Compounding Non-Sterile
DBA:

Form #1

Details for SPECTRUM SOLUTIONS RX, LLC

License Information

Name:	SPECTRUM SOLUTIONS RX, LLC
City, State, Zip, Country:	Draper UT 84020 United States
Profession:	Pharmacy
License Type:	Pharmacy - Class A
License Number:	14266761-1703
Obtained By:	Application
License Status:	Active
Original Issue Date:	01/26/2026
Expiration Date:	07/26/2026
Agency and Disciplinary Action*:	NO DISCIPLINARY ACTIONS WITHIN THE TIME FRAME ESTABLISHED IN UTAH CODE 63G-4-106 AND 107**
Docket and Citation Number(s):	N/A
E-Prescriber:	

Specialty(s):
Compounding Non-Sterile

Controlled Substance License(s) 14266761-8913	View Controlled Substance License

Give Feedback

This information is accurate as far as is contained in the Division's official records. It does not reflect whether an entity required to maintain a current registration with the Division of Corporations is current in that registration. You can verify such status at https://secure.utah.gov/bes/bes. Additionally, this verification does not show a complete

Privacy - Terms

license history or interruptions of licensure. Original issue dates listed as 01/01/1910 and 01/01/1911 were unknown at the time the Division implemented its first electronic licensing database.

*NOTE: The disciplinary documents linked to this website include final orders issued by DOPL, with the exception of citations. Click here for citations.

Give Feedback

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Spectrum Solutions Rx, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04425

Physical Address 12278 S Lone Peak Pky, Suite 106

City Draper State UT Zip 84020

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-500-4711 Website _____

Licensing Company Email pharmacy@genesiscompounding.com

Section 2: Personal Information

First William Middle _____ Last Phillips

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
GRANGER HIGH SCHOOL		1985 - 1987	
Address	City	State	Zip
3580 S. 3600 W	W.V.C.	UT	84119
Diploma/Degree obtained, if any			
HIGH SCHOOL			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/21 - 2026	[redacted]			
4/18 - 11/21				
3/09 - 4/18				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
SPECTRUM SOLUTIONS			08/05 - CURRENT
Business Address	**City**	**State**	**Zip**
12298 S. LONE PEAK PKWY #106	DRAPER	UT	84020
Phone	**Title**		
801- 589-0468	COO - CEO		
Description of Duties			
OVERSIGHT OF ALL OPERATIONS			

Business Name			From - To (MM/YY – MM/YY)
SPECTRUM RX - SAME AS ABOVE			2022 - CURRENT
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

WILLIAM PHILLIPS

Print Name (First, Last)

William Phillips

Original Signature (electronic, copies or stamps not accepted)

02/05/2026

Date

Please have this section completed in the presence of a Notary Public.

State of UTAH, ss. County of SALT LAKE

I, DANIEL SPRINGER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/5/2026

Date

Subscribed and Sworn to before me this 5 day of FEBRUARY 2026

Notary Public Signature

DANIEL SPRINGER
Notary Public - State of Utah
Comm. No. 723389
My Commission Expires on
Mar 3, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Spectrum Solutions Rx, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04425

Physical Address 12278 S Lone Peak Pky, Suite 106

City Draper State UT Zip 84020

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-500-4711 Website _____

Licensing Company Email pharmacy@genesiscompounding.com

Section 2: Personal Information

First Ryan Middle _____ Last Davies

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
BRIGHAM YOUNG UNIVERSITY		1995 - 1997	
Address	**City**	**State**	**Zip**
	PROVO	UT	84602
Diploma/Degree obtained, if any			
BACHELOR OF SCIENCE - POLITICAL SCIENCE			

School Name		From - To (MM/YY – MM/YY)	
RICKS COLLEGE		1993 - 1994	
Address	**City**	**State**	**Zip**
	REXBURG	ID	83460
Diploma/Degree obtained, if any			
ASSOCIATES DEGREE - BUSINESS MANAGEMENT			

School Name		From - To (MM/YY – MM/YY)	
MARTIN COUNTY HIGH SCHOOL		1986 - 1990	
Address	**City**	**State**	**Zip**
	STUART	FL	34996
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11 - 2007 - PRESENT	[redacted]			
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
GENESIS COMPOUNDING	AUG 2025 – PRESENT

Business Address	City	State	Zip
12278 S. LONE PEAK PKWY #106	DRAPER	UT	84020

Phone	Title
	CEO

Description of Duties: FOUNDER, OWNER & OPERATOR

Business Name	From - To (MM/YY – MM/YY)
CANCERVAX	2021 - 2025

Business Address	City	State	Zip
851 PASEO NUEVO, 2ND FLOOR	SANTA BARBARA	CA	93101

Phone	Title
	CEO

Description of Duties: OPERATIONS, MANAGEMENT, CAPITAL RAISING

Business Name	From - To (MM/YY – MM/YY)
CYMRU VENTURES	2019 – PRESENT

Business Address	City	State	Zip
1594 LA COSTA CT	DRAPER	UT	84020

Phone	Title
	OWNER

Description of Duties: BUSINESS ADVISORY SERVICES FOR BIOTECH COMPANIES

Business Name	From - To (MM/YY – MM/YY)
SALT COAST VENTURES	2019 - 2022

Business Address	City	State	Zip
26 RIO GRANDE ST. #2702	SALT LAKE CITY	UT	84111

Phone	Title
	PARTNER

Description of Duties: HELPED MANAGE INVESTMENT PORTFOLIO & CONDUCT DUE DILIGENCE FOR NEW INVESTMENTS

Business Name	From - To (MM/YY – MM/YY)
CURZA	2013 - 2019

Business Address	City	State	Zip
650 KOMAS DRIVE, SUITE 202	SALT LAKE CITY	UT	84101

Phone	Title
	CEO

Description of Duties: FOUNDED, MANAGED & OPERATED A BIOTECH COMPANY

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
CLARKE CAPITAL PARTNERS			2013 - 2018	
Business Address		**City**	**State**	**Zip**
5701 EDGEWOOD DR.		PROVO	UT	84602
Phone	**Title**			
	SENIOR VICE PRESIDENT			
Description of Duties				
MANAGED & EVALUATED ALL NEW INVESTMENTS. MANAGED PORTFOLIO OF INVESTMENTS				

Business Name			From - To (MM/YY – MM/YY)	
RENEWABLE ENERGY DEVELOPMENT CORP.			2008 - 2013	
Business Address		**City**	**State**	**Zip**
		SOUTH JORDAN	UT	
Phone	**Title**			
	CEO			
Description of Duties				
CO-FOUNDER & CEO - MANAGED BUSINESS, NEGOTIATED PARTNERSHIPS & CONTRACTS FOR SOLAR & WIND PROJECTS				

Business Name			From - To (MM/YY – MM/YY)	
O2 BLUE			2001 - 2008	
Business Address		**City**	**State**	**Zip**
		SANDY	UT	84047
Phone	**Title**			
	CO-FOUNDER, VP BIZ DEV			
Description of Duties				
CO-FOUNDED, MANAGED OPERATIONS & ALL NEW BUSINESS, BUILT ENVIRONMENTAL COMMODITY MARKETPLACE.				

Business Name			From - To (MM/YY – MM/YY)	
FOUND, INC			1997 - 2001	
Business Address		**City**	**State**	**Zip**
		SALT LAKE CITY	UT	84111
Phone	**Title**			
	CO-FOUNDER, VP BIZ DEV			
Description of Duties				
DEVELOPED THE FIRST ONLINE INVENTORY MANAGEMENT & ECOMMERCE TOOL.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

RYAN DAVIES

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-5-2026

Date

Please have this section completed in the presence of a Notary Public.

State of UTAH, ss. County of SALT LAKE

I, DANIEL SPRINGER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/5/2026

Date

Subscribed and Sworn to before me this 5 day of FEBRUARY 2026.

Notary Public Signature

DANIEL SPRINGER
Notary Public - State of Utah
Comm. No. 723389
My Commission Expires on
Mar 3, 2026
(Seal)

4FFF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

4

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☒ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: SWYFT SCRIPTS - DFW

Physical Address: 1550 Norwood Dr STE 300

City: Hurst State: TX Zip: 76054

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 281-336-9927 Toll Free # (NAC 639.708, NRS 639.23286): 888-799-3879

Fax: 281-335-6645 Contact Email: DFW@SWYFTSCRIPTS.COM

Website: WWW.SWYFTSCRIPTS.COM

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Vard Tyrone II

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 25027

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Christopher Vard Tyrone II	NV Pharmacist Registration #: TX #66844
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✔	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): Prestige Health Solutions, LLC

Corporation/Organization Name: Rejuvenation Pharmacy Incorporated, LLC

Mailing Address: 1550 Norwood Dr STE 300

City: Hurst State: TX Zip: 76054

Telephone: 888-799-3879 Email: DFW@SWYFTSCRIPTS.COM

Contact Person Name: Chris Tyrone

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Chief Pharmacy Officer (title) for SWYFT SCRIPTS - DFW (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Christopher Vard Tyrone II

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

06/10/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Christopher Vard Tyrone II hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Chief Pharmacy Officer (title) for SWYFT SCRIPTS - DFW (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 10 day of June, 2025

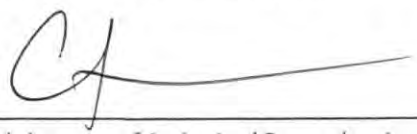
Notary Public

Stephanie Aros
My Commission Expires
10/26/2026
Notary ID 134034677

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Vard Tyrone

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

6-10-25

Date

Board Use Only	Date Received: 6/30/25	Amount: $500 CK 6862801746

Subject: Explanation Regarding Board Order for SWYFT SCRIPTS - DFW

To Whom It May Concern,

I am writing on behalf of SWYFT SCRIPTS - DFW to address a previous board order issued by the Texas State Board of Pharmacy. This order pertained to a failure to engage in the business of pharmacy within six months of licensure.

This delay in initiating operations was due to unforeseen logistical and operational challenges that arose during the setup phase. These issues were promptly addressed, and since that time, we have worked diligently to ensure full compliance with all state regulations.

We are pleased to report that SWYFT SCRIPTS - DFW has since passed all required inspections by the Texas State Board of Pharmacy and is now fully operational. Our pharmacy provides retail services and home delivery options for patients and contracts with employers to deliver cost-effective prescription solutions.

We remain committed to upholding the highest standards of care and compliance in the pharmacy industry. Should you require any further information or documentation regarding this matter, please do not hesitate to contact me.

Sincerely,

Chris Tyrone, PharmD
Chief Pharmacy Officer

SwyftScripts

SwyftScripts
chris@swyftscripts.com
682 438 2904
1800 West Loop South
Suite 2110
Houston, TX 77027
www.swyftscripts.com

RE: IN THE MATTER OF
SWYFT SCRIPTS - SOUTHLAKE
(PHARMACY LICENSE #34513)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 34513 issued to Swyft Scripts - Southlake (Respondent), 771 East Southlake Boulevard, Suite 223, Southlake, Texas 76092.

By letter dated February 15, 2024, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Sections 565.001(a)(1), (2), (12) and (13); and 565.002(a)(3) and (7) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2023); and

Sections 281.7(a)(13), 291.11(a) and (b); 291.32(a)(2)(H); and 295.3 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2023), in that allegedly:

COUNT

From on or about May 2, 2023, through on or about September 19, 2023, Swyft Scripts - Southlake (previously licensed as Rejuvenation Pharmacy), 771 East Southlake Boulevard, Suite 223, Southlake, Texas 76092 (previously located at 12423 Cutten Road, Suite C, Houston, Texas 77066 and 2815 North Main Street, Stafford, Texas 77477), failed to legally operate, in that the pharmacy failed to engage in the business of pharmacy within six months of the date of the issuance of its license. Specifically, Swyft Scripts - Southlake became licensed as a Class A pharmacy on November 1, 2022. Subsequently, on or about September 19, 2023, a Texas State Board of Pharmacy inspector received dispensing records from the pharmacy, which indicated that only one prescription was dispensed during the time period alleged above, such that the pharmacy was unable to demonstrate observable pharmacy business activity on a regular and routine basis.

An informal conference was held via videoconference on April 3, 2024, with Christopher Tyrone Vard II, R.Ph., Pharmacist-in-Charge, on behalf of Respondent, in attendance. The informal conference was heard by a Board panel comprised of: Donna Montemayor, R.Ph., Board Member; Jenny Downing Yoakum, R.Ph., Board Member; and Daniel Carroll, Pharm.D., Executive Director/Secretary, with Megan G. Holloway, General Counsel. Kelly M. Souza, Staff Attorney, was also in attendance.

At the aforementioned conference, Christopher Tyrone Vard II, on behalf of Respondent, waived the right to be represented by legal counsel. By signing this Order, Zaryan Hamidani,

Managing Officer, Rejuvenation Pharmacy Incorporated LLC, on behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent shall pay an administrative penalty of three thousand dollars ($3,000) due one hundred twenty (120) days after the entry of this Order.

(2) Respondent shall be responsible for all costs relating to compliance with the requirements of this Order.

(3) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2023), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2024).

And it is so ORDERED

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 6th day of August, 2024.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Daniel Carroll. Pharm.D.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Zaryan Hamidani, Managing Officer, Rejuvenation Pharmacy Incorporated LLC
On behalf of Swyft Scripts - Southlake

APPROVED AS TO FORM:

Megan G. Holloway. General Counsel
Texas State Board of Pharmacy

	Richmond	DFW	Central
License Number	TX #30906 Expires: 06/30/2026	TX #34513 (11/30/26) CO #0007915 (10/31/26) SD #400-2571 (6/30/26) IA #5847 (12/31/25) WY #NR-52553 (6/30/26) CT #0004479 (8/31/25) MT #114295 (11/30/25) PA #NP002327 (8/31/27) MO #2025022197 (10/31/25) OK #99-9963 (06/30/26) NJ #28RO00269100 (6/30/26)	TX #33628 Expires: 01/31/2027
NPI	1033560735 Enumeration Date: 06/24/2016	1780327122 Enumeration Date: 04/14/2022	1851994859 Enumeration Date: 11/20/2020
NCPDP	5919406 Open Date: 08/01/2016	5942291 Open Date: 02/01/2024	5936476 Open Date: 04/01/2022
DEA	FU6206874 Issued: 04/13/2022 Expires: 02/29/2028	FR3396404 Issued: 09/07/2023 Expires: 02/28/2026	N/A
TIN/EIN	81-1485846	88-1667727	83-4072151
LLC Name	USPS Retail Pharmacy, LLC	Rejuvenation Pharmacy Incorporated, LLC	Prestige Health Solutions, LLC
DBA Name	Swyft Scripts – Richmond	Swyft Scripts - DFW	Swyft Scripts
Liability Insurance	Pharmacist Mutual VST 000661700 (General), PSP 016195801 (Professional) Issued: 08/17/2024 Expires: 08/17/2025		
Phone	713-325-2700	281-336-9927	888-799-3879
Fax	281-605-6644	281-335-6645	281-326-6564
Email	Richmond@SwyftScripts.com	DFW@SwyftScripts.com	Admin@SwyftScripts.com
Address	22001 Southwest Fwy Suite 110, Richmond, TX 77469 Fort Bend County	1550 Norwood Dr STE 300, Hurst, TX 76054 Tarrant County	1800 West Loop South STE 2110, Houston, TX 77027 Harris County
GLN	1100093267966	1200144828563	N/A
Pharmacist in Charge (PIC)	Jane Ijoma TX #65933 Expires: 09/30/2025	Chris Tyrone TX #66844 (1/31/26) OK #19068 (1/31/26) MI #5302417561 (6/16/27) FL #68967 (09/30/27)	Chris Tyrone TX #66844 (1/31/26) OK #19068 (1/31/26) MI #5302417561 (6/16/27) FL #68967 (09/30/27)
Medicare Number	N/A	N/A	N/A
Rx Switch	RxLinc	RxLinc	RxLinc
835 File Processor	ReconRx	ReconRx	N/A
Purchase Date	03/20/2024	06/06/2023	Original Owner

Owner (100%)	Yasser Almuaala	Yasser Almuaala	Yasser Almuaala
Managing Officers			
Legal Name	Yasser Hilal Almuaala	Zaryan Ahmed Hamidani	Christopher Vard Tyrone II
Title	Owner, CEO	Chief Operating Officer	Chief Pharmacy Officer
DOB	5-5-1992	11-14-1990	01-12-1996
Address	3419 Apple Dale Dr, Houston, TX 77084	18023 Lumsden Ln, Richmond, TX 77407	421 Circleview Dr N, Hurst, TX 76054
Email	Yasser@SwyftScripts.com	Zaryan@SwyftScripts.com	Chris@SwyftScripts.com
Phone	832-716-0267	281-844-8626	682-438-2904
Fax	281-335-6645	281-335-6645	281-335-6645
TX DL #	34067007	28326777	34709108
Ownership	100%	0%	0%

Pharmacy Staff				
Legal Name	Title	License	DOB	Address
Christopher Vard Tyrone II	PharmD	TX # 66844 Expires 01/31/26 OK # 19068 Expires 01/31/26	01/12/1996	421 Circleview Dr N, Hurst, TX 76054
Jane NTO Ijoma	PharmD	TX # 65933 Expires 09/30/25	09/12/1989	5007 Lucky Fawn Ln, Richmond, TX 77406
Clara Inez Estrada	Tech	TX # 273114 Expires 06/30/25	05/21/1992	11428 Amber Plains Dr, Houston, TX 77048
Jameellah Yasmeen Robinson	Tech	TX # 372323 Expires 06/30/26	03/13/1995	150 Cobia Dr, Katy, TX 77494
Ryleigh Elizabeth Parks	Tech	TX # 316126 Expires 12/31/26	06/03/2001	709 Mountain Laurel Ln, Bedford, TX 76021
Mayra Vanessa Mendoza	Tech	TX # 358269 Expires 06/30/26	10/16/1997	6600 Marie St, North Richland Hills, TX 76021
Stachia Michelle Baxter	Tech	TX #110291 Expires 04/30/26	04/06/1984	13217 Charlotte Ann Ln, Haslet, TX 76052
Xia Yana Paredez	Tech	TX #330630 Expires 8/31/25	06/22/1997	1505 Tennis Dr Apt 112, Bedford, TX 76022
Naomi Grace Tyrone	Tech in Training	TX # 369923 Expires 04/30/26	06/16/2008	5941 Diamond Oaks Dr S, Haltom, TX 76117
Sabrina Isabella Quintanilla	Tech in Training	TX #380422 Expires 11/30/26	06/10/2005	7223 Sandpiper Dr, Houston, TX 77074
Aaliyah Hilal Almuaala	Tech in Training	TX # 379950 Expires 11/30/26	06/01/1986	70 Prospect St Apt #8, Westbrook, ME 04092

Ownership Structure

Rejuvenation Pharmacy Incorporated, LLC (DBA: Swyft Scripts – DFW) is owned by Prestige Health Solutions, LLC (DBA: Swyft Scripts) is owned by Yasser Almuaala (100%)

USPS Retail Pharmacy, LLC (DBA: Swyft Scripts – Richmond) is owned by Prestige Health Solutions, LLC (DBA: Swyft Scripts) is owned by Yasser Almuaala (100%)

FRANCHISE TAX ACCOUNT STATUS

This record as of May 12, 2025 at 16:15:13

REJUVENATION PHARMACY INCORPORATED LLC

Texas Taxpayer Number:	32084309114
Mailing Address:	1550 NORWOOD DR STE 300 HURST, TX 76054 - 3653
Right to Transact Business in Texas:	ACTIVE
State of Formation:	TX
SOS Registration Status (SOS status updated each business day):	ACTIVE
Effective SOS Registration Date:	04/27/2022
Texas SOS File Number:	0804540582
Registered Agent Name:	PRESTIGE HEALTH SOLUTIONS, LLC DBA SWYFT SCRIPTS
Registered Office Street Address:	7324 SOUTHWEST FREEWAY SUITE 975 HOUSTON, TX 77074

Public Information Report for Year 2024

Title	Name and Address
DIRECTOR	**YASSER ALMUAALA** 7324 SOUTHWEST FREEWAY STE 975 HOUSTON, TX 77074
MANAGING M	**YASSER ALMUAALA** 7324 SOUTHWEST FREEWAY STE 975 HOUSTON, TX 77074
MANAGING M	**ZARYAN HAMIDANI** 18023 LUMSDEN LN RICHMOND, TX 77407
DIRECTOR	**ZARYAN HAMIDANI** 18023 LUMSDEN LN RICHMOND, TX 77407

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for Rejuvenation Pharmacy Incorporated LLC (file number 804540582), a Domestic Limited Liability Company (LLC), was filed in this office on April 26, 2022.

It is further certified that the entity status in Texas is in existence.

Delayed Effective date: April 27, 2022

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on May 12, 2025.

Jane Nelson
Secretary of State

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Rejuvenation Pharmacy Incorporated, LLC (DBA: SWYFT SCRIPTS - DFW)

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 1550 Norwood Dr STE 300

City Hurst State TX Zip 76054

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-799-3879 Website www.swyftscripts.com

Licensing Company Email DFW@SwyftScripts.com

Section 2: Personal Information

First Christopher Middle Vard Last Tyrone

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Swyft Scripts			11/22 - Current	
Business Address		**City**	**State**	**Zip**
1800 W Loop S STE 2110		Houton	TX	77027
Phone	**Title**		**Number of Employed Hours**	
888-799-3879	Chief Pharmacy Officer, PIC		1,000	
Description of Duties				
Establish all operational and security protocols. Prepare all necesarry documentation and credentialing for Class G pharmacy. Oversee all transition of ownership and employee transfers, training and documentation for acquisitions.				

Business Name			From - To (MM/YY – MM/YY)	
Swyft Scripts - DFW			09/23 - Current	
Business Address		**City**	**State**	**Zip**
1550 Norwood Dr STE 300		Hurst	TX	76054
Phone	**Title**		**Number of Employed Hours**	
888-799-3879	Chief Pharmacy Officer, PIC		3,250	
Description of Duties				
Establish all operational and security protocols. Prepare all necesarry documentation and credentialing for all state applications. Oversee all transition of ownership and employee transfers, training and documentation for acquisitions.				

Business Name			From - To (MM/YY – MM/YY)	
Grapevine Drug Mart			08/21 - Current	
Business Address		**City**	**State**	**Zip**
1115 W Northwest Hwy STE H		Grapevine	TX	76051
Phone	**Title**		**Number of Employed Hours**	
817-481-5780	Pharmacist		4,750	
Description of Duties				
Perform standard pharmacist verification and oversight at a community independent pharmacy. Previously worked full time and now work as relief pharmacist approx 5-15 hours per week.				

Business Name			From - To (MM/YY – MM/YY)	
USPS Retail Pharmacy (Now Swyft Scripts - Richmond)			01/24 - 03/24	
Business Address		**City**	**State**	**Zip**
22001 Southwest Freeway STE 110		Richmond	TX	77469
Phone	**Title**		**Number of Employed Hours**	
713-325-2700	Chief Pharmacy Officer, Interim PIC		500	
Description of Duties				
Establish all operational and security protocols. Oversee the transition of ownership and employee transfers, training and documentation for acquisitions.				

Business Name			From - To (MM/YY – MM/YY)	
Advanced Prescription Services			08/20 - 08/21	
Business Address		**City**	**State**	**Zip**
3671 Broadway Blvd #300		Garland	TX	75043
Phone	**Title**		**Number of Employed Hours**	
214-703-9100	Pharmacy Manager		1,000	
Description of Duties				
Oversee all operations, contracts and relationships with LTCF, Assisted Living and other facilities we provided pharmacy services for. Immunized thousands of patients at bedside or facility wide clinics.				

Continue on next page if additional space is needed.

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Southwestern Oklahoma State University College of Pharmacy		08/16 - 05-20	
Address	**City**	**State**	**Zip**
100 W Campus Dr	Weatherford	OK	73096
Diploma/Degree obtained, if any			
Doctorate of Pharmacology			

School Name		From - To (MM/YY – MM/YY)	
Southwestern Oklahoma State University		08/14 - 07/16	
Address	**City**	**State**	**Zip**
100 W Campus Dr	Weatherford	OK	73096
Diploma/Degree obtained, if any			
Bachelors in Pharmaceutical Sciences			

School Name		From - To (MM/YY – MM/YY)	
Grapevine High School		01/12 - 05/14	
Address	**City**	**State**	**Zip**
3223 Mustang Dr	Grapevine	TX	76051
Diploma/Degree obtained, if any			
Highschool Diploma			

School Name		From - To (MM/YY – MM/YY)	
Bethesda Christian School		08/10 - 12/11	
Address	**City**	**State**	**Zip**
4700 N Beach St	Fort Worth	TX	76137
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/22 - Current	[redacted]			
09/21-03/22				
09/20 - 09/21				
05/20 - 09/20				
05/19 - 05/20				
08/17 - 05/19				
08/16 - 08/17				
08/15 - 08/16				
08/14 - 08/15				

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Business Name			From - To (MM/YY – MM/YY)	
Garland Independent Pharmacy			08/20 - 08/21	
Business Address		City	State	Zip
3641 Broadway Blvd # 100		Garland	TX	75043
Phone	Title		Number of Employed Hours	
972-864-1110	Pharmacist in Charge		1,750	
Description of Duties				
Oversee all operations and transition wholesalers, PSAO and many other suppliers to increase profitability. Organized and facilitied mass Covid-19 vaccine clinics immunizing > 500 patients daily.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
02/15/24	08/06/2024	TX	Southlake	Tarrant

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2024-01330	Texas Board of Pharmacy

Reason/Charge
Failure to operate a pharmacy within 6 months of licensure

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
Rejuvenation Pharmacy Incorporated, LLC

Provide explanation below:

I am writing on behalf of SWYFT SCRIPTS - DFW to address a previous board order issued by the Texas State Board of Pharmacy. This order pertained to a failure to engage in the business of pharmacy within six months of licensure.

This delay in initiating operations was due to unforeseen logistical and operational challenges that arose during the setup phase. These issues were promptly addressed, and since that time, we have worked diligently to ensure full compliance with all state regulations.

We are pleased to report that SWYFT SCRIPTS - DFW has since passed all required inspections by the Texas State Board of Pharmacy and is now fully operational. Our pharmacy provides retail services and home delivery options for patients and contracts with employers to deliver cost-effective prescription solutions.

We remain committed to upholding the highest standards of care and compliance in the pharmacy industry. Should you require any further information or documentation regarding this matter, please do not hesitate to contact me.

CT

Original Signature (electronic, copies or stamps not accepted)

6-26-25

Date

I, Christopher Vard Tyrone II, **certify that as the designated representative for**

Rejuvenation Pharmacy Incorporated, LLC (DBA: Swyft Scripts - DFW),

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CT I am at least 21 years of age;
3. CT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Vard Tyrone II

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-26-25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Vard Tyrone II

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-26-25

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Tarrant

I, ~~Ros~~ PB Christopher Vard Tyrone II, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6-26-25

Date

Subscribed and Sworn to before me this 26th day of June, 2025

Rosemarie Bray

Notary Public Signature

(Seal)

TEXAS STATE BOARD OF PHARMACY

Re:	Christopher Vard Tyrone II, R.Ph.
License No.:	66844
Date Issued:	July 16, 2020
Licensure Status:	Active
Expiration Date:	January 31, 2026
Granted by:	Examination
Prior Disciplinary Orders:	No

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Christopher Vard Tyrone II, R.Ph. (Texas Pharmacist License #66844) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

Eamon D. Briggs
Deputy General Counsel
Texas State Board of Pharmacy

May 9, 2025
Date

1801 Congress Avenue Suite 13.100 Austin, Texas 78701-1319 512-305-8000 (voice) 512-305-6778 (fax) www.pharmacy.texas.gov

Board of Pharmacy Remedial Plan Update
SwyftScripts, LLC (33628)
Chris Tyrone II, PharmD (66844)

To whom it may concern,

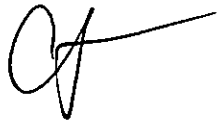
On January 11, 2022 the Texas Board of Pharmacy requested records and determined that SwyftScripts (33628) had failed to engage in the business of pharmacy within 6 months of the date we received our license on January 26, 2021. SwyftScripts has rectified this error by engaging in the practice of pharmacy to the extent that is allowed by our Class G license. We are now processing prescriptions that we receive from prescribers and transferring them to one of our network pharmacies that can fulfill the patient's prescriptions quickly and at the lowest cost to the patient. We are working with prescribers to correct any omitted instructions in their prescriptions and find alternatives that will be covered by insurance and are available on the market before we transfer the prescription to one of our partner pharmacies.

The first step we took to rectify our negligence to practice pharmacy was to establish our pharmacy network and begin marketing to prescribers. We have also contracted with a pharmacy management system (DRX) to allow us to receive, process, transfer and store prescription information in accordance with State and Federal requirements. We have also updated our policies and procedures to reflect our current business practices and to adhere to the standards set forth by the State Board of Pharmacy. This year we have processed 1,179 prescriptions from multiple different prescribers and currently have 12 partner pharmacies in our network.

During our most recent inspection by the board of Pharmacy it was determined by Keya Henry that SwyftScripts was in full compliance with the Texas State Board of Pharmacy rules and regulations. The inspection included an on site visit where she determined that we were not in possession of any prescription medications and had all required licenses and public disclaimers posted. The virtual component of the inspection included a review of our prescription files, contracts, policies and procedures along with our pharmacy management software (DRX) and their security safeguards to protect patient information. Keya also confirmed our other technical safeguards such as two factor authentication to access our servers, IP address verification for those permitted to access databases and HIPAA compliant email and communication services.

Please let me know if there is any additional information required or concerns that the Texas Board of Pharmacy may have that I can address.

Thank You,
Chris Tyrone II, PharmD



Dear Texas Board of Pharmacy,

Christopher Tyrone joined Swyft Scripts in November of 2021. At the time, we were in discussions with a large tech company to form a joint venture in which we would be processing transfers on their behalf. When this organization decided to change their path, we had to pivot quickly and Chris was instrumental in that process. He has helped us in overcoming the failures of the previous pharmacist we recruited and spearheaded our growth. He has recently been informed that the board is considering disciplinary action against him for the failure to operate a pharmacy. We, Swyft Scripts, have taken full responsibility for this and we recognize that whether or not there was a reason that it took us longer than it should have to begin operations, it was a failure on our behalf and we immediately took action to rectify. We humbly and respectfully ask the Board to recognize that Mr. Tyrone was not at fault for this failure, and that he in fact was a major contributor to our ability to quickly recover and begin operations.

Please feel free to reach out if you have any questions or concerns.

Respectfully,

Yasser Almuaala

Chief Executive Officer

Prestige Health Solutions

Yasser@prestigehealthsolutions.net

Mobile [redacted]

7324 Southwest Freeway Suite 975

Houston, TX 77074

www.prestigehealthsolutions.net
www.swyftscripts.com

REMEDIAL PLAN #2022-02717

RE: IN THE MATTER OF CHRISTOPHER VARD TYRONE II (PHARMACIST LICENSE #66844)

BEFORE THE TEXAS STATE BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacist license number 66844 issued to Christopher Vard Tyrone II (Respondent).

By letter dated March 15, 2022, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated the applicable law set forth below. An informal conference was held via videoconference on June 8, 2022, with Respondent in attendance. The informal conference was heard by a Board panel comprised of: Julie Spier, R.Ph., Board Member; Donna Montemayor, R.Ph., Board Member; and Tim Tucker, Pharm.D., Executive Director/Secretary; with Megan G. Holloway, General Counsel. Mary Moretti, Staff Attorney, was also in attendance.

BOARD HISTORY

Respondent has not previously been offered a Remedial Plan and has not been the subject of disciplinary action with the Board.

FINDINGS

1. From on or about November 12, 2021, through on or about January 11, 2022, Christopher Vard Tyrone II, while acting as an employee (pharmacist-in-charge) of Swyft Scripts, 15915 Katy Freeway, Suite 440, Houston, Texas 77094, failed to legally operate Swyft Scripts, in that the pharmacy failed to engage in the business of pharmacy within six months of the date of the issuance of its license. Specifically, Swyft Scripts became licensed as a Class G pharmacy on January 26, 2021. Subsequently, a Texas State Board of Pharmacy investigator requested records of the pharmacy processing prescription drug or medication drug orders covering the time period previously mentioned, and the pharmacy did not produce records of processing any prescription drug or medication drug orders.

2. Respondent does not admit or deny the Finding(s) and Applicable Law contained herein but, rather, has agreed to settle in good faith to avoid the cost, expense, and uncertainty of litigation.

APPLICABLE LAW

1. The Board has jurisdiction over the subject matter and Respondent pursuant to Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2021).

2. The Board is authorized to take disciplinary action for a violation of Section 565.001(a)(1), (2), (12) and (13) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2021); and Sections 281.7(a)(13); 291.11(a) and (b); 291.153(a)(2) and (b)(1); 291.153(c)(1)(A) and (B)(iv); and 295.3 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2021).

3. Section 565.060 of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2021), and Section 281.68 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2022), authorize the Board to resolve this matter with a Remedial Plan.

REMEDIAL PLAN TERMS

1. This Remedial Plan shall be in effect from the date of entry of the Plan and shall terminate five (5) years after the date of entry. Respondent agrees to comply with the terms set forth herein for the duration of the Plan.

2. Respondent shall obtain fifteen (15) hours of continuing education, which shall be in addition to the hours of continuing education required for renewal. Respondent shall submit proof of completion of the continuing education hours to Board staff within one (1) year after the entry of this Remedial Plan. All continuing education must be in compliance with the continuing education requirements set forth in the Texas Pharmacy Board Rules, and must be completed after the entry of this Remedial Plan and before one (1) year after the entry of this Remedial Plan.

3. Respondent shall submit written documentation of modifications implemented by Respondent to improve Respondent's practice of pharmacy. Such report shall be due one hundred twenty (120) days after the Remedial Plan is entered by the Board.

4. Respondent shall pay a Remedial Plan fee of one thousand dollars ($1,000) due one hundred twenty (120) days after the Remedial Plan is entered by the Board.

5. Respondent shall be responsible for all costs relating to compliance with the requirements of this Remedial Plan.

RESPONDENT HAS READ AND UNDERSTANDS THE FOREGOING REMEDIAL PLAN. RESPONDENT UNDERSTANDS THAT BY SIGNING, RESPONDENT WAIVES CERTAIN RIGHTS. RESPONDENT SIGNS IT VOLUNTARILY. RESPONDENT UNDERSTANDS THIS REMEDIAL PLAN IS A FINAL, NON-APPEALABLE AGREEMENT THAT CONTAINS THE ENTIRE AGREEMENT, AND THERE IS NO OTHER AGREEMENT OF ANY KIND, VERBAL, WRITTEN, OR OTHERWISE. RESPONDENT UNDERSTANDS

AND AGREES THAT ANY VIOLATION OF THE REMEDIAL PLAN WILL RESULT IN THE RE-INSTITUTION OF DISCIPLINARY ACTION.

And it is so ORDERED.

THIS REMEDIAL PLAN IS A PUBLIC RECORD.
THIS REMEDIAL PLAN IS NON-DISCIPLINARY.

SIGNED AND ENTERED ON THIS _____ day of _____, _____.

_____
MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

_____
Tim Tucker, Pharm.D.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

_____
Christopher Vard Tyrone II, R.Ph.

APPROVED AS TO FORM:

_____
Megan G. Holloway, General Counsel
Texas State Board of Pharmacy

AGREED BOARD ORDER #2022-00840

RE: IN THE MATTER OF SWYFT SCRIPTS (PHARMACY LICENSE #33628)

BEFORE THE TEXAS STATE BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 33628 issued to Swyft Scripts (Respondent), 7324 Southwest Freeway, Suite 975, Houston, Texas 77074.

By letter dated March 15, 2022, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

> Sections 551.003(29); 565.001(a)(1), (2), (12) and (13); and 565.002(a)(3) and (7) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2021); and
>
> Sections 281.7(a)(13); 291.11(a) and (b); 291.153(a)(2) and (b)(1); 291.153(c)(1)(A) and (B)(iv); and 295.3 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2021), in that allegedly:

COUNTS

(1) From on or about July 27, 2021, through on or about January 11, 2022, Swyft Scripts, 7324 Southwest Freeway, Suite 975, Houston, Texas 77074 (previously located at 15915 Katy Freeway, Suite 440, Houston, Texas 77094), failed to legally operate, in that the pharmacy failed to engage in the business of pharmacy within six months of the date of the issuance of its license. Specifically, Swyft Scripts became licensed as a Class G pharmacy on January 26, 2021. Subsequently, a Texas State Board of Pharmacy investigator requested records of the pharmacy processing prescription drug or medication drug orders covering the time period previously mentioned, and the pharmacy did not produce records of processing any prescription drug or medication drug orders.

(2) On or about September 11, 2021, through on or about November 10, 2021, Swyft Scripts, 7324 Southwest Freeway, Suite 975, Houston, Texas 77074 (previously located at 15915 Katy Freeway, Suite 440, Houston, Texas 77094), was engaged in the operation of a pharmacy in violation of Texas State Board of Pharmacy Rules, in that the pharmacy was not under the supervision of a pharmacist-in-charge.

Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Yasser Almuaala, Chief Executive Officer, Prestige Health Solutions LLC, on

behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to an informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent shall pay an administrative penalty of four thousand dollars ($4,000) due one hundred twenty (120) days after the entry of this Order.

(2) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2021), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2022).

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 2nd day of August, 2022.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Tim Tucker, Pharm.D.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Yasser Almuaala, Chief Executive Officer, Prestige Health Solutions LLC On behalf of Swyft Scripts

APPROVED AS TO FORM:

Megan G. Holloway, General Counsel
Texas State Board of Pharmacy

Subject: Explanation Regarding Board Order for SWYFT SCRIPTS - DFW

To Whom It May Concern,

I am writing on behalf of SWYFT SCRIPTS - DFW to address a previous board order issued by the Texas State Board of Pharmacy. This order pertained to a failure to engage in the business of pharmacy within six months of licensure.

This delay in initiating operations was due to unforeseen logistical and operational challenges that arose during the setup phase. These issues were promptly addressed, and since that time, we have worked diligently to ensure full compliance with all state regulations.

We are pleased to report that SWYFT SCRIPTS - DFW has since passed all required inspections by the Texas State Board of Pharmacy and is now fully operational. Our pharmacy provides retail services and home delivery options for patients and contracts with employers to deliver cost-effective prescription solutions.

We remain committed to upholding the highest standards of care and compliance in the pharmacy industry. Should you require any further information or documentation regarding this matter, please do not hesitate to contact me.

Sincerely,

SwyftScripts

Chris Tyrone, PharmD
Chief Pharmacy Officer

SwyftScripts

chris@swyftscripts.com
682 438 2904
1800 West Loop South
Suite 2110
Houston, TX 77027
www.swyftscripts.com

AGREED BOARD ORDER #2024-01330

RE: IN THE MATTER OF
SWYFT SCRIPTS - SOUTHLAKE
(PHARMACY LICENSE #34513)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 34513 issued to Swyft Scripts - Southlake (Respondent), 771 East Southlake Boulevard, Suite 223, Southlake, Texas 76092.

By letter dated February 15, 2024, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Sections 565.001(a)(1), (2), (12) and (13); and 565.002(a)(3) and (7) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2023); and

Sections 281.7(a)(13); 291.11(a) and (b); 291.32(a)(2)(H); and 295.3 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2023), in that allegedly:

COUNT

From on or about May 2, 2023, through on or about September 19, 2023, Swyft Scripts - Southlake (previously licensed as Rejuvenation Pharmacy), 771 East Southlake Boulevard, Suite 223, Southlake, Texas 76092 (previously located at 12423 Cutten Road, Suite C, Houston, Texas 77066 and 2815 North Main Street, Stafford, Texas 77477), failed to legally operate, in that the pharmacy failed to engage in the business of pharmacy within six months of the date of the issuance of its license. Specifically, Swyft Scripts - Southlake became licensed as a Class A pharmacy on November 1, 2022. Subsequently, on or about September 19, 2023, a Texas State Board of Pharmacy inspector received dispensing records from the pharmacy, which indicated that only one prescription was dispensed during the time period alleged above, such that the pharmacy was unable to demonstrate observable pharmacy business activity on a regular and routine basis.

An informal conference was held via videoconference on April 3, 2024, with Christopher Tyrone Vard II, R.Ph., Pharmacist-in-Charge, on behalf of Respondent, in attendance. The informal conference was heard by a Board panel comprised of: Donna Montemayor, R.Ph., Board Member; Jenny Downing Yoakum, R.Ph., Board Member; and Daniel Carroll, Pharm.D., Executive Director/Secretary; with Megan G. Holloway, General Counsel. Kelly M. Souza, Staff Attorney, was also in attendance.

At the aforementioned conference, Christopher Tyrone Vard II, on behalf of Respondent, waived the right to be represented by legal counsel. By signing this Order, Zaryan Hamidani,

Managing Officer, Rejuvenation Pharmacy Incorporated LLC, on behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent shall pay an administrative penalty of three thousand dollars ($3,000) due one hundred twenty (120) days after the entry of this Order.

(2) Respondent shall be responsible for all costs relating to compliance with the requirements of this Order.

(3) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2023), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2024).

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 6th day of August, 2024.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Daniel Carroll, Pharm.D.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Zaryan Hamidani, Managing Officer, Rejuvenation Pharmacy Incorporated LLC
On behalf of Swyft Scripts - Southlake

APPROVED AS TO FORM:

Megan G. Holloway, General Counsel
Texas State Board of Pharmacy

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 34513

SWYFT SCRIPTS - DFW

License Information

License Status Active
License # 34513
Expiration Date 11/30/2026
Date License Issued 11/01/2022

Address

1550 NORWOOD DR STE 300
HURST, TX 76054
County TARRANT
Phone (281) 336-9927

Pharmacy Details

Prior Disciplinary Orders* Yes

- 3254551 P34513 Swyft Scripts - Southlake ABO #2024-01330 2024-08.pdf

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy Community Pharmacy
Type of Ownership LLC
Type of Pharmacy Community Independent
# of Hospital beds

Employment Information

Pharmacist in Charge
TYRONE, CHRISTOPHER VARD II

Pharmacy Profile ¥

Accessible to disabled persons?	Yes
Participates in the Texas Medicaid program?	No

Translating services (Listed Below If Available)

Spanish

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans and/or Inspection Reports

- 3254551 34513 REJUVENATIONPHARMACY 2022-10 10-2027.pdf
- 3254551 34513 REJUVENATIONPHARMACY 2023-09 09-2028.pdf
- 3254551 34513 SWYFTSCRIPTSDFW 2025-05 05-2030.pdf
- 3254551 34513 SWYFTSCRIPTSSOUTHLAKE 2024-03 03-2029.pdf
- 3254551 34513 SWYFTSCRIPTS DFW 2025-05 05-2030.pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

Nuclear	No
Out-Patient Prescriptions	Yes
Ship Prescription Out of State	No
Class D (Expanded Formulary)	No
Class D (Alternative Visit Schedule)	No
Compounding Sterile-Risk Level Low	No
Compounding Sterile-Risk Level Med	No
Compounding Sterile-Risk Level High	No
Compounding Non-Sterile	No
24 Hour Service	No
Closed Door	No
Compounding, Office Use	No
Home Delivery	Yes
Infusion	No
Pharmacist Administered Immunizations	No
Veterinary Prescriptions	No
In-Patient Medication Orders	No
Out-Patient Surgery	No
Rural Hospital	No
Tech Check Tech	No
503b Outsourcing Facility	No
Other Services	No

Texas Pharmacist Employment information

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
DONOVAN-HAMILTON, MICHELLE LE'DIT	36212	08/02/1996	11/30/2026	Staff	Active
TYRONE, CHRISTOPHER VARD	66844	07/16/2020	01/31/2028	PIC	Active

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Texas Registered Technicians/Trainees Employment information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status
ALMUAALA, AALIYAH	379950	11/12/2024	11/30/2026	Staff	Active
MENDOZA JUAREZ, JANET	327223	09/13/2021	05/31/2027	Staff	Active
MENDOZA, DAISY	243971	06/11/2015	01/31/2028	Staff	Active
MENDOZA, MAYRA VANESSA	358269	08/01/2023	06/30/2026	Staff	Active
PARKS, RYLEIGH	316126	12/29/2020	12/31/2026	Staff	Active
QUINTANILLA, SABRINA ISABELLA	380422	11/25/2024	11/30/2026	Staff	Active
TYRONE, NAOMI GRACE	369923	04/18/2024	04/30/2026	Staff	Active

Page 1 of 1 20 View 1 - 7 of 7

Texas Remote Pharmacy information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode

Page 0 of 0 20 No records to view

Texas Pharmacy Owner information

Owner Name	Owner Title	Address	City	State	Zipcode
REJUVENATION PHARMACY INCORPORATED LL	OWNER				

HAMIDANI, ZARYAN	OFFICER	,			
ALMUAALA, YASSER HILAL	OFFICER	,			

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The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacist License # 66844

License Information

License Status Active
License # 66844
Expiration Date 01/31/2026
Date License Issued 07/16/2020

Pharmacist Details

School Graduated SOUTHWESTERN OK ST UNIV
Graduation Year 2020
Degree at time of licensure Pharm D
License Method Exam
Preceptor Yes
Prior Disciplinary Order(s)* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

TYRONE, CHRISTOPHER VARD

Names

Last Name TYRONE
First Name CHRISTOPHER
Middle Name VARD
Other Name
Certificate Name TYRONE, CHRISTOPHER VARD, II

More Pharmacist Details

Specialty Board Certification ¥ Unknown

¥ Data regarding Specialty Board Certification is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder for clarification.

Remedial Plans and Drug Therapy Management

- 736539 66844 Tyrone II, Christopher Vard REM #2022-02717 2022-08.pdf

Remedial plans (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Pharmacy Name	Pharmacy License #	Employment Status
GRAPEVINE DRUG RX	30574	Relief
SWYFT SCRIPTS	33628	PIC
SWYFT SCRIPTS - DFW	34513	PIC
SWYFT SCRIPTS - RICHMOND	30906	Staff

Page 1 of 1 20 View 1 - 4 of 4

The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Notice of Inspection

Facility Information

Name: *SWYFT SCRIPTS - DFW*
License Number: *34513*
Address: *1550 NORWOOD DR STE 300, HURST, TX 76054*
Phone: *(281) 336-9927*
Email:
Class of License: *A*
License Expiration: *11/30/2026*
DEA #: [redacted]
DEA Expiration: *02/28/2026*

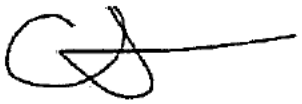
Inspection Information

Type: *Compliance*
Purpose: *Licensee Request*
Date: *05/06/2025*
Arrival Time: *9:30 AM*

Acknowledgment

This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.



Chris Tyrone *PIC* *66844*

Witness



Robert Moura

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *SWYFT SCRIPTS - DFW* License Number: *34513*

Class of License: *A*

Inspection Information

Type: *Compliance* Purpose: *Licensee Request*

Date: *05/06/2025* Arrival Time: *9:30 AM* Departure Time: *11:00 AM*

Action Taken: *Inspection*

General Comments:

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary	*Satisfactory*
01. Required licenses posted	*Satisfactory*
09. Active licenses/certifications	*Satisfactory*
62. No aiding and abetting	*Satisfactary*
65. Proper registration procedures	*Satisfactory*
79. Identification badges	*Satisfactory*

Inventory Records

15. Change of PIC inventory	*Not Applicable*
17. Meets inventory requirements	*Satisfactory*
59. Proper drug destruction	*Satisfactory*
68. Change of ownership controlled substance inventory	*Not Applicable*
69. Annual controlled substance inventory	*Satisfactory*

291.17(c).

Annual inventory.

(1) A Class A, Class A-S, Class C, Class C-S, or Class F pharmacy shall take an inventory on May 1 of each year, or on the pharmacy's regular general physical inventory date. Such inventory may be taken within four days of the specified inventory date and shall include all stocks of all controlled substances (including out-of-date drugs).

(2) A Class A, Class A-S, Class C, Class C-S, or Class F pharmacy applying for renewal of a pharmacy license shall include as a part of the pharmacy license renewal application a statement attesting that an annual inventory has been conducted, the date of the inventory, and the name of the person(s) taking the inventory.

(3) The person(s) taking the annual inventory and the pharmacist-in-charge shall indicate the time the inventory

69. Annual controlled substance inventory *(continued)* *Satisfactory*

was taken (as specified in subsection (a)(7) of this section) and shall sign and date the inventory with the date the inventory was taken. The signature of the pharmacist-in-charge and the date of the inventory shall be notarized within three days after the day the inventory is completed, excluding Saturdays, Sundays, and federal holidays.

Comment

Annual controlled substance inventory completed on: 5/1/2025 9:47 am. Ensure to notarize the annual controlled substance inventory within 3 days of taking the inventory.

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?) *Satisfactory*

34. Notifications *Satisfactory*

76. PIC (Does the pharmacy have a pharmacist-in-charge?) *Satisfactory*

Environment/Equipment/Security

03. Orderly/Clean *Satisfactory*

04. Balance inspection *Satisfactory*

Comment

Number of balances: 1 balance registered. None are available

05. Equipment Inspection *Satisfactory*

07. Security *Satisfactory*

08. Environment *Satisfactory*

48. Drugs (procurement, temperature, security, out-of-date, samples) *Satisfactory*

90. TSBP complaint notification *Satisfactory*

Controlled Substances

10. Prescriptions separated *Satisfactory*

24. Theft/Loss *Satisfactory*

Comment

No theft or loss has occurred.

26. Controlled substance prescription compliance *Satisfactory*

30. Controlled substance invoices dated/initialed by pharmacist *Satisfactory*

35. Controlled substance invoices separated *Satisfactory*

46. Drug distribution *Satisfactory*

53. Possession of controlled substances — *Satisfactory*

Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?) — *Satisfactory*

Labeling/Prepackaging

32. Prescription label (Is prescription label complete?) — *Satisfactory*

45. Proper dispensing/labeling — *Satisfactory*

54. Proper prepackaging procedures — *Not Applicable*

Library

06. Required Library — *Satisfactory*

Training

60. Documentation of required training — *Satisfactory*

297.6(e).

Pharmacy technician and pharmacy technician trainee training shall be outlined in a training manual. Such training manual shall, at a minimum, contain the following:

(1) written procedures and guidelines for the use and supervision of pharmacy technicians and pharmacy technician trainees. Such procedures and guidelines shall:

(A) specify the manner in which the pharmacist responsible for the supervision of pharmacy technicians and pharmacy technician trainees will supervise such personnel and verify the accuracy and completeness of all acts, tasks, and functions performed by such personnel; and

(B) specify duties which may and may not be performed by pharmacy technicians and pharmacy technician trainees; and

(2) instruction in the following areas and any additional areas appropriate to the duties of pharmacy technicians and pharmacy technician trainees in the pharmacy:

(A) Orientation;

(B) Job descriptions;

(C) Communication techniques;

(D) Laws and rules;

(E) Security and safety;

(F) Prescription drugs:

(i) Basic pharmaceutical nomenclature;

(ii) Dosage forms;

(G) Drug orders:

(i) Prescribers;

(ii) Directions for use;

(iii) Commonly-used abbreviations and symbols;

(iv) Number of dosage units;

(v) Strengths and systems of measurement;

(vi) Routes of administration;

(vii) Frequency of administration; and

(viii) Interpreting directions for use;

60. Documentation of required training *(continued)* *Satisfactory*

(H) Drug order preparation:
(i) Creating or updating patient medication records;
(ii) Entering drug order information into the computer or typing the label in a manual system;
(iii) Selecting the correct stock bottle;
(iv) Accurately counting or pouring the appropriate quantity of drug product;
(v) Selecting the proper container;
(vi) Affixing the prescription label;
(vii) Affixing auxiliary labels, if indicated; and
(viii) Preparing the finished product for inspection and final check by pharmacists;
(I) Other functions;
(J) Drug product prepackaging;
(K) Written policy and guidelines for use of and supervision of pharmacy technicians and pharmacy technician trainees; and
(L) Confidential patient medication records.

Comment

Advised to complete documentation of initial training and/or in-service training for all technicians.

61. Supervision of supportive personnel *Satisfactory*

Patient/Computer/Dispensing Records

18. Records available *Satisfactory*

22. Data processing system compliance *Satisfactory*

25. Prescriptions (complete, retrievable, auto-refills, accelerated refills) *Satisfactory*

37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?) *Satisfactory*

56. Prescription transfers *Satisfactory*

67. Written drug information provided *Satisfactory*

80. Patient counseling *Satisfactory*

82. Patient Medication Records *Satisfactory*

84. Drug regimen review *Satisfactory*

86. Absence of pharmacist records *Not Applicable*

Policies & Procedures/SOPs

70. Required policies & procedures/SOPs *Satisfactory*

92. Automated dispensing policy & procedures/SOPs *Not Applicable*

Non-Sterile Compounding

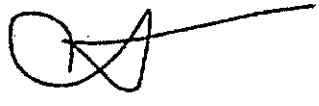
03. Orderly/Clean/Hand Hygiene *Not Applicable*

04. Balance inspection (for non-sterile compounding)	*Not Applicable*
05. Equipment Inspection	*Not Applicable*
06. Non-sterile Library	*Not Applicable*
32. Non-sterile compound label (Is label complete?)	*Not Applicable*
38. Area/Environment for non-sterile compounding	*Not Applicable*
43. Records for non-sterile compounding	*Not Applicable*
60. Documentation of non-sterile required training	*Not Applicable*
70. Required policies & procedures/SOPs	*Not Applicable*
87. Quality Control/Assurance	*Not Applicable*

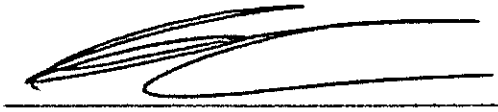
Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



TYRONE, CHRISTOPHER VARD II



Robert Moura

TEXAS STATE BOARD OF PHARMACY

Pharmacist in Charge Attestation:

I hereby attest the following statements are true and accurate (initial each statement below):

CA — I am the Pharmacist-in-Charge (PIC) of *SWYFT SCRIPTS - DFW*, pharmacy license number *34513*, and I ☑ was/ ☐ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *05/06/2025*.

CA — I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

CA — I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF.

CA — If applicable, the Warning Notice issued contains *0* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

CA — I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please email this completed form to the TSBP Compliance Inspector for your area or to inspections@pharmacy.texas.gov within 7 days of the date of the inspection.

Signed: CA **Date:** *05/06/2025*

Printed Name: *TYRONE, CHRISTOPHER VARD II* **License No.(if applicable):** *66844*

TEXAS STATE BOARD OF PHARMACY

Re:	Swyft Scripts - DFW
Address:	1550 Norwood Drive, Suite 300 Hurst, Texas 76054
License No.:	34513
Date Issued:	November 1, 2022
Licensure Status:	Active
Expiration Date:	November 30, 2026
Type of Pharmacy:	Community – Class A
Prior Disciplinary Orders:	Yes

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Swyft Scripts - DFW (Texas Pharmacy License #34513) has been subject to disciplinary action by the Texas State Board of Pharmacy (see attached).

Form Completed by:

Eamon D. Briggs
Deputy General Counsel
Texas State Board of Pharmacy

May 9, 2025
Date

The Texas Department of State Health Services, Drugs and Medical Devices Division, Wholesaler Registration, 1100 W. 49th Street, Austin, TX 78756, is responsible for issuing registrations to wholesale drug distributors and drug manufacturers in Texas.

TEXAS STATE BOARD OF PHARMACY
1801 Congress Avenue, Suite 13.100
Austin, TX 78701-1319
(512) 305-8000

License Number: 34513

(Date PDF Version Generated: 3/13/2025)

HELPFUL PHARMACY INFORMATION

- Pharmacies are required to notify TSBP within 10 days of a discontinuance of service, change of location or closure. See the TSBP website here Pharmacy - Renew & Update (texas.gov) for changes.
- Renewals open about 60 days prior to your expiration date, renewal information can be found here Renew | Pharmacy (texas.gov).
- Change of Employment or Change of PIC information can be found here Update | Employment (texas.gov).
- Change of Ownership – Call (512) 305-8021 or see Apply | Change of Ownership (texas.gov).
- For questions or assistance regarding rules, contact TSBP Rules Queue line at (512) 305-8070 see www.pharmacy.texas.gov.
- Non-Resident Pharmacy questions call (512) 305-9127 or email NonResPhcy@pharmacy.texas.gov.

An up-to-date License Verification is always available on the Board's website: http://www.pharmacy.texas.gov/

CERTIFICATE
BOARD OF PHARMACY

This certifies that the pharmacy named below is hereby licensed to operate as a Class **A** pharmacy.

License No. **34513** Expiration Date: **11/30/2026**

Balances: **1**

SWYFT SCRIPTS - DFW
1550 NORWOOD DR STE 300
HURST, TX 76054

Daniel R. Carroll, Pharm.D.,
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Rejuvenation Pharmacy Incorporated, LLC DBA SwyftScripts DFW

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): TX#34513

Physical Address: 1550 Norwood Dr STE 300

City: Hurst State: TX Zip: 76054

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 281-336-9927 Website: swyftscripts.com

Licensing Company Email: DFW@SwyftScripts.com

Section 2: Personal Information

First: Yasser Middle: Hilal Last: Almuaala

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The University of Texas at Tyler		08/2013-05/2018	
Address: 3900 University Blvd	City: Tyler	State: TX	Zip: 75799
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Houston Community College		08/2011-05/2013	
Address: 3100 Main St	City: Houston	State: TX	Zip: 77002
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Westside High School		08/2010-06/2011	
Address: 14201 Briar Forest Dr	City: Houston	State: TX	Zip: 77077
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Elkins High School		08/2009-06/2010	
Address: 7007 Knights Ct	City: Missouri City	State: TX	Zip: 77459
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Stafford High School		08/2006-06/2008	
Address: 1625 Staffordshire Rd	City: Stafford	State: TX	Zip: 77477
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2022-Present	[redacted]			
2018-2022				
2015-2018				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
SwyftScripts			2019-Present	
Business Address		**City**	**State**	**Zip**
1800 W Loop South Suite 2110		Houston	TX	77027
Phone	**Title**			
888-799-3879	Founder & Chief Executive Officer			
Description of Duties				
Oversees company operations, compliance, and financial strategy, leads cross-functional teams, drives product development, and builds strategic partnerships to support growth.				

Business Name			From - To (MM/YY – MM/YY)	
Houston Methodist			2017-2020	
Business Address		**City**	**State**	**Zip**
6565 Fannin St		Houston	TX	77030
Phone	**Title**			
713-790-3311	Revenue Cycle Manager			
Description of Duties				
Led a 36-person team managing $4B in revenue cycle operations and $1B in charitable care, improving performance through KPIs , tech upgrades, and executive committee leadership.				

Business Name			From - To (MM/YY – MM/YY)	
Nobilis Health			2015-2017	
Business Address		**City**	**State**	**Zip**
4120 Southwest Fwy #150		Houston	TX	7027
Phone	**Title**			
713-355-8614	Revenue Cycle Supervisor			
Description of Duties				
Supervised a 25-person Financial Clearance team and oversaw Patient Access at 10 facilities, improving A/R, reimbursement, and workflows. Supported business development, physician onboarding, and policy alignment.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4,5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
January 2023	02/2023	TX	Houston	Harris
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
202318063		127th Judicial District Harris County		
Reason/Charge				
Breach of contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Plaintiff			Lawsuit	
Name of Business/Industry/Entity				

Provide explanation below:

We filed suit for breach of contract

Original Signature (electronic, copies or stamps not accepted)

June 16, 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Yasser Almuaala

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 16, 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Harris

I, YASSER ACMUAACA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/16/25

Date

Subscribed and Sworn to before me this 16th day of June.

Notary Public Signature

Myah Rachael Laroe
My Commission Expires
4/23/2029
Notary ID 135512258

(Seal)

4GGG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility

- ☒ Ambulatory Surgical Center (ASC)
- ☐ Recovery Center (RC)

Type of Application (check applicable box)		Ownership Type (check applicable box)
☒ New ASC/RC	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
☐ Ownership Change*		☒ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *	N/A	☐ Partnership (complete sections 1, 2, 5, 7, 8, 9)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Desert Rose Surgery Center

Physical Address: 7475 W. Sahara Ave., Suite 103

City: Las Vegas State: NV Zip: 89117

Mailing Address (if different from physical address): 2031 McDaniel St., Suit e200

City: Las Vegas State: NV Zip: 89030

Telephone: 702-408-1526 Fax: pendi ng

Contact Email: kkrueger910@gmail.com Website pending

Nevada Business License # NV20243080395

Employed/Contracted Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

Medical Director Name: Sherif Haraway, MD

Days of Operation

☒ Monday	☒ Tuesday	☒ Wednesday	☒ Thursday	☒ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☒ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): N/A

Corporation/Organization Name: Desert Rose Surgery Center

Mailing Address: 2031 McDaniel St., Suite 200

City: Las Vegas State: NV Zip: 89030

Telephone: 312-282-2855 Email: sh@rrnpm.com

Contact Person Name: Sherif Haraway, MD

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☒ No

Section 5: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

As the employed/contracted pharmacist, for (ASC/RC Name): Desert Rose Surgery Center :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Michelle McCarthy

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

2-19-26

Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months.**	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sherif Haraway, MD

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

2/16/26

Date

Board Use Only	Date Received: 2/24/26	Amount: $500 - ck 4089

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Desert Rose Surgery Center** as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 03/25/2024, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/09/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202602096476413
You may verify this certificate online at https://www.nvsilverflume.gov/home

Desert Rose Surgery Center

Officers and Directors

Sherif Haraway, MD – President and Secretary

Quan Haduong, MD – Vice President, Treasurer

Stockholder – Owner

Sherif Haraway, MD – 100% Ownership

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Desert Rose Surgery Center

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) pending

Physical Address 7475 W. Sahara suite 103

City Las Vegas State NV Zip 89117

Mailing Address (if different from physical address) 2031 McDaniel ST #200

City North Las Vegas State NV Zip 89030

Telephone 702-408-1526 Website pending

Licensing Company Email

Section 2: Personal Information

First Sherif Middle George Last Haraway

Alias(es, nicknames, name changes, etc.) previous Sherif Al-Hawary

[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Oregon Health and Science Univ. OHSU			7/1/2015 – 6/30/2016	
Address	City		State	Zip
3181 SW Sam Jaellon PK	Portland		OR	97239
Diploma/Degree obtained, if any				
Pain management fellowship → obtained / completed				
School Name			From - To (MM/YY – MM/YY)	
University of Saint Louis / SLU			7/1/2010 – 6/30/2011	
Address	City		State	Zip
1 N. Grand Blvd	St. Louis		MO	63103
Diploma/Degree obtained, if any				
clinical Neuro Physiology fellowship → obtained/Comp				
School Name			From - To (MM/YY – MM/YY)	
University of Illinois, College of Medicine			7/1/2004 – 6/30/2008	
Address	City		State	Zip
1 illini Drive	Peoria		IL	61605
Diploma/Degree obtained, if any				
4 Years Neurology residency				
School Name			From - To (MM/YY – MM/YY)	
Cairo University / Medical school			9/1989 → 03/1997	
Address	City		State	Zip
20 El manial st	Cairo / Egypt		Egypt	
Diploma/Degree obtained, if any				
Bachelor of Medicine and Bachelor of surgery (MB BCh)				
School Name			From - To (MM/YY – MM/YY)	
Ben-Taimia High School			9/1986 → 6/1989	
Address	City		State	Zip
Doha, southside	Doha		Qatar	No Zip
Diploma/Degree obtained, if any				
High school Diploma				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/2021 – Cur	[redacted]			
9/2018 – 5/20				
11/2017 – 8/201				
7/2016 – 11/201				
7/2015 – 6/2016				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Haraway Medical Group, PLLC			From - To (MM/YY – MM/YY): 11/2019 - Current	
Business Address: 2031 N. McDaniel st #200	City: N. Las Vegas	State: NV	Zip: 89030	
Phone: 702-294-0080	Title: CEO - Owner			
Description of Duties: See Patients and Manage Practice & Practice				

Business Name: ~~SA Khavkin~~ Khavkin clinic			From - To (MM/YY – MM/YY): 9/2018 - 1/2020	
Business Address: 653 N. Town center Dr. ~~#200~~	City: Las Vegas	State: NV	Zip: 89144	
Phone: 702-888-1188	Title:			
Description of Duties: Worked as a pain management provider for Khavkin clinic				

Business Name: Sanford Medical Center Through Compdealth			From - To (MM/YY – MM/YY): 11/2017 - 9/2018	
Business Address: 300 N 7th St	City: Bismarck	State: ND	Zip: 58501	
Phone: 701-323-6000	Title: Neurologist			
Description of Duties: treat Neurlgy patient, clinic & in-patient				

Business Name: Anderson Hospital			From - To (MM/YY – MM/YY): 9/2016 - 11/2017	
Business Address: 6800 IL-162	City: Maryville	State: IL	Zip: 62062	
Phone: 618-288-5711	Title: Neurology & Pain managmt Physician			
Description of Duties: Seeing pain manmgt & Neurl Patient				

Business Name: OHSU Fellowship 7/2015 -			From - To (MM/YY – MM/YY): 6/2016	
Business Address:	City:	State:	Zip:	
Phone:	Title: mentioned in education.			
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sherif Haraway
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/16/2026
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Sherif George Haraway, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/16/2026
Date

Subscribed and Sworn to before me this 16th day of February.

Notary Public Signature

SANFORD DAVID JONES
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 20-6205-01
My Appt. Expires 01/29/2029

(Seal)

4HHH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacist to Engage in the Practice of Pharmacy at a Site other than a Licensed Pharmacy

Rev (04/18/2023)

This application cannot be returned by fax or email.
We must have an original signature to process.

Section 1: Select the following that applies to you.

- ☐ I am employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 3, 5, 7)
- ☐ I am a pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution (If you marked this answer complete section 1, 2, 3, 5, 7)
- ☒ I am NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 4, 5, 6, 7)

Section 2: General Information

First: Ivan Middle: _____ Last: Fernandez

NV Pharmacist Registration # 22664

[redacted]

Section 3: Nevada Licensed Pharmacy as defined in NRS 639.012, or Nevada State Government Entity Information

Pharmacy/State Government Entity Name: _____

NV Pharmacy License # (if Pharmacy) or State Issued License # (if State Government Entity): _____

Address: _____

City: _____ State: _____ Zip: _____

Employer Contact Name: _____

Employer Contact Telephone: _____ Employer Contact email: _____

Section 4: Employer Information

Name or Identity of Employer or Business as registered with the Nevada Secretary of State chapter 76 of NRS:

Molina Healthcare

Address: 7050 Union Park Center, Suite 200

City: Midvale State: UT Zip: 84047

Employer Contact Name: Lydia Nace

Employer Contact Telephone: 1-801-613-1327 Employer Contact email: lydia.nace@molinahealthcare.co

Section 5: Place where the Pharmacist will Engage in the Practice of Pharmacy (list all sites)

Name of Site (if applicable): Home

Address: [redacted]

City: [redacted] State [redacted] Zip: [redacted]

Country/Territory/Province: United States

Is this a medical, residential, or business site? ☐ Medical ☒ Residential ☐ Business

Days of the week and hours services will be provided at this site? Monday - Friday. 40 hours/week

---

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

(Use and make copies of this page if necessary)

Section 6: NAC 639.403 A registered pharmacist who is NOT employed by or under contract with a pharmacy and who is NOT an employee of the State Government MUST complete this section.

1. Provide a description of the services that you intend to provide at the site, to include only those services listed in Section 7 (A) of this application.

Facilitate Medication Therapy Management (MTM) support including examination of member medical records, comprehensive medication reviews, and communication with members and providers (includes outbound calls to members to discuss medications). Contribute to overarching pharmacy strategy for optimization of medication-related health care outcomes, quality, and cost-effective member care.

2. Provide the identification of the types of patients or other persons to whom you intend to provide services.

Molina Healthcare provides health insurance to individuals through government programs such as Medicaid and Medicare.

3. Provide a description of all resources, both paper and electronic, that will be available to you in the course of providing the services.

No paper resources will be provided per Molina Healthcare policy. A company-issued laptop for use with a secure VPN is provided, with software and applications such as claims information and EHRs to view the medication list, provider information, and pharmacy information to perform job duties.

4. Provide an explanation of the policy for users of the services when you are unavailable.

Additional MTM staff is available from 7:00 a.m. - 6:00 p.m., MT, Monday – Friday at (855) 658-0918 TTY/TDD 711. MTM does not include emergency services, but a nurse line is available 24 hours a day, 7 days a week. Patients may also be directed to the provider's office for an appointment, quick care, or the emergency department as appropriate.

5. Provide an explanation of the policy regarding the confidentiality and security of the patient data that will be gathered, made, and maintained as part of the services which are provided, including without limitation, paper and electronic records.

Patient information will be accessed via a secure laptop and a secure VPN with user-specific logins and passwords. Training titled HIPAA 101: HIPAA Privacy Training - New Hire (This course is designed to train new hires on basic HIPAA principles. Compliance, HIPAA , HR, Ethics, & Compliance) as well as HIPAA: Molina Work from Home or Remote Worksite Privacy & Security Training (The information contained in this course is designed to provide the enrollee with pertinent information regarding how to protect and the safeguarding of PHI and confidential information while Molina employees, work from home.) and Cybersecurity Checkup Curriculum (Phishing and Insider threat).

6. Provide a description of the business plan for the services provided.

Employee for Molina Healthcare

Section 7: Laws pertaining to engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy. Please read Section 7 in its entirety. By signing this application, you attest you have read and understood the components in this section.

A. NAC 639 - For all registered pharmacists engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy

1. While engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy, a registered pharmacist may perform only:
    a. The functions described in paragraphs (b), (c), (d) and (g) to (j), inclusive, of subsection 1 or NRS 639.0124, except for dispensing or administering drugs;
    b. The functions described in section 4 of LCB File No. R036.21, except for dispensing a self-administered hormonal contraceptive; and
    c. The administration of immunizations pursuant to a written protocol established in accordance with NAC 639.297 to 639.2978, inclusive.
2. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall:
    a. Provide written notice of the site of practice to the Executive Secretary in accordance with NAC 639.225 on this application; (NAC 639.225 states that a Nevada pharmacist, within 10 days after changing residence or place of practice, must give written notice of the change to the Board.)
    b. Ensure that the records of the registered pharmacist are made readily accessible to members of the Board and employees, agents and designees of the Board; and
    c. Comply with all applicable federal and state laws and regulations, including, without limitation:
        i. The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and the regulations adopted pursuant thereto, and any other applicable federal or state law concerning the privacy of information regarding health care; and
        ii. Requirements relating to the maintenance or records.
3. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not maintain an inventory of drugs at that location.
4. A registered pharmacist shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy if he or she:
    a. Serves as a managing pharmacist; or
    b. Provides pharmaceutical services at:
        i. A facility for modified medical detoxification, as defined in NRS 449.00385;
        ii. An independent center for emergency medical care, as defined in NRS 449.013;
        iii. A facility for intermediate care, as defined in NRS 449.0038;
        iv. A facility for skilled nursing, as defined in NRS 449.0039; or
        v. A surgical center for ambulatory patients, as defined in NRS 449.019.

B. NAC 639 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity.

For a registered pharmacist who is employed by or under contract with a pharmacy or who is an employee of the State Government may engage in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy unless he or she is provided with the same computerized system and access to data regarding a patient for whom a prescription has been submitted that is available to a registered pharmacist in the pharmacy. Such data must include, without limitation:

a. A legible copy of the prescription that is available as an electronic copy or a scanned image in the computerized system of the pharmacy or by facsimile machine; and
b. Any information that is available in the computerized system of the pharmacy that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.

C. NAC 639.403 - For a registered pharmacist who is NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity.

For a registered pharmacist who is NOT employed by or under contract with a pharmacy or who is an employee of the State Government shall not engage in the practice of pharmacy at a site other than the site of a licensed pharmacy unless he or she obtains the approval of the Board to engage in the practice of pharmacy at a site other than the site of a licensed pharmacy. To request such approval, the registered pharmacist must submit this application. The application must be approved before a registered pharmacist may commence any practice.

D. NAC 639.4916 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution.

1. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide the remote chart order processing services to the hospital or correctional institution that the pharmacy is required by NAC 639.4915 to provide must:
    a. Be trained in the policies and procedures of the hospital or correctional institution regarding all policies and procedures of the hospital or correctional institution with which the registered pharmacist must comply, including, without limitation, the provisions of pharmaceutical services, security, and confidentiality of patient records; and
    b. Be provided with the same computerized system and access to data regarding a patient for whom a chart order has been submitted that would be available to a registered pharmacist employe by the pharmacy located within the hospital or correctional institution, including, without limitation:
        i. The height, weight and age of the patient and any allergies that the patient may have;
        ii. The medical records regarding any medications prescribed to the patient;
        iii. The results of any relevant laboratory tests;
        iv. The health history and notes regarding physical examinations, to the extent that the information is available in the computerized system of the hospital or correctional institution;
        v. Any notes provided by a physician, nurse or other medical staff of the institution, to the extent that those notes are available in the computerized system of the hospital or correctional institution;
        vi. A legible copy of the chart order that is available through a scanned image in the computerized system of the hospital or correctional institution or by facsimile machine; and
        vii. Any other information that is available in the computerized system of the hospital or correctional institution that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.
2. Before a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution, the registered pharmacist must review any relevant information regarding the patient for whom a chart order has been submitted. The registered pharmacist must, before approving a chart order to be filled, evaluate:
    a. The overutilization or underutilization of a medication;
    b. Therapeutic duplication;
    c. The appropriateness of the prescribed dosage and route of administration;
    d. The appropriateness of the directions for use of the medication;
    e. The appropriateness of the duration of the treatment with the prescribed medication;
    f. Any contraindication of the medication and a particular disease, ailment or allergy of the patient;
    g. Any contraindication or interactions between multiple medications prescribed for the patient; and
    h. The potential abuse or misuse of a medication.
3. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution shall comply with the requirements of Section 7 (A) to the same extent as a registered pharmacist engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy pursuant to the provisions in Section 7 (B) and Section 7 (C).
4. In an emergency, a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may render remote chart order processing services without being provided with all the information required by paragraph (b) of subsection 1 of Section 7 (D) if the registered pharmacist believes, in his or her professional judgement, that he or she has received sufficient information from the staff of the hospital or correctional institution to render the services.
5. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may refuse to approve the filling of a chart order if, in the judgement of the registered pharmacist, the chart order is not safe or reasonable for the patient. A registered pharmacist who refuses to approve the filling of a chart order pursuant to this subsection must notify the hospital or correctional institution as soon as practicable that he or she has refused to approve the filling of the chart order.
6. Each time that a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution

provides remote chart order processing services pursuant to this section, the registered pharmacist shall make a notation in the computerized system of the hospital or correctional institution that indicates:

a. The name or identifier of the registered pharmacist;
b. The date and time that the registered pharmacist provided the services and, if applicable, approved the filling of a chart order; and
c. The specific services provided by the registered pharmacist.

7. The managing pharmacist of a pharmacy located within a hospital or a correctional institution may limit the remote chart order processing services provided pursuant to this section (Section 7 (D)).

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I attest to the knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. NRS 639.132

I understand that Nevada law requires a registered pharmacist who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Ivan Fernandez

Print Name

Original Signature, no copies or stamps accepted

2/24/2026

Date

Board Use Only	Date Received: _____ For applicants who marked box 1 or 2 in Section 1: Executive staff to review, scanned into applicant file. For applicants who marked box 3 in Section 1: Executive staff to review, place on consent agenda.

4III

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New OUTSOURCING FACILITY
☐ Ownership Change (Provide current license number if making changes.) OUT_____
☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☑ Non Publicly Traded Corporation – Pages 1-3 & 5
☐ Partnership - Pages 1-3 & 6
☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Hyalo Technologies, LLC

Physical Address: 408 Elizabeth Avenue

City: Somerset State: New Jersey Zip Code: 08873

Telephone: 908-399-3600 Fax: _____

Toll Free Number: _____ (Required per NAC 639.708)

E-mail: shalabhjain@hyalotechnologies.com Website: hyalotechnologies.com

Supervising Pharmacist: Jimmy Tran Thuan Nevada License #: 15795

SERVICES PROVIDED

Yes/No

☑ ☐ Parenteral
☑ ☐ Sterile Compounding
☐ ☑ Non Sterile Compounding
☐ ☑ Mail Service Sterile Compounding
☐ ☑ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: 11/24/25 Amount: $500 CK 1001115965

FEI Number (From FDA application): 3017172374

Please provide the name of the facility as registered with the FDA and the registration number:
Hyalo Technologies, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Jimmy Tran Thuan Nevada License Number: 15795

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☑

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Shalabh Jain
Print Name of Authorized Person

11/17/2025
Date

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: N/A

Address: 408 Elizabeth Avenue

City: Somerset State: NJ Zip: 08873

Telephone: 908-399-3600 Fax: _____

Contact Person: Shalabh Jain

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Shalabh Jain [redacted]
Name Address

b) Sanjeevani Jain [redacted]
Name Address

c) Sanjay Jain [redacted]
Name Address

d) Robert Oliver [redacted]
Name Address

2) Provide the number of shares issued by the corporation. 10 million

3) What was the price paid per share? $1.00

4) What date did the corporation actually receive the cash assets? 3/17/2017

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

- List of officers and directors

Registered Outsourcing Facilities

Facilities Registered as Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Updated as of 11/19/2025

- Information Concerning Outsourcing Facility Registration (/drugs/compounding/questions-and-answers-outsourcing-facility-registration)
- Outsourcing Facility Product Reporting Information (/drugs/compounding/information-outsourcing-facilities#reporting)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Search: hyalo

Show 10 entries

Export Excel

Facility	Contact	Initial Registration Date [1]	Most Recent Registration Date [1]	Last Inspection [2]	Form 483 Issued? [3]	Recall Conducted? [9]	Action Based on Last Inspection [4,5]	Intends to Compound Sterile Drugs From Bulk Substances [6]
Hyalo Technologies Limited Liability Company, Somerset, NJ	Shalabh Jain [redacted]	5/1/2025	5/1/2025	Not yet Inspected	N/A	N/A	N/A	Yes

Showing 1 to 1 of 1 entries (filtered from 93 total entries)

Previous 1 Next

Feedback

Notes

1. The "initial date of registration as an outsourcing facility" is the date the facility was first registered (i.e., the date FDA determined that the initial registration information submitted for the facility was complete, and the establishment fee was paid in full).

   Under section 503B(b) of the FD&C Act, after the initial registration, a facility that elects to continue to be registered with FDA as an outsourcing facility must re-register annually. A facility that elects to register (or re-register) with FDA as an outsourcing facility must pay an annual establishment fee. The "date of most recent registration as an outsourcing facility" reflects the date FDA determined the most recently submitted registration information was complete and the annual establishment fee for that fiscal year paid in full.

   Unless a previously registered outsourcing facility re-registers and pays the annual establishment fee in full during the registration period (between October 1 and December 31 of each calendar year), the facility will be removed from the list of registered outsourcing facilities on January 1 of the next calendar year.

2. Once an outsourcing facility is registered, the facility will be added to the list of facilities FDA intends to inspect according to a risk-based schedule. FDA plans to inspect outsourcing facilities within a reasonable period of time following initial registration, once it is confirmed that the facility has initiated drug production and distribution. However, the exact timing of the inspections can be affected by a number of variables, including the number of outsourcing facility registrants, other inspection priorities, and the operational status of the newly registered outsourcing facility.

   Inspections identified in this table are associated with the facility at the listed address. A company may own or operate more than one registered outsourcing facility. FDA's web page Compounding: Inspections, Recalls, and other Actions (/node/363232) may contain information about compounding facilities under the same ownership as the listed registered outsourcing facility.

Inspections may take place over several days, weeks or longer. The date of the inspection is the date a Form FDA 483 listing the investigators' observations was issued. If no FDA Form 483 was issued, the date is the last day of the inspection.

3. A Form FDA 483 is issued when investigators observe any significant objectionable conditions. It does not constitute a final agency determination of whether any condition is in violation of the FD&C Act or any relevant regulations.
4. This table does not include State Board of Pharmacy actions, if any. To determine whether a registered outsourcing facility has been the subject of a state enforcement action, check with the State Board of Pharmacy for the state in which the facility is located. Some states post disciplinary or other actions on their web sites.
5. "Closed" means the inspection has been closed without further action. "Open" means FDA has not determined whether further action will be taken. If an action has been taken, it will be listed. Possible FDA actions include warning letter, seizure or injunction.
6. The information in this column was provided by the registered outsourcing facility at the time of registration and has not been verified by FDA. "N/A" indicates the registered outsourcing facility has not provided this information.
7. This outsourcing facility was the subject of at least one previous inspection relating to compounding that resulted in a Form FDA 483, warning letter or other action. For information about such inspections and resulting actions, visit Compounding: Inspections, Recalls, and other Actions (/node/363232).
8. A remote regulatory assessment (RRA) is an examination of an FDA-regulated establishment and/or its records, conducted remotely, to evaluate compliance with applicable FDA requirements. These assessments assist in protecting human and animal health, inform regulatory decisions and verify certain information submitted to the agency.
9. Based on inspectional findings, the inspection revealed significant issues. As a result, the outsourcing facility may have either initiated a recall on their own following conversation(s) with the FDA investigator or FDA recommended a recall at the conclusion of the inspection or both. Additionally, the outsourcing facility may have conducted multiple recalls or recalled multiple drugs.

Was this page helpful? * (required)

Yes

No

Submit

An official form of the United States government. Provided by Touchpoints



From: [redacted]
To:
Cc:

May 27, 2025 at 15:19

RE: [EXTERNAL] FDA 503B Outsourcing Facility Registration

Dear Mr. Jain,

Thank you for May 19, 2025, email. The Registered Outsourcing Facility webpage was updated today. Hyalo Technologies Limited Liability Company is listed.

Thank you,
Office of Compounding Quality and Compliance
Office of Compliance
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration
U.S. Department of Health and Human Services

Registered Outsourcing Facilities

Facilities Registered as Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Updated as of 7/29/2025

- Information Concerning Outsourcing Facility Registration (/drugs/compounding/questions-and-answers-outsourcing-facility-registration)
- Outsourcing Facility Product Reporting Information (/drugs/compounding/information-outsourcing-facilities#reporting)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Search: Hya

Show 10 entries

Export Excel

Facility	Contact
+ Hyalo Technologies Limited Liability Company, Somerset, NJ	Shalabh Jain 1-908-399-3600

Showing 1 to 1 of 1 entries (filtered from 94 total entries)

Previous 1 Next

Notes

1. The "initial date of registration as an outsourcing facility" is the date the facility was first registered (i.e., the date FDA determined that the initial registration

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0753945

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☒ manufacturer ☐ wholesaler which conducts business at the following locations in this State:

408 ELIZABETH AVE SOMERSET, NJ 08872-

Reg. No.
5006772

HYALO TECHNOLOGIES LLC
408 ELIZABETH AVE
SOMERSET, NJ 08872-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2026

Establishment Copy

503B FDA Outsourcing Facilities are not required to have an initial FDA inspection before starting operations; they may begin compounding and operations once registered with the FDA. Registration does not constitute FDA approval or endorsement; instead, it subjects the facility to future inspection and regulatory oversight.frierlevitt+2

Registration and Initial Operations

- Facilities must register with the FDA and are permitted to operate immediately upon registration, without waiting for the initial inspection.fda+1
- Facilities should ensure full compliance with cGMP requirements and have robust quality systems in place prior to starting commercial operations to mitigate regulatory risk. frierlevitt

In summary, 503B FDA Outsourcing Facilities can start operations upon FDA registration, with the facility bearing responsibility for immediate compliance with cGMP and regulatory requirements.fda+2

1. https://www.frierlevitt.com/articles/thinking-about-starting-a-503b-outsourcing-facility-heres-what-you-need-to-know/
2. https://www.fda.gov/drugs/human-drug-compounding/questions-and-answers-outsourcing-facility-registration
3. https://www.safemedicines.org/2025/07/503b-fda-inspections.html
4. https://pmc.ncbi.nlm.nih.gov/articles/PMC5912243/
5. https://www.fda.gov/media/156354/download
6. https://www.americanpharmaceuticalreview.com/Featured-Articles/594402-Establishing-a-Robust-Quality-System-in-a-503B-Outsourcing-Facility/
7. https://www.restorehealthconsulting.com/news/preparing-for-an-fda-inspection-a-comprehensive-guide-for-503b-outsourcing-facilities
8. https://www.youtube.com/watch?v=dCZkx0mL98k
9. https://www.fda.gov/drugs/human-drug-compounding/compounding-inspections-and-oversight-frequently-asked-questions
10. https://www.fda.gov/media/185146/download?attachment

Gmail

Shalabh Jain <shalabhjain@hyalotechnologies.com>

503B Facility Inspection

DCA NJBOPoffice <njbopoffice@dca.njoag.gov> Fri, Oct 31, 2025 at 5:53 PM
To: Shalabh Jain <shalabhjain@hyalotechnologies.com>

Hello,

Please be advised that manufacturers, wholesalers, and distributors fall under the jurisdiction of the New Jersey Department of Health. The New Jersey Board of Pharmacy does not hold regulatory authority over these entities. For assistance regarding your inquiry, please contact the Department of Health using the contact information provided below:

New Jersey Department of Health
Consumer, Environmental and Occupational Health Service
P. O. Box 369
Trenton, NJ 08625-0369
Phone: 609-826-4935
Email: dmd@doh.nj.gov
Website: www.nj.gov/health/ceohs/phfpp/dmd

Regards,

New Jersey Board of Pharmacy
New Jersey Division of Consumer Affairs
Office: 973-504-6450 • **Fax:** 973-504-6326
Street Address: 124 Halsey St, 6th FL, Newark, NJ 07102
Mailing Address: P.O. Box 45013, Newark, NJ 07101
njbopoffice@dca.njoag.gov • njconsumeraffairs.gov/phar

From: Shalabh Jain <shalabhjain@hyalotechnologies.com>
Sent: Friday, October 31, 2025 5:09 PM
To: DCA NJBOPoffice <njbopoffice@dca.njoag.gov>
Subject: [EXTERNAL] 503B Facility Inspection

Gmail

Shalabh Jain <shalabhjain@hyalotechnologies.com>

REQUEST FOR INSPECTION

DOH-NJ Drug and Medical Device Registration [DOH] <DMD@doh.nj.gov> Fri, Oct 31, 2025 at 4:04 PM
To: Shalabh Jain <shalabhjain@hyalotechnologies.com>

This office inspects wholesale distribution operations only. 503B outsourcing facilities are inspected by FDA. Your request cannot be processed.

Jennifer Steffee | Public Health Representative

NJ Drug and Medical Device Registration Project

NJ Department of Health | Public Health & Food Protection

https://nj.gov/health/ceohs/phfpp | dmd@doh.nj.gov

[Quoted text hidden]

Confidentiality Notice: This e-mail, including any attachments, may include advisory, consultative and/or deliberative material and, as such, would be privileged and/or confidential and not a public document. Any information in this e-mail identifying a client of the Department of Health or including protected health information is confidential. If you received this e-mail in error, you are not authorized to review, transmit, convert to hard copy, copy, or in any way further use or disseminate this e-mail or any attachments to it. You must immediately notify the sender, delete the email/attachment(s), confirm in writing to the sender that you deleted the email/attachment(s) and that you did not/will not further use or disclose the information contained in the email.

Stocks Register.

10 Million 1.2 Mln ~~Jeanneau~~

Name of Member	Address of Member	Certificates Issued			From Person/Entity Interest/Units Were Transferred. If first issue, enter as such.
		Certificate Number	Number of Interest/ Units	Date of Issue	
Shalabh Jain	[redacted]	3	6,000,000	3/7/17	
Sanjeevani Jain		4	2,000,000	3/7/17	
# 2.15 Robert Oliver		1	100,000	3/7/17	
Sanjay Jain		5	500,000	3/7/17	
# 2.15 Robert Oliver		2	200,000	5/1/17	

HYALO TECHNOLOGIES
408 Elizabeth Avenue • Somerset, NJ 08873

Hyalo Technologies Corporate Officers & Directors

Dr. Shalabh Jain: Founder, Chairman & CEO

Dr. Sanjay Jain: Co-Founder & Vice Chairman

Mr. Robert Oliver: Executive Advisor & Board of Directors

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "HYALO TECHNOLOGIES LIMITED LIABILITY COMPANY" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF NOVEMBER, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE AFORESAID "HYALO TECHNOLOGIES LIMITED LIABILITY COMPANY" IS A SERIES LIMITED LIABILITY COMPANY.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

6339124 8300E

SR# 20254529938

Authentication: 205288266

Date: 11-11-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

3901

HYALO TECHNOLOGIES
408 Elizabeth Avenue • Somerset, NJ 08873

Hyalo Technologies Sterile Manufacturing

Hyalo Technologies Sterile Manufacturing Services is a trusted solution healthcare facilities across the nation can rely on. We are a globally integrated 503B outsourcing partner, creating supply chain resiliency while advancing patient safety. Our cGMP compliant facility manufactured high-quality sterile medications and expertise in pharmaceutical manufacturing, repackaging, and patient safety.

Given increasing regulatory requirements for sterile compounding, it is likely hospitals are beginning to feel the growing pressures associated with compounding including tightening regulations, shorter Beyond Use Dates (BUDs), waste reduction initiatives, risk mitigation and increases in quality control.

503B outsourcing can assist hospital pharmacies by freeing up time and capital that may otherwise be spent compounding products in the hospital pharmacy. It can also reduce the regulatory and compliance risk.

Hyalo Technologies' fundamental purpose is to provide your hospital pharmacy the additional qualified resources so that you can focus more time on improving health care delivery, patient safety, and clinical outcomes.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Hyalo Technologies LLC

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 408 Elizabeth Ave

City: Somerset State: New Jersey Zip: 08873

Mailing Address (if different from physical address): 408 Elizabeth Ave

City: Somerset State: New Jersey Zip: 08873

Telephone: _____ Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: shalabhjain@hyalotechnologies.com

Website: https://www.hyalotechnologies.com/

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Jimmy T. Tran

Supervising/Managing Pharmacist NV Pharmacist Registration #: 15795

Name of Designated Person(s) as defined by revised USP-797 guidelines: Ankur Sharma, PhD

Email of Designated Person(s): asharma@hyalotechnologies.com

Telephone of Designated Person(s): _____

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

   ☑ Category 1 ☑ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☑ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☑ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ☑ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? ISO 7 and ISO 5

6. What is the frequency of the recertification for the ISO classified areas? ISO 5 every 6 months, ISO 7 once a year

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ☑ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☑ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Monthly

10. Will you be performing sterile hazardous drug compounding? ☐ Yes ☑ No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Triamcinolone acetonide

12. What laboratory performs your sterility or endotoxin testing?

Name: Focus Labs

Address: 894 Marcon Blvd suite 150

City: Allentown State: PA Zip: 18109

Telephone: 610-866-7272

13. What is your procedure for visual inspection of compounded sterile products?
This procedure applies to all sterile compounded preparations (CSPs) prepared in the cleanroom, including:Parenteral solutionsIV admixturesSyringesOphthalmic preparationsHazardous and non-hazardous CSPs
Required Conditions & ToolsAdequate lighting (1000 lux, glare-free)Clean inspection area outside the PECWhite and black background for contrastCorrect prescription/order and compounding recordPPE per USP <797>/<800>
Inspection TimingVisual inspection must be performed:After compounding is complete Before labeling and dispensing
Container & Closure IntegrityVerify:Container is intact with no cracks, leaks, or punctures, Stoppers, seals, and caps are secureSyringes are properly cappedNo visible leakage or compromised sterility inspect against both light and dark backgrounds for:Particulate matter (fibers, glass, rubber, precipitate)Cloudiness or haze,Discoloration,Phase separation

14. How often do you perform glove fingertip and medial fill testing?
Every 6 Months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
Didactic (Theoretical) TrainingTraining shall include, at minimum:Principles of aseptic technique Cleanroom design and airflow (ISO Class 5, 7, 8)Sources of contamination (personnel, environment, materials)Hand hygiene and garbing proceduresCleaning and disinfection procedures, Sterile compounding calculations and accuracy CSP risk categories and BUD assignmentLabeling and documentation requirements, Incident reporting and deviation management
Practical (Hands-On) Training: Demonstration of proper hand hygiene and garbing Aseptic manipulations within ISO Class 5 PECProper staging and material transferSyringe, vial, ampule, and bag handlingCleaning and disinfection techniques Waste handling and spill response, Media-Fill Testing, Glove Fingertip Sampling. At least every 12 months: Didactic review and practical competency, At least every 6 months:Media-fill testing, Glove fingertip

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
PEC Cleaning ProcedureDon appropriate PPE per garbing SOP.Remove all materials from the PEC.Clean surfaces using sterile water and lint-free wipes to remove residue.Apply disinfectant (sterile 70% IPA) using unidirectional strokes: Ceiling back wall side walls work surfaceAllow appropriate contact time per manufacturer instructions.Apply sporicidal agent per schedule; neutralize if required.Allow PEC to run for required recovery time before use.Document cleaning in PEC cleaning log. Disinfection of work surfaces At the beginning of each shift Before each batch After spills or contamination At least every 30 minutes during continuous compounding At the end of each shiftDecontamination (HD PECs only) Before cleaning, after spills, and as required.
Cleaning agent:Sterile Water for Injection (SWFI) or sterile purified waterDisinfectant:Sterile 70% Isopropyl Alcohol (IPA)
SEC Cleaning ProcedureDon appropriate cleanroom PPE.Remove visible debris and clutter.Clean surfaces using approved detergent as needed.Disinfect using approved disinfectant with lint-free wipes or mops.Apply sporicidal agent per monthly schedule.Follow top-to-bottom, clean-to-dirty technique.Allow proper contact time and drying.Document completion in SEC cleaning log.
Work surfaces & counters Daily, Floors Daily, Walls, doors, carts Weekly, Ceilings Monthly, , After spills or contamination Immediately.

17. Who performs the sterile compounding process at your facility?

it is done by one of our Scientist and Pharmacist

18. Who is responsible and accountable for the sterile compounding process at your facility?
Scientist and Pharmacist

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
When compounded sterile preparations (CSPs) are shipped or mailed, procedures are in place to ensure product safety, sterility, stability, temperature control and efficacy are maintained throughout transit. All shipments comply with applicable USP <797> requirements, manufacturer stability data, and state and federal regulations. we have SOPs in Place.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? The facility uses the following primary engineering controls (PECs) to provide an ISO Class 5 environment for sterile compounding:Laminar Airflow Workbenches (LAFWs)Used for non-hazardous sterile compounding.		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	■ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	■ No
8. Will you be utilizing a closed system transfer device?	Yes	■ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

N/A as we don't manufacture Hazardous Drugs

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?
N/A

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:
N/A

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?
Garb & Aseptic Technique Observation At least annually Review proper garbing, hand hygiene, and aseptic technique; more frequent if deviations occur.
Gloved Fingertip and Thumb Sampling Every 6 months After garbing and hand hygiene; pass criteria: 3 CFUs per plate, no pathogenic organisms.
Media-Fill Testing (Aseptic Manipulation Competency) Every 6 months Simulates sterile compounding; incubation and evaluation as per SOP; pass required before independent compounding.

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? **N/A** Yes No

4. What is the frequency for completing volumetric active air sampling?
Class 5 areas (PEC work zones, e.g., BSC, LAFW):At least every 6 months
ISO Class 7 (buffer rooms) and ISO Class 8 (ante-rooms):At least every 6 months

5. What is the frequency for completing surface sampling? ISO Class 5 (PEC Work Surfaces: BSC, CACI, LAFW, CAI)At least monthly . ISO Class 7 (Buffer Room Surfaces)At least monthly ISO Class 8 (Ante-Room Surfaces)At least monthly
6. What is the frequency for using sporicidal agents? Primary Engineering Controls (PECs - ISO Class 5)At least monthly: Apply a EPA-registered sporicidal disinfectant to work surfaces, walls, and other critical areas inside PECs.Additional use:After spills or contamination eventsAfter PEC relocation or repairs Secondary Engineering Controls (SECs - ISO Class 7/Buffer Rooms and ISO Class 8/Ante-Rooms)At least monthly:

7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	■ Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	■ Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shalabh Jain

Name of Person who Completed the Form

Chairman & CEO

Title

Signature (copies or stamps not accepted)

01/15/2026

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

5

ANNUAL DISCIPLINE CASES Reporting Period: January 2026 – March 2026			
FINDING	**HARM**	**DISCIPLINE INDIVIDUAL**	**DISCIPLINE FACILITY**
CVS is responsible for the acts of its employees who made an error in a prescription that results in negative outcome to the patient.	Yes	N/A	Respondent fined $10,000 for the violations; and assessed $1,000 in attorney's fees and costs.
Respondent KA made an error in a prescription that resulted in negative outcome to the patient.	Yes	Respondent's Certificate of Registration No. 19679 is suspended for a period of one year. The suspension is stayed, and Respondent is placed on probation subject to the following conditions: 1) Respondent fined $2,000 for the violations; 2) Respondent assessed $500 in attorney's fees and costs; and 3) Respondent shall comply with all federal and state statutes and regulations regarding the practice of pharmacy, and have no additional charges filed against him.	N/A
Respondent RA allowed non-practitioners to independently access, possess, furnish, and administer dangerous drugs without direct practitioner supervision.	No	Respondent's Certificate of Registration No. CS30228 is suspended for a period of one year. The suspension is stayed, and Respondent is placed on probation subject to the following conditions: 1) Respondent shall accept the Stipulation and Order is a public reprimand; 2) Respondent fined $5,000 for the violations; 3) Respondent assessed $1,000 in attorney's fees and costs; 4) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against her while on probation.	N/A

Respondent CL prescribed dangerous drugs to patients with whom Respondent had not established a bona fide therapeutic relationship and failed to timely report disciplinary action.	No	Respondent's Certificate of Registration No. CS31815 is suspended for a period of one year. The suspension is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent shall accept the Stipulation and Order as a public reprimand; 2) Respondent fined $5,000 for the violations; 3) Respondent assessed $1,000 in attorney's fees and costs; 4) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.	N/A
Respondent GO dispensed controlled substances without a valid dispensing practitioner registration and failed to review PMP.	No	Respondent's Certificate of Registration No. CS35044 is suspended for a period of one year. The suspension is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent shall accept the Stipulation and Order as a public reprimand; 2) Respondent fined $5,000 for the violations; 3) Respondent assessed $1,000 in attorney's fees and costs; 4) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.	N/A
As pharmacy/pharmacy owner, Costco Pharmacy is responsible for the acts of its employees who made an error in a prescription.	Yes	N/A	Respondent fined $2,000 for the violations; and assessed $1,000 in attorney's fees and costs.
Respondent CV made an error in a prescription.	No	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A

Respondent DY allowed a non-practitioner to independently access, possess, furnish, and administer dangerous drugs without direct practitioner supervision.	No	Respondent's Certificate of Registration No. CS06454 is placed on probation for one year subject to the following conditions: 1) Respondent shall accept the Stipulation and Order is a public reprimand; 2) Respondent fined $5,000 for the violations; 3) Respondent assessed $1,000 in attorney's fees and costs; 4) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.	N/A
The Nevada BOP took reciprocal disciplinary action on AW's Certificate of Registration No. 22724 based upon disciplinary action by the Arizona Board of Pharmacy for diversion.	No	Respondent's Certificate of Registration No. 22724 is placed on probation until October 29, 2029, and Respondent shall fully comply with the Arizona BOP Consent Order in Case No. 24-0394. Respondent fined $1,000 for the violations.	N/A
As pharmacy/pharmacy owner, SP is responsible for the acts of its employees who mailed dangerous drugs in California, Louisiana, Ohio, Texas, and Wisconsin when they did not hold a pharmacy, wholesaler, or mail pharmacy license in those states.	No	N/A	Respondent accepts the Stipulation as a public reprimand. Respondent has forfeited License No. PH03880 when they failed to renew their license on November 1, 2020. Respondent fined $5,000 for the violations and assessed $1,000 in attorney's fees and costs.
As managing pharmacist during the time of the events, Respondent TA was aware and is responsible for the acts of its employees who mailed dangerous drugs in California, Louisiana, Ohio, Texas, and Wisconsin when they did not hold a pharmacy, wholesaler, or mail pharmacy license in those states.	No	Respondent's Certificate of Registration No. 19070 is revoked. The revocation is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent fined $2,000 for the violations; 2) Respondent assessed $1,000 in attorney's fees and costs; 3) Respondent shall complete two additional hours of continuing education on duties of a managing pharmacist; and 4) As a condition or probation, Respondent shall not engage in any conduct for which disciplinary action may be imposed pursuant to the provisions.	N/A

Respondent RM dispensed dangerous drugs without a dispensing registration; held for sale an adulterated drug; failed to produce complete and accurate records of all dangerous drugs dispensed to patients; failed to store and/or possess dangerous drugs from patients and employees that were not in stock containers properly labeled and procured from a manufacturer, wholesaler or pharmacy; and did not acquire the dangerous drugs from patients and employees pursuant to a prescription written by himself or another practitioner, and/or were not dispensed to Respondent by a pharmacy or dispensing practitioner.	No	Respondent accepts the Stipulation as a public reprimand. Respondent fined $5,000 for the violations and assessed $500 in attorney's fees and costs.	N/A
Respondent EW failed to disclose on his 2022 controlled substance application renewal that he had been subject to disciplinary action before numerous state boards of medicine.	No	Respondent fined $1,000 for the violations.	N/A
As pharmacy/pharmacy owner, WP is responsible for the acts of its employees who made an error in a prescription that resulted in a negative outcome to the patient.	Yes	N/A	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs. Respondent will ensure all pharmacies in Nevada that use automated filling cells required pharmacists to review the SOPs for filling automated cells with medications from stock bottles within 60 days of the effective date of the Order. In addition, Walgreens #8342 will cease using the Yuyama EV-1 automated filling cells as of January 31, 2026.

As managing pharmacist during the time of the events, Respondent DW is responsible for the acts of its employees at Partell Pharmacy who dispensed invalid “Emergency Kits” or “COVID Kits” for which the drugs in each kit were not identified on the prescription, and they would substitute Budesonide in the “COVID Kit” with a Medrol DosePak and Albuterol without the knowledge or consent of the prescribing practitioner.	No	Respondent accepts this Stipulation as a public reprimand; Respondent’s Certificate of Registration No. 13635 has been forfeited since he failed to renew it on November 1, 2025; Respondent shall pay a fine of $5,000 for the violations; and assessed $1,000 in attorney’s fees and costs.	N/A
Respondent SS was arrested for a DUI and was under the influence of alcohol and Diazepam, a controlled substance. He did not have a valid U.S. prescription as he obtained the medication from a prescription issued by a licensed physician in Thailand. Respondent was disciplined by the California BOP where the Nevada BOP took reciprocal action.	No	Respondent accepts the Stipulation as a public reprimand; and assessed $500 in attorney’s fees and costs.	N/A
TU committed numerous violations related to controlled substances.	No	Respondent’s Certificate of Registration No. PD00512 is revoked. Respondent’s Certificate of Registration No. CS1604 is suspended for a period of two years. The suspension is stayed and Respondent is placed on probation subject to the following conditions: a) Respondent fined $5,000 for the violations; b) Respondent assessed $1,000 attorney’s fees and costs; and c) Respondent shall comply with all federal and status statues and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.	N/A

IG failed to timely renew his Certificate of Registration No. CS33713 prior to issuing controlled substance prescriptions and failed to review patient utilization reports in the PMP database prior to issuing controlled substance prescriptions.	No	Respondent subject to the following penalties: Public reprimand. Respondent's Certificate of Registration No. CS33713 is suspended for a period of two years. The suspension is stayed and Respondent is placed on probation subject to the following conditions: a) Respondent accepts the Stipulation and Order as a public reprimand; b) Respondent find $5,000 for the violations; c) Respondent assessed $1,000 in attorney's fees and costs; d) Respondent shall complete training with Board staff on the use of the PMP database within 60 days of the Order; and e) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed again him while on probation.	N/A
SN failed to disclose prior Iowa Board of Nursing disciplinary action on her 2022 Nevada controlled substance application. She also issued at least 148 prescriptions between April 18, 2024, and June 11, 2024, without a valid Nevada DEA registration and without a registered practice location on file with the Board. In addition, she did not timely report her 2025 disciplinary action from the Nevada Board of Nursing. Finally, she unlawfully accessed the PMP database and disseminated a patient utilization report for J.S., with whom she had no bona fide therapeutic relationship.	No	Respondent 's Certificate of Registrations No. CS34530 and PR16791 are revoked. Respondent fined $5,000 for the violations; and assessed $1,500 in attorney's fees and costs.	N/A
As pharmacy/pharmacy owner, Respondent purchased prescription drugs from pharmacies not licensed for wholesale distribution in Nevada.	No	N/A	Respondent accepts the Stipulation and Order as a public reprimand. Respondent fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.

As managing pharmacist at the time of the events of January 2023 and October 2023, NS purchased prescription drugs from pharmacies not licensed for wholesale distribution in Nevada.	No	Respondent accepts the Stipulation and Order as a public reprimand. Respondent fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs. Respondent shall complete two additional CE hours on duties of a management pharmacist.	N/A
As managing pharmacist at the time of the events of December 2023 and April 2024, KB purchased prescription drugs from pharmacies not licensed for wholesale distribution in Nevada.	No	Respondent accepts the Stipulation and Order as a public reprimand. Respondent fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs. Respondent shall complete two additional CE hours on duties of a management pharmacist.	N/A
JO allowed an employee to perform duties of a dispensing technician in training without the required registration.	No	Respondent's Certificate of Registration No. CS15479 and PD15479 are suspended. The suspension is stayed and placed on probation for a period of one year subject to the following conditions: a) Respondent shall pay a fine of $2,000 for the violations; and b) Respondent shall pay $500 in attorney's fees and costs.	N/A
AP made an error in a prescription while using virtual verification.	No	Respondent fined $500 for the violations; and assessed $500 in attorney's fees and costs.	N/A
TS made an error in a prescription while using virtual verification.	No	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
As managing pharmacist at the time of the events, GS filled prescriptions that were not valid from October 22, 2025, to November 4, 2025.	No	Respondent accepts the Stipulation and Order as a public reprimand. Respondent fined $2,500 for the violations; and assessed $750 in attorney's fees and costs. Additionally, Respondent agrees to participate in training with Board staff on laws related to controlled substances.	N/A
RC made an error in a prescription that resulted in a negative patient outcome. Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	Yes	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A

As pharmacy/pharmacy owners, CVS is responsible for the acts of its employees who made an error in a prescription that resulted in a negative patient outcome.	Yes	N/A	CVS fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.
As pharmacy/pharmacy owner, CVS is responsible for the acts of its employees who made an error in a prescription while using virtual verification.	No	N/A	CVS fined $5,000 for the violations; and assessed $500 in attorney's fees and costs. In addition, CVS corporate management shall provide the Board's staff with copies of written policies, procedures, training manuals or other materials, if any, that specifically confirm or corroborate its contention that all CVS pharmacists in Nevada have the discretion to perform visual inspections by physical or manual manipulation of prescription drug products before dispensing them to patients. If no such policies, procedures, training manuals or other materials exist, CVS shall provide a written statement to that effect. Additionally, CVS corporate management shall provide a written statement or summary of its plan, if any, to provide ongoing periodic reminders to or conduct training with its pharmacists concerning their discretion to perform visual inspections by physical or manual manipulation of prescription drug products before dispensing them to patients. If no such plan exists, CVS shall provide a written statement to that effect.

5A & 5B

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**Case No. 19-012-CS-S** **ORDER TO SHOW CAUSE**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), makes the following that will serve both a notice of intended action under NRS 233B.127(3) and as an order to show cause under NAC 639.965:

1. Festus Ebonka, APRN, Certificate of Registration No. CS23430, is hereby directed to appear before the Board for a hearing to show cause scheduled at April 15, 2026 at the following location:

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

2. On September 4, 2024, the Board entered its Findings of Fact, Conclusions of Law, and Order in Case No. 19-012-CS-S, revoking Certificate of Registration No. CS23430, staying the revocation, placing Respondent on probation and imposing discipline on Respondent pursuant to NRS 453.241(1)(b) and NRS 639.255 (Order).

3. Respondent has failed to make payment of Four Thousand Two Hundred Sixty-Eight Dollars and Ninety-Seven Cents ($4,268.97) for reasonable attorney's fees and recoverable costs pursuant to the Order.

4. Respondent has failed to complete two (2) hours of continuing education (CE) on ethics pursuant to the Order.

5. Respondent has had the following additional charges filed against him while on probation:

A. On or about May 5, 2025, in *United States of America v. Festus Onymaliosia Ebonka*, United States District Court for the District of Nevada, Case No. 2:22-cr-00156-CDS-NJK-1, Respondent pled guilty to and was convicted on one misdemeanor count of conversion of government property, in violation of 18 U.S. Code § 641, for falsely billing Medicaid for services that Respondent did not personally provide, and received reimbursement for those services.

B. On or about July 25, 2025, Respondent was served with the Notice of Intended Action and Accusation in Case No. 25-215-CS-S.

C. On or about October 6, 2025, the Nevada State Board of Nursing (NSBN) entered an order in Case No. 2024100049 suspending Respondent's License No. APRN000902 to practice nursing for cause.

6. Respondent is therefore directed to show cause why he should not be subject to further discipline pursuant to NRS Chapters 453 and 639, including, without limitation, revocation of Certificate of Registration No. CS23430, or otherwise demonstrate that his conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3).

IT IS SO ORDERED.

Entered this 6th day of March 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 10th day of March 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Festus Ebonka
[redacted]
Las Vegas, NV [redacted]

Nevada Treatment Center
c/o Festus Ebonka
1721 E Charleston Blvd
Las Vegas, NV 89104

Liborius Agwara, Esq.
2785 E Desert Inn Rd, Ste 270
Las Vegas, NV 89121

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**Case No. 19-012-CS-S** **FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER**

This matter came before the Nevada State Board of Pharmacy (Board) at its regularly scheduled meeting on Wednesday, September 4, 2024. Brett Kandt, Esq., prosecuted the case before the Board. Respondent Festus Ebonka, APRN, Certificate of Registration No. CS23430, was represented by counsel, Libo Agwara, Esq. The Board heard the case and, based on the evidence presented, the Board makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

The Board finds that probative evidence exists in the record to establish each of the following facts by a preponderance of the evidence:

1. The Board has jurisdiction over this matter and this Respondent because, at the time of the events herein, Respondent Festus Ebonka, APRN, held a controlled substance registration, Certificate of Registration No. CS23430, issued by the Board.

2. Respondent pre-signed two (2) controlled substance prescriptions that were issued to patients by his staff - on February 28, 2017, for patient J.J., and on March 2, 2017, for patient D.R. - while he was engaged in overseas travel outside of the United States from February 25 to March 11, 2017.

3. Board staff incurred at least $4,268.097 in attorney's fees and recoverable costs investigating and prosecuting this administrative action. The attorney's fees are reasonable based upon legal counsel's professional qualities, the nature of this administrative enforcement action, the work performed, and the result as evidenced by this Order.

CONCLUSIONS OF LAW

Based on the forgoing findings of fact, the Board concludes as a matter of law:

1. The Board has jurisdiction over this matter and Respondent because, at the time of the events herein, Respondent held a controlled substance registration issued by the Board.

2. The applicable law in this matter is as follows:

A. It is unlawful for a practitioner to prescribe a controlled substance except as authorized by law. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR §§ 1306.03-1306.05; NRS 453.226(1); NRS 453.321(1)(a); NRS 453.381(1); NRS 639.100(1); NRS 639.235(1); NRS 639.2353.

B. Falsifying a prescription for a controlled substance and the possession of signed prescription blanks are felony offenses. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1)(f), (h) and (i).

C. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

D. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

E. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or

revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

F. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(11).

G. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(12).

H. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

3. Respondent is GUILTY on Count One of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1), 21 CFR § 1306.04(a) and/or 21 CFR § 1306.05(a), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

4. Respondent is GUILTY on Count Two of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1) (f), (h) and (i), NRS 453.381(1), NRS 453.401(l)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2353, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

5. Respondent is NOT GUILTY on Count Three of the Accusation.

6. Respondent is GUILTY on Count Four of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

7. Respondent is GUILTY on Count Five of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(4).

8. Respondent is GUILTY on Count Six of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

ORDER

THEREFORE, THE BOARD HEREBY ORDERS AS FOLLOWS:

1. The certificate of registration of Respondent Festus Ebonka, APRN, Certificate of Registration No. CS23430, is revoked pursuant to NRS 453.241(1)(b). The revocation is stayed, and Respondent is placed on probation for a period of three (3) years pursuant to NRS 639.255(1)(b) subject to the following conditions:

A. Pursuant to NRS 622.400, Respondent shall pay Four Thousand Two Hundred Sixty-Eight Dollars and Ninety-Seven Cents ($4,268.97) to partially reimburse the Board

for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by due and payable by September 4, 2025;

B. Respondent shall complete two (2) hours of training from Board staff on Nevada Prescription Monitoring Program (PMP) compliance by September 4, 2025;

C. Respondent shall complete two (2) hours of continuing education (CE) on ethics by September 4, 2025; and

D. Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. CS23430 will be fully restored.

2. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay and immediately revoke Respondent's Certificate of Registration No. CS23430, and impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

3. This Order constitutes a final decision in a contested case and a public record pursuant to NRS 639.255(5), and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

4. This Order is effective immediately.

IT IS SO ORDERED.

Entered this 4th day of September, 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of September 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Festus Ebonka
c/o Liborius Agwara, Esq.
2785 E Desert Inn Rd., Ste 270
Las Vegas, NV 89121

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT I
BOARD COORDINATOR

FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**Case No. 25-215-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the events alleged herein, Respondent Festus Ebonka, APRN, held a controlled substance registration, Certificate of Registration No. CS23430, issued by the Board.

FACTUAL ALLEGATIONS

1. On or about May 5, 2025, in *United States of America v. Festus Onymaliosia Ebonka*, United States District Court for the District of Nevada, Case No. 2:22-cr-00156-CDS-NJK-1, Respondent pled guilty to and was convicted on one misdemeanor count of conversion of government property, in violation of 18 U.S. Code § 641.

2. The conviction resulted from Respondent falsely billing Medicaid for services that Respondent did not personally provide, and received reimbursement for those services.

APPLICABLE LAW

3. Medicaid fraud is a felony offense under State law. NRS 422.540(1).

4. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

5. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

6. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

7. Conviction of a crime involving moral turpitude, dishonesty or corruption is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(7)(c).

COUNT ONE

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

8. By his federal conviction on one criminal count of conversion of government property for falsely billing Medicaid for services that Respondent did not personally provide, and receiving reimbursement for those services, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(h) and is therefore subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT TWO

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

4. By his federal conviction on one criminal count of conversion of government property for falsely billing Medicaid for services that Respondent did not personally provide, and receiving reimbursement for those services, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(4).

COUNT THREE

Criminal Conviction for Conversion of Government Property

9. By his federal conviction on one criminal count of conversion of government property for falsely billing Medicaid for services that Respondent did not personally provide, and receiving reimbursement for those services, an act that also constitute a felony offense under NRS 422.540(1), Respondent is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or 639.210(7)(c).

COUNT FOUR

Commission of Acts that Render Registration Inconsistent with the Public Interest

10. By his federal conviction on one criminal count of conversion of government property for falsely billing Medicaid for services that Respondent did not personally provide, and receiving reimbursement for those services, an act that also constitute a felony offense under NRS 422.540(1), Respondent has committed acts that render his Nevada controlled substance registration inconsistent with the public interest, and is therefore subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 25th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**Case No. 25-215-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. A **hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 15, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 25th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**Case No. 25-215-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Festus Ebonka, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Festus Ebonka
[redacted]
Las Vegas, NV [redacted]

Nevada Treatment Center
c/o Festus Ebonka
1721 E Charleston Blvd
Las Vegas, NV 89104

Liborius Agwara, Esq.
2785 E Desert Inn Rd, Ste 270
Las Vegas, NV 89121

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
SEP 03 2025
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. **FESTUS EBONKA, APRN,** Certificate of Registration No. CS23430 Respondent.	**Case No. 25-215-CS-S**

ANSWER AND NOTICE OF DEFENSE

Respondent, **FESTUS EBONKA, APRN,** by and through counsel, LIBORIUS AGWARA, ESQ., of the Law Offices of Libo Agwara, Ltd., hereby files his Answer and Notice of Defense to THE NEVADA STATE BOARD OF PHARMACY'S ("Board") Complaint and states as follows:

1. Answering Paragraphs 1, 1, and 2, Respondent admits the allegations contained therein.

2. Answering Paragraphs 2, 8, 4, 9, and 10, Respondent denies the allegations contained therein.

3. Answering Paragraphs 3, 4, 5, 6, and 7, Respondent states that he is without sufficient knowledge as to the truth or falsity of the allegations contained therein, and as such denies them.

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2785 E. Desert Inn Rd., Ste. 270
Las Vegas, NV 89121
702-385-4800 Phone

WHEREFORE, Respondent, respectfully requests that the Board find that he did not violate the Control Substance Act. Respondent further requests such other and additional relief as the Board may deem just and proper under the circumstances.

Dated this 3rd day of September 2025.

LAW OFFICES OF LIBO AGWARA, LTD

LIBORIUS AGWARA, ESQ.
Nevada Bar No.: 7576
2785 E. Desert Inn Rd., Ste. 270
Las Vegas, NV 89121
Tel: (702) 385-4800 Phone
Libolaw@yahoo.com
Attorney for Respondent

2785 E. Desert Inn Rd., Ste. 270
Las Vegas, NV 89121
702-385-4800 Phone

VERIFICATION

STATE OF NEVADA)
) ss.
COUNTY OF CLARK)

I, FESTUS EBONKA, under penalties of perjury, being first duly sworn, deposes and says:

That I am the Respondent in the above-entitled action; that I have read the foregoing ANSWER AND NOTICE OF DEFENSE and know the contents thereof; that the same is true of my own knowledge, except for those matters therein contained stated upon information and belief, and as to those matters, I believe them to be true.

DATED this 2nd day of September 2025.

FESTUS EBONKA

2785 E. Desert Inn Rd., Ste. 270
Las Vegas, NV 89121
702-385-4800 Phone

SEALED

Office of the United States Attorney
District of Nevada
501 Las Vegas Boulevard, Suite 1100
Las Vegas, Nevada 89101
(702) 388-6336

FILED ENTERED RECEIVED SERVED ON COUNSEL/PARTIES OF RECORD
JUL 19 2022
CLERK US DISTRICT COURT DISTRICT OF NEVADA
BY: DEPUTY

JASON M. FRIERSON
United States Attorney
Nevada Bar Number 7709
RICHARD ANTHONY LOPEZ
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Attorneys for the United States

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

UNITED STATES OF AMERICA,

Plaintiff,

v.

FESTUS ONYEMALIOSIA EBONKA,

Defendant.

SEALED
CRIMINAL INDICTMENT

Case No. 2:22-cr-156 CDS NJK

VIOLATION:

Health Care Fraud (18 U.S.C. § 1347)

THE GRAND JURY CHARGES THAT:

Introductory Allegations

At times material to this Indictment:

1. Defendant FESTUS ONYEMALIOSIA EBONKA, a resident of Las Vegas, Nevada, was a registered nurse and a certified nurse practitioner licensed to practice in Nevada. EBONKA was a Medicare provider and was required to abide by all Medicare rules and regulations.

2. EBONKA owned and operated three Nevada companies (collectively, "the Ebonka Entities") enrolled in the Medicare program: Nevada Integrated Behavioral Services Inc.; Ebonny Behavioral Care Services Corporation; and CBH Wellness Clinic, Inc.

3. D.B., E.G., Ge.A., Gw.A., J.G., K.K., Mi.H., My.H., T.H., and Y.H. were Medicare beneficiaries residing in the District of Nevada.

4. E.H., J.L., and L.S. were former Medicare beneficiaries who were deceased.

The Medicare Program

5. The Medicare program ("Medicare") was a federal health care program, as defined in Title 18, United States Code, Section 24(b), that provided free or below cost health care benefits to certain eligible beneficiaries, primarily persons who were 65 years of age or older or disabled. The Centers for Medicare and Medicaid Services (CMS), a federal agency within the U.S. Department of Health and Human Services, administers the Medicare program.

6. Medicare was divided into four parts and covered specific benefits, items, and services: hospital insurance (Part A), medical insurance (Part B), Medicare Advantage (Part C), and prescription drug benefits (Part D).

7. Medicare Part B covered outpatient physician and non-physician practitioner services, durable medical equipment, and some preventive services.

8. Physicians, nurses, nurse practitioners, clinics, laboratories, and other health care providers that provided services to Medicare beneficiaries were able to apply for and obtain a "provider number." A health care provider that received a Medicare provider number was able to file claims with Medicare to obtain reimbursement for services provided to beneficiaries.

9. To receive Medicare reimbursement, providers had to fill out an application and execute a written provider agreement, known as CMS Form 855. The application contained certifications that the provider agreed to abide by Medicare laws and regulations, and that the provider "[would] not knowingly present or cause to be presented a false or

fraudulent claim for payment by Medicare, and [would] not submit claims with deliberate ignorance or reckless disregard of their truth or falsity." Medicare providers were given access to Medicare manuals and service bulletins describing procedures, rules, and regulations.

HCPCS Code L8679

10. CMS established the Healthcare Common Procedure and Coding System (HCPCS) Level II Code Set. The HCPCS Level II Code Set is a standardized five-digit alphanumeric coding system that is used by federal, state, and private health insurance entities primarily to identify products, supplies, and services provided by healthcare professionals. These codes are also used to bill and submit claims to federal, state, and private insurance entities for reimbursement of medical services provided to beneficiaries. The coding system adheres to the following format: the first digit is a letter that identifies the HCPCS code chapter and payment category that the service belongs to and group similar services together, while the last four digits are numeric characters. For example, codes beginning with an "L" belong to the prosthetics and orthotics services/payment category.

11. HCPCS code L8679 is used to bill for Medicare-covered neurostimulator devices that require surgical implantation. The use of a neurostimulator involves implantation of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver which is implanted under the skin at a depth not greater than ½ inch. Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of the stimulating electrodes requires a surgical process that takes at least one to two hours and usually necessitates an operating room.

The Stivax Device

12. Stivax is a medical device placed on the top of a patient's inner ear, has a battery, and stays on for about two weeks. The Food and Drug Administration describes Stivax as a single use, battery-powered, electrical nerve stimulator which is used for the stimulation of the vagus nerve through the ear. The stimulator is taped to the patient's ear. The FDA stated that the Stivax device is indicated for use as an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners as determined by the states. Medicare does not provide reimbursement for acupuncture services, such as the provision and use of the Stivax device.

COUNTS ONE TO THIRTEEN
Health Care Fraud
(18 U.S.C. § 1347)

13. Beginning in or around March 2017, and continuing through in or around September 2018, within the State and Federal District of Nevada and elsewhere,

FESTUS ONYEMALIOSIA EBONKA,

defendant herein, knowingly and willfully executed, attempted to execute, and participated in a scheme and artifice to defraud a health care benefit program, namely Medicare, and to obtain, by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of, a health care benefit program, in connection with the delivery of, and payment for, health care benefits, items, and services, as described below.

14. The purpose of the scheme and artifice to defraud was for EBONKA to unlawfully enrich himself by causing the submission of materially false and fraudulent claims to Medicare through the Ebonka Entities.

15. It was part of the scheme that EBONKA submitted and caused to be submitted false and fraudulent claims requesting reimbursement under Procedure Code L8679 that were ineligible for Medicare reimbursement.

16. These claims were false and fraudulent in that EBONKA and the Ebonka Entities had not provided medical services that qualified for reimbursement under Procedure Code L8679, including, for example:

a. Claims in the name of beneficiaries who received services related to the Stivax device, which did not qualify for any Medicare reimbursement, on the date indicated on the claim.

b. Claims in the name of beneficiaries who received no services related to the Stivax device on the date indicated on the claim.

c. Claims in the names of beneficiaries who were deceased at the time EBONKA purportedly provided them with medical services.

17. From in or around March 2017 through in or around September 2018, EBONKA caused the submission to Medicare of at least 2,500 false and fraudulent claims requesting at least $25 million in reimbursement. Medicare paid the Ebonka Entities more than $10 million as a result of EBONKA's fraudulent claim submissions.

18. On or about the dates set forth below, within the State and Federal District of Nevada and elsewhere, EBONKA did knowingly and willfully execute, attempt to execute, and participate in the above-described scheme and artifice in that EBONKA caused the submission of the false and fraudulent claims described below to Medicare seeking reimbursement for the approximate amount of $10,000 per claim, each submission a separate violation of 18 U.S.C. § 1347:

COUNT	DATE	BENEFICIARY	CLAIM ID NUMBER
ONE	7/26/2017	My.H.	332217226279930
TWO	7/26/2017	Y.H.	332217226279900
THREE	11/30/2017	Ge.A.	332217334233980
FOUR	12/4/2017	J.L.	332217338272650
FIVE	1/2/2018	L.S.	332218002134640
SIX	1/15/2018	E.G.	332218015227810
SEVEN	1/16/2018	J.G.	332218016244790
EIGHT	8/29/2018	Gw.A.	332218241165940
NINE	8/31/2018	Mi.H.	332218243184230
TEN	9/4/2018	E.H.	332218247168190
ELEVEN	9/4/2018	K.K.	332218247167770
TWELVE	9/5/2018	T.H.	332218248189290
THIRTEEN	9/7/2018	D.B.	338518250351150

DATED this 19th day of July, 2022.

A TRUE BILL:

/S/
FOREPERSON OF THE GRAND JURY

JASON M. FRIERSON
United States Attorney

RICHARD ANTHONY LOPEZ
Assistant United States Attorney

SUE FAHAMI
Acting United States Attorney
District of Nevada
Nevada Bar Number 5634
RICHARD ANTHONY LOPEZ
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Attorneys for the United States

FILED
ENTERED
RECEIVED
SERVED ON
COUNSEL/PARTIES OF RECORD
FEB 04 2025
CLERK US DISTRICT COURT
DISTRICT OF NEVADA
BY: DEPUTY

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEVADA

UNITED STATES OF AMERICA,

Plaintiff,

v.

FESTUS ONYEMALIOSIA EBONKA,

Defendant.

No. 2:22-cr-00156-CDS-NJK

Plea Agreement for Defendant Festus Onyemaliosia Ebonka Pursuant to Fed. R. Crim. P. 11(c)(1)(A) and (B)

This plea agreement between Festus Onyemaliosia Ebonka ("defendant") and the United States Attorney's Office for the District of Nevada (the "USAO") sets forth the parties' agreement regarding the criminal charges referenced herein and the applicable sentences, fines, and restitution in the above-captioned case. This agreement binds only defendant and the USAO and does not bind the district court, the U.S. Probation Office, or any other federal, state, local, or foreign prosecuting, enforcement, administrative, or regulatory authorities. This agreement does not prohibit the USAO or any agency or third party from seeking any other civil or administrative remedies, including administrative forfeiture or civil forfeiture *in rem* actions, directly or indirectly against defendant or defendant's property.

This agreement becomes effective upon signature by defendant, defendant's counsel, and an Assistant United States Attorney.

I. DEFENDANT'S OBLIGATIONS

1. Defendant agrees to:

a. Give up the right to indictment by a grand jury and, at the earliest opportunity requested by the USAO and provided by the Court, appear and plead guilty to a one-count information in the form attached to this agreement as Exhibit A or a substantially similar form, which charges defendant with Conversion of Government Money, a Class A misdemeanor, in violation of 18 U.S.C. § 641.

b. Stipulate to the facts agreed to in this agreement;

c. Abide by all agreements regarding sentencing contained in this agreement;

d. Not seek to withdraw defendant's guilty pleas once it is entered;

e. Appear for all court appearances, surrender as ordered for service of sentence, obey all conditions of any bond, and obey any other ongoing court order in this matter;

f. Not commit any federal, state, or local crime;

g. Be truthful at all times with the U.S. Probation and Pretrial Services Offices and the Court;

h. Before and after sentencing, upon request by the Court, the USAO, or the Probation Office, provide accurate and complete financial information, submit sworn statements, and/or give depositions under oath concerning defendant's assets and defendant's ability to pay. As part of the required disclosure, defendant agrees to provide any and all financial information and authorizations requested by the Probation Office for preparation of the Presentence Report. Defendant further agrees that, upon filing of this agreement, the USAO is authorized to obtain defendant's credit report. Defendant will also complete a financial form

provided by the USAO, to include all supporting documentation, and return it to the USAO within ten (10) days from entry of the plea. Defendant agrees that the district court may enter any order necessary to effectuate or facilitate disclosure of defendant's financial information;

i. To facilitate payment of any fine, restitution, or assessment, surrender assets defendant obtained directly or indirectly as a result of defendant's crimes. Defendant agrees to voluntarily release funds and property under defendant's control or in which defendant has any property interest, before and after sentencing, to pay any fine or restitution identified in this agreement, agreed to by the parties, or ordered by the Court;

j. Defendant agrees that restitution shall be ordered due and payable in full immediately after the judgment is entered, and that the full amount of any restitution ordered is subject to immediate enforcement and collection by the USAO or defendant's victims, or both. Defendant agrees that any schedule of payments entered by the district court is a schedule of the minimum payment due and does not prohibit or limit the methods by which the USAO may immediately enforce and collect the judgment in full. Defendant acknowledges that restitution may not be discharged, in whole or in part, in any present or future bankruptcy proceeding.

II. THE USAO'S OBLIGATIONS

2. The USAO agrees to:

a. Stipulate to facts agreed to in this agreement;

b. Abide by all agreements regarding sentencing contained in this agreement;

c. At sentencing, provided that defendant demonstrates an acceptance of responsibility for the offenses up to and including the time of sentencing, recommend a two-level reduction in the applicable sentencing guidelines offense level, pursuant to USSG § 3E1.1;

d. At sentencing, move to dismiss the indictment against defendant. Defendant agrees, however, that the district court may consider any dismissed charges in

determining the applicable sentencing guidelines range, the propriety and extent of any departure from that range, and the sentence to be imposed; and

e. Not bring any additional charges against defendant arising out of the factual basis set forth in this agreement. However, the USAO reserves the right to prosecute defendant for (a) any crime of violence as defined by 18 U.S.C. § 16; and (b) any criminal tax violations (including conspiracy to commit such violations chargeable under 18 U.S.C. § 371). Defendant agrees that the district court at sentencing may consider any uncharged conduct in determining the applicable sentencing guidelines range, the propriety and extent of any departure from that range, and the sentence to be imposed after consideration of the sentencing guidelines and all other relevant factors under 18 U.S.C. § 3553(a).

III. ELEMENTS OF THE OFFENSE

3. Count One: The elements of Conversion of Government Money under 18 U.S.C. § 641 are as follows:

First: The defendant knowingly converted to the defendant's use money with the intention of depriving the owner of the use or benefit of the money; and

Second: the money belonged to the United States.

See Ninth Circuit Model Criminal Jury Instruction 23.1 (2022 ed.).

4. Deliberate Indifference: A defendant acts knowingly if:

First: The defendant was aware of a high probability that he was not entitled to reimbursement by Medicare, and

Second: the defendant deliberately avoided learning the truth.

See Ninth Circuit Model Criminal Jury Instruction 4.9 (2022 ed.).

IV. CONSEQUENCES OF CONVICTION

5. Maximum Statutory Penalties: Defendant understands that the statutory maximum sentence the district court can impose for a violation of 18 U.S.C. § 641 as charged in the Information, is: one year of imprisonment; a one-year period of supervised release; a fine of $250,000 or twice the gross gain or gross loss resulting from the offense, whichever is greatest; and a mandatory special assessment of $25.

6. Restitution: Defendant understands that defendant will be required to pay full restitution to the victim(s) of the offense to which defendant is pleading guilty. The parties currently believe that the applicable amount of restitution is approximately $6,519.69, but recognize and agree that this amount could change based on facts that come to the attention of the parties prior to sentencing.

7. Parole Abolished: Defendant acknowledges that defendant's prison sentence cannot be shortened by early release on parole because parole has been abolished.

8. Supervised Release: Defendant understands that supervised release is a period of time following imprisonment during which defendant will be subject to various restrictions and requirements. Defendant understands that if defendant violates one or more of the conditions of any supervised release imposed, defendant may be returned to prison for all or part of the term of supervised release authorized by statute for the offense that resulted in the term of supervised release, which could result in defendant serving a total term of imprisonment greater than the statutory maximum stated above.

9. Factors under 18 U.S.C. § 3553: Defendant understands that the district court must consider the factors set forth in 18 U.S.C. § 3553(a) in determining defendant's sentence. However, the statutory maximum sentence limits the district court's discretion in determining defendant's sentence.

10. Potential Collateral Consequences of Conviction: Defendant understands that, by pleading guilty, defendant may be giving up valuable government benefits and valuable civic rights. Defendant understands that the conviction in this case may subject defendant to various other collateral consequences, including but not limited to revocation of probation, parole, or supervised release in another case and suspension or revocation of a professional license. Defendant understands that unanticipated collateral consequences will not serve as grounds to withdraw defendant's guilty plea.

11. Potential Removal/Deportation Consequences of Conviction: Defendant understands that, if defendant is not a United States citizen, the conviction in this case may subject defendant to removal, also known as deportation, which may, under some circumstances, be mandatory; denial of citizenship; and denial of admission to the United States in the future. The district court cannot advise defendant fully regarding the immigration consequences of the conviction in this case, but defendant's attorney has advised him about the deportation risks of his guilty plea. Defendant understands that unexpected immigration consequences will not serve as grounds to withdraw defendant's guilty plea.

V. FACTUAL BASIS

12. Defendant admits that defendant is, in fact, guilty of the offense to which defendant is agreeing to plead guilty. Defendant acknowledges that if defendant elected to go to trial instead of pleading guilty, the USAO could prove defendant's guilt beyond a reasonable doubt. Defendant further acknowledges that defendant's admissions and declarations of fact set forth below satisfy every element of the charged offense. Defendant waives any potential future claim that the facts defendant admitted below are insufficient to satisfy the elements of the charged offense. Defendant admits and declares under penalty of perjury that the facts set forth below are true and correct:

a. At all relevant times, defendant Festus Onyemaliosia Ebonka, a resident of Las Vegas, Nevada, was a registered nurse and a certified nurse practitioner licensed to practice in Nevada. Ebonka was a provider enrolled in Medicare and was required to abide by all Medicare rules and regulations.

b. From in or around March 2017 through in or around September 2018, Ebonka, through businesses under his control, caused the submission to Medicare of claims requesting reimbursement under Procedure Code L8679.

c. Ebonka submitted those claims based on the purported application of a device called Stivax to patients covered by Medicare.

d. However, these claims were false because Procedure Code L8679 does not cover the application of the Stivax device, which Medicare considers a non-reimbursement acupuncture treatment.

e. On September 13, 2018, Ebonka caused the submission to Medicare of a request for $10,000 of reimbursement under Procedure Code L8679 for services rendered to B.A., a patient of Ebonka. The claim was false because the services provide to B.A. – the application of the Stivax device – were not covered by Procedure Code L8679. Based on this clam, Medicare, a federal agency, reimbursed Ebonka $6,519.69, which he converted to his own use.

f. At the time Ebonka caused the above submission for services provided to B.A., he was deliberately ignorant to the false nature of this claim, that is, he was aware of a high probability that Procedure Code L8679 did not cover the application of the Stivax device and deliberately avoided learning the truth.

g. All of the above occurred in the District of Nevada and elsewhere.

VI. SENTENCING FACTORS

13. Discretionary Nature of Sentencing Guidelines: Defendant understands that in determining defendant's sentence, the district court is required to calculate the applicable sentencing guidelines range and to consider that range, possible departures under the sentencing guidelines, and the other sentencing factors set forth in 18 U.S.C. § 3553(a). Defendant understands that the sentencing guidelines are advisory only, that defendant cannot have any expectation of receiving a sentence within the calculated sentencing guidelines range, and that after considering the sentencing guidelines and the other § 3553(a) factors, the district court will be free to exercise its discretion to impose any sentence it finds appropriate up to the maximum set by statute for the crime of conviction.

14. Offense Level Calculations: The parties jointly agree and stipulate that, in calculating defendant's advisory guidelines sentencing range, the district court should use the following base offense level and adjustments; acknowledge that these stipulations do not bind the district court; and agree that they will not seek to apply or advocate for the use of any other base offense level(s) or any other specific offense characteristics, enhancements, or reductions in calculating the advisory guidelines range:

Base Offense Level [USSG § 2B1.1(a)(2)]:	6
Loss Exceeds $6,500 [USSG § 2B1.1(b)(1)(B)]:	+2
Adjusted Offense Level:	8

The parties further agree that, if, at the time of sentencing, the district court determines that defendant has not received any criminal history points from Chapter Four, Part A, the parties will jointly recommend that defendant receive a two-level reduction pursuant to § 4C1.1(a).

15. Reduction for Acceptance of Responsibility: Under USSG § 3E1.1(a), the USAO will recommend that defendant receive a two-level downward adjustment for acceptance of

responsibility unless defendant (a) fails to truthfully admit facts establishing a factual basis for the guilty plea when defendant enters the plea; (b) fails to truthfully admit facts establishing the amount of restitution owed when defendant enters the guilty plea; (c) fails to truthfully admit facts establishing the forfeiture allegations when defendant enters the guilty plea; (d) provides false or misleading information to the USAO, the Court, Pretrial Services, or the Probation Office; (e) denies involvement in the offense or provides conflicting statements regarding defendant's involvement or falsely denies or frivolously contests conduct relevant to the offense; (f) attempts to withdraw defendant's guilty plea; (g) commits or attempts to commit any crime; (h) fails to appear in court; or (i) violates the conditions of pretrial release.

16. Criminal History Category: Defendant acknowledges that the district court may base defendant's sentence in part on defendant's criminal record or criminal history. The district court will determine defendant's criminal history category under the sentencing guidelines.

17. Additional Sentencing Information: The stipulated sentencing guidelines calculations are based on information now known to the parties. Defendant understands that both defendant and the USAO are free to (a) supplement the facts in this agreement by supplying relevant information to the U.S. Probation and Pretrial Services Offices and the district court regarding the nature, scope, and extent of defendant's criminal conduct and any aggravating or mitigating facts or circumstances; and (b) correct any and all factual misstatements relating to the district court's sentencing guidelines calculations and determination of sentence. While this paragraph permits both the USAO and defendant to submit full and complete factual information to the U.S. Probation and Pretrial Services Offices and the district court, even if that factual information may be viewed as inconsistent with the facts agreed to in this agreement, this paragraph does not affect defendant's and the USAO's obligations not to contest the facts agreed

to in this agreement. Good faith efforts to provide truthful information or to correct factual misstatements shall not be grounds for defendant to withdraw defendant's guilty plea.

18. Defendant acknowledges that the U.S. Probation Office may calculate the sentencing guidelines differently and may rely on additional information it obtains through its investigation. Defendant also acknowledges that the district court may rely on this and other additional information as it calculates the sentencing guidelines range and makes other sentencing determinations, and the district court's reliance on such information shall not be grounds for defendant to withdraw defendant's guilty plea.

VII. POSITIONS REGARDING SENTENCING

19. The parties will jointly recommend that the district court sentence defendant to sentence of three years of probation. In the event that a sentence of three years of probation is outside defendant's advisory Guideline range as determined by the district court, the parties will jointly request a variance to three years of probation.

20. Defendant acknowledges that the district court does not have to follow the recommendation of either party.

21. Notwithstanding its agreement to recommend a sentence as described above, the USAO reserves its right to defend any lawfully imposed sentence on appeal or in any post-conviction litigation.

22. If defendant commits any act that results in the district court finding that defendant is not entitled to a downward adjustment for acceptance of responsibility, the USAO is entitled to argue for any sentence it deems appropriate under 18 U.S.C. § 3553(a). In any such event, Defendant remains bound by the provisions of this agreement and shall not have the right to withdraw defendant's guilty plea.

VIII. WAIVER OF CONSTITUTIONAL RIGHTS

23. Defendant understands that by pleading guilty, defendant gives up the following rights:

a. The right to persist in a plea of not guilty;

b. The right to a speedy and public trial by jury;

c. The right to be represented by counsel—and if necessary have the court appoint counsel—at trial. Defendant understands, however, that, defendant retains the right to be represented by counsel—and if necessary have the court appoint counsel—at every other stage of the proceeding;

d. The right to be presumed innocent and to have the burden of proof placed on the USAO to prove defendant guilty beyond a reasonable doubt;

e. The right to confront and cross-examine witnesses against defendant;

f. The right to testify and to present evidence in opposition to the charges, including the right to compel the attendance of witnesses to testify;

g. The right not to be compelled to testify, and, if defendant chose not to testify or present evidence, to have that choice not be used against defendant; and

h. The right to pursue any affirmative defenses; Fourth Amendment or Fifth Amendment claims; any other pretrial motions that have been or could have been filed; and challenges to any adverse pre-trial rulings (unless specifically reserved in the following section).

24. Having been fully advised by defendant's attorney regarding application of the statute of limitations to the offense to which defendant is pleading guilty, defendant hereby knowingly, voluntarily, and intelligently waives, relinquishes, and gives up: (a) any right that defendant might have not to be prosecuted for the offense to which defendant is pleading guilty because of the expiration of the statute of limitations for that offense prior to the filing of the

information alleging that offense; and (b) any defense, claim, or argument defendant could raise or assert that prosecution of the offense to which defendant is pleading guilty is barred by the expiration of the applicable statute of limitations, pre-indictment delay, or any speedy trial violation.

IX. WAIVER OF APPELLATE RIGHTS

25. Waiver of Appellate Rights: Defendant knowingly and expressly waives the right to appeal: (a) any sentence imposed within or below the applicable Sentencing Guideline range as determined by the district court; (b) the manner in which the district court determined that sentence on the grounds set forth in 18 U.S.C. § 3742; (c) any other aspect of the conviction, including but not limited to the constitutionality of the statutes of conviction; and (d) any other aspect of the sentence, including but not limited to the constitutionality of any mandatory or standard conditions of supervised release; the denial of any motion for early termination of supervised release; and any order of restitution or forfeiture.

26. Defendant reserves only the right to appeal any portion of the sentence that is an upward departure or variance from the applicable Sentencing Guideline range as determined by the district court.

27. Waiver of Post-Conviction Rights: Defendant also knowingly and expressly waives all collateral challenges, including any claims under 28 U.S.C. § 2255, to defendant's conviction, sentence, and the procedure by which the district court adjudicated guilt and imposed sentence, except non-waivable claims of ineffective assistance of counsel.

28. Preservation of Evidence: Defendant acknowledges that the USAO and the agencies investigating this case are not obligated or required to preserve any evidence obtained in the investigation of this case.

X. RESULT OF WITHDRAWAL OF GUILTY PLEA OR VACATUR/REVERSAL/SET-ASIDE OF CONVICTION

29. Consequence of Withdrawal of Guilty Plea: Defendant agrees that if, after entering a guilty plea pursuant to this agreement, defendant seeks to withdraw and succeeds in withdrawing defendant's guilty plea on any basis other than a claim and finding that entry into this agreement was involuntary, then (a) the USAO will be relieved of all of its obligations under this agreement and (b) should the USAO choose to pursue any that was either dismissed or not filed as a result of this agreement, or that the government agreed to move to dismiss at sentencing as part of this agreement, or that the government agreed to move to dismiss at sentencing as part of this agreement, then (i) any applicable statute of limitations will be tolled between the date of defendant's signing of this agreement and the filing commencing any such action; and (ii) defendant waives and gives up all defenses based on the statute of limitations, any claim of pre-indictment delay, or any speedy trial claim with respect to any such action, except to the extent that such defenses existed as of the date of defendant's signing this agreement.

30. Consequence of Vacatur, Reversal, or Set-aside: Defendant agrees that if defendant's conviction is vacated, reversed, or set aside, both the USAO and defendant will be released from all their obligations under this agreement, except that, should the USAO choose to pursue any charge that was either dismissed or not filed as a result of this agreement, then (i) any applicable statute of limitations will be tolled between the date of defendant's signing of this agreement and the filing commencing any such action; and (ii) defendant waives and gives up all defenses based on the statute of limitations, any claim of pre-indictment delay, or any speedy trial claim with respect to any such action, except to the extent that such defenses existed as of the date of defendant's signing this agreement.

XI. BREACH OF AGREEMENT

31. Defendant agrees that if, at any time after this agreement becomes effective, defendant knowingly violates or fails to perform any of defendant's obligations under this agreement ("a breach"), the USAO may declare this agreement breached. All of defendant's obligations are material, a single breach of this agreement is sufficient for the USAO to declare a breach, and defendant shall not be deemed to have cured a breach without the express agreement of the USAO in writing. If the USAO declares this agreement breached, and the district court finds such a breach to have occurred, then: (a) if defendant has previously entered a guilty plea pursuant to this agreement, defendant will remain bound by the provisions of this agreement and will not be able to withdraw the guilty plea; and (b) the USAO will be relieved of all its obligations under this agreement.

32. Following the Court's finding of a knowing breach of this agreement by defendant, should the USAO choose to pursue any charge that was either dismissed or not filed as a result of this agreement, or that the government agreed to move to dismiss at sentencing as part of this agreement, then:

a. Defendant agrees that any applicable statute of limitations is tolled between the date of defendant's signing of this agreement and the filing commencing any such action.

b. Defendant waives and gives up all defenses based on the statute of limitations, any claim of pre-indictment delay, or any speedy trial claim with respect to any such action, except to the extent that such defenses existed as of the date of defendant's signing this agreement.

c. Defendant agrees that: (i) any statements made by defendant, under oath, at the guilty plea hearing (if such a hearing occurred prior to the breach); (ii) the agreed to factual basis statement in this agreement; and (iii) any evidence derived from such statements, shall be

admissible against defendant in any such action against defendant, and defendant waives and gives up any claim under the United States Constitution, any statute, Federal Rule of Evidence 410, Federal Rule of Criminal Procedure 11(f), or any other federal rule, that the statements or any evidence derived from the statements should be suppressed or are inadmissible.

XII. COURT AND UNITED STATES PROBATION AND PRETRIAL SERVICES OFFICE NOT PARTIES

33. Defendant understands that the Court and the U.S. Probation and Pretrial Services Office are not parties to this agreement and need not accept any of the USAO's sentencing recommendations or the parties' agreements to facts or sentencing factors.

34. Defendant understands that both defendant and the USAO are free to argue on appeal and collateral review that the district court's sentencing guidelines calculations and the sentence it chooses to impose are not error.

35. Defendant understands that even if the district court ignores any sentencing recommendation, finds facts or reaches conclusions different from those agreed to by the parties, or imposes any sentence up to the maximum established by statute, defendant cannot, for that reason, withdraw defendant's guilty plea[s], and defendant will remain bound to fulfill all defendant's obligations under this agreement. Defendant understands that no one—not the prosecutor, defendant's attorney, or the Court—can make a binding prediction or promise regarding the sentence defendant will receive, except that it will be within the statutory maximum.

XIII. ADDITIONAL ACKNOWLEDGMENTS

36. Defendant acknowledges that:

a. Defendant read this agreement, and defendant understands its terms and conditions.

b. Defendant had adequate time to discuss this case, the evidence, and this agreement with defendant's attorney.

c. Defendant carefully and thoroughly discussed all terms of this agreement with defendant's attorney.

d. Defendant understands the terms of this agreement and voluntarily agrees to those terms.

e. Defendant has discussed with defendant's attorney the following: the evidence; defendant's rights; possible pretrial motions that might be filed; possible defenses that might be asserted either prior to or at trial; the sentencing factors set forth in 18 U.S.C. § 3553(a); the relevant sentencing guidelines provisions; and consequences of entering into this agreement.

f. The representations contained in this agreement are true and correct, including the factual basis for defendant's offense set forth in this agreement.

g. Defendant was not under the influence of any alcohol, drug, or medicine that would impair defendant's ability to understand the agreement when defendant considered signing this agreement and when defendant signed it.

37. Defendant understands that defendant alone decides whether to plead guilty or go to trial, and acknowledges that defendant has decided to enter defendant's guilty plea knowing of the charges brought against defendant, defendant's possible defenses, and the benefits and possible detriments of proceeding to trial.

38. Defendant understands that no promises, understandings, or agreements other than those set forth in this agreement have been made or implied by defendant, defendant's attorney, or the USAO, and no additional promises, agreements, or conditions shall have any force or effect unless set forth in writing and signed by all parties or confirmed on the record before the district court.

39. Defendant acknowledges that defendant decided to plead guilty voluntarily and that no one threatened, coerced, or forced defendant to enter into this agreement.

40. Defendant is satisfied with the representation of defendant's attorney, and defendant is pleading guilty because defendant is guilty of the charges and chooses to take advantage of the promises set forth in this agreement and for no other reason.

XIV. PLEA AGREEMENT PART OF THE GUILTY PLEA HEARING

41. The parties agree that this agreement will be considered part of the record of defendant's guilty plea hearing as if the entire agreement had been read into the record of the proceeding.

AGREED AND ACCEPTED

UNITED STATES ATTORNEY'S OFFICE
FOR THE DISTRICT OF NEVADA

SUE FAHAMI
Acting United States Attorney

2.4.25

RICHARD ANTHONY LOPEZ
JESSICA OLIVA
Assistant United States Attorneys

Date

2/4/25

FESTUS ONYEMALIOSIA EBONKA
Defendant

Date

CRANE M. POMERANTZ, ESQ.
LIBORIUS AGWARA, ESQ.
Attorneys for Defendant EBONKA

Date

EXHIBIT A
Form of One-Count Information
Charging Defendant Ebonka

THE UNITED STATES ATTORNEY CHARGES THAT

COUNT ONE
Conversion of Government Property
(18 U.S.C. § 641)

On or about September 13, 2018, in the State and Federal District of Nevada,

FESTUS ONYEMALIOSIA EBONKA,

defendant herein, willfully and knowingly did convert to his own use money from Medicare, an agency of the United States, to which defendant knew he was not entitled, all in violation of Title 18, United States Code, Section 641.

UNITED STATES DISTRICT COURT

District of Nevada

UNITED STATES OF AMERICA
v.
FESTUS ONYEMALIOSIA EBONKA

JUDGMENT IN A CRIMINAL CASE

Case Number: 2:22-cr-00156-CDS-NJK-1

USM Number: 12204-510

Crane Pomerantz and Liborius Agwara
Defendant's Attorney

THE DEFENDANT:

☑ pleaded guilty to count(s) 1 of the Information ECF No. 106

☐ pleaded nolo contendere to count(s) which was accepted by the court.

☐ was found guilty on count(s) after a plea of not guilty.

The defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
18 U.S.C. § 641	Conversion of Government Property	9/1/2018	1

The defendant is sentenced as provided in pages 2 through 6 of this judgment. The sentence is imposed pursuant to the Sentencing Reform Act of 1984.

☐ The defendant has been found not guilty on count(s)

☑ Count(s) all remaining ☐ is ☑ are dismissed on the motion of the United States.

It is ordered that the defendant must notify the United States attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant must notify the court and United States attorney of material changes in economic circumstances.

5/5/2025
Date of Imposition of Judgment

Signature of Judge

Cristina D. Silva, United States District Judge
Name and Title of Judge

5/5/2025
Date

DEFENDANT: FESTUS ONYEMALIOSIA EBONKA
CASE NUMBER: 2:22-cr-00156-CDS-NJK-1

PROBATION

You are hereby sentenced to probation for a term of:

3 Years.

MANDATORY CONDITIONS

1. You must not commit another federal, state or local crime.
2. You must not unlawfully possess a controlled substance.
3. You must refrain from any unlawful use of a controlled substance. You must submit to one drug test within 15 days of placement on probation and at least two periodic drug tests thereafter, as determined by the court.
   - ☑ The above drug testing condition is suspended, based on the court's determination that you pose a low risk of future substance abuse. *(check if applicable)*
4. ☐ You must cooperate in the collection of DNA as directed by the probation officer. *(check if applicable)*
5. ☐ You must comply with the requirements of the Sex Offender Registration and Notification Act (34 U.S.C. § 20901, *et seq*.) as directed by the probation officer, the Bureau of Prisons, or any state sex offender registration agency in the location where you reside, work, are a student, or were convicted of a qualifying offense. *(check if applicable)*
6. ☐ You must participate in an approved program for domestic violence. *(check if applicable)*
7. ☑ You must make restitution in accordance with 18 U.S.C. §§ 2248, 2259, 2264, 2327, 3663, 3663A, and 3664. *(check if applicable)*
8. You must pay the assessment imposed in accordance with 18 U.S.C. § 3013.
9. If this judgment imposes a fine, you must pay in accordance with the Schedule of Payments sheet of this judgment.
10. You must notify the court of any material change in your economic circumstances that might affect your ability to pay restitution, fines, or special assessments.

You must comply with the standard conditions that have been adopted by this court as well as with any other conditions on the attached page.

DEFENDANT: FESTUS ONYEMALIOSIA EBONKA
CASE NUMBER: 2:22-cr-00156-CDS-NJK-1

STANDARD CONDITIONS OF SUPERVISION

As part of your probation, you must comply with the following standard conditions of supervision. These conditions are imposed because they establish the basic expectations for your behavior while on supervision and identify the minimum tools needed by probation officers to keep informed, report to the court about, and bring about improvements in your conduct and condition.

1. You must report to the probation office in the federal judicial district where you are authorized to reside within 72 hours of the time you were sentenced, unless the probation officer instructs you to report to a different probation office or within a different time frame.
2. After initially reporting to the probation office, you will receive instructions from the court or the probation officer about how and when you must report to the probation officer, and you must report to the probation officer as instructed.
3. You must not knowingly leave the federal judicial district where you are authorized to reside without first getting permission from the court or the probation officer.
4. You must answer truthfully the questions asked by your probation officer.
5. You must live at a place approved by the probation officer. If you plan to change where you live or anything about your living arrangements (such as the people you live with), you must notify the probation officer at least 10 days before the change. If notifying the probation officer in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.
6. You must allow the probation officer to visit you at any time at your home or elsewhere, and you must permit the probation officer to take any items prohibited by the conditions of your supervision that he or she observes in plain view.
7. You must work full time (at least 30 hours per week) at a lawful type of employment, unless the probation officer excuses you from doing so. If you do not have full-time employment you must try to find full-time employment, unless the probation officer excuses you from doing so. If you plan to change where you work or anything about your work (such as your position or your job responsibilities), you must notify the probation officer at least 10 days before the change. If notifying the probation officer at least 10 days in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.
8. You must not communicate or interact with someone you know is engaged in criminal activity. If you know someone has been convicted of a felony, you must not knowingly communicate or interact with that person without first getting the permission of the probation officer.
9. If you are arrested or questioned by a law enforcement officer, you must notify the probation officer within 72 hours.
10. You must not own, possess, or have access to a firearm, ammunition, destructive device, or dangerous weapon (i.e., anything that was designed, or was modified for, the specific purpose of causing bodily injury or death to another person such as nunchakus or tasers).
11. You must not act or make any agreement with a law enforcement agency to act as a confidential human source or informant without first getting the permission of the court.
12. If the probation officer determines that you pose a risk to another person (including an organization), the probation officer may require you to notify the person about the risk and you must comply with that instruction. The probation officer may contact the person and confirm that you have notified the person about the risk.
13. You must follow the instructions of the probation officer related to the conditions of supervision.

U.S. Probation Office Use Only

A U.S. probation officer has instructed me on the conditions specified by the court and has provided me with a written copy of this judgment containing these conditions. For further information regarding these conditions, see *Overview of Probation and Supervised Release Conditions*, available at: www.uscourts.gov.

Defendant's Signature _____ Date _____

DEFENDANT: FESTUS ONYEMALIOSIA EBONKA
CASE NUMBER: 2:22-cr-00156-CDS-NJK-1

SPECIAL CONDITIONS OF SUPERVISION

1. Access to Financial Information – You must provide the probation officer access to any requested financial information and authorize the release of any financial information. The probation office will share financial information with the U.S. Attorney's Office.

2. Financial Penalty – If the judgment imposes a financial penalty, you must pay the financial penalty in accordance with the Schedule of Payments sheet of this judgment. You must also notify the court of any changes in economic circumstances that might affect the ability to pay this financial penalty.

DEFENDANT: FESTUS ONYEMALIOSIA EBONKA
CASE NUMBER: 2:22-cr-00156-CDS-NJK-1

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments on Sheet 6.

	Assessment	Restitution	Fine	AVAA Assessment*	JVTA Assessment**
TOTALS	$ 25.00	$ 6,519.69	$ WAIVED	$	$

☐ The determination of restitution is deferred until _____. An *Amended Judgment in a Criminal Case (AO 245C)* will be entered after such determination.

☐ The defendant must make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss***	Restitution Ordered	Priority or Percentage
See attached Restitution List.		$6,519.69	

TOTALS	$ 0.00	$ 6,519.69

☐ Restitution amount ordered pursuant to plea agreement $ _____

☑ The defendant must pay interest on restitution and a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 6 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

☐ The court determined that the defendant does not have the ability to pay interest and it is ordered that:

☐ the interest requirement is waived for the ☐ fine ☐ restitution.

☐ the interest requirement for the ☐ fine ☐ restitution is modified as follows:

* Amy, Vicky, and Andy Child Pornography Victim Assistance Act of 2018, Pub. L. No. 115-299.
** Justice for Victims of Trafficking Act of 2015, Pub. L. No. 114-22.
*** Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

DEFENDANT: FESTUS ONYEMALIOSIA EBONKA
CASE NUMBER: 2:22-cr-00156-CDS-NJK-1

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties is due as follows:

A ☑ Lump sum payment of $ 25.00 due immediately, balance due

☐ not later than _____, or
☑ in accordance with ☐ C, ☐ D, ☐ E, or ☑ F below; or

B ☐ Payment to begin immediately (may be combined with ☐ C, ☐ D, or ☐ F below); or

C ☐ Payment in equal _____ *(e.g., weekly, monthly, quarterly)* installments of $ _____ over a period of _____ *(e.g., months or years)*, to commence _____ *(e.g., 30 or 60 days)* after the date of this judgment; or

D ☐ Payment in equal _____ *(e.g., weekly, monthly, quarterly)* installments of $ _____ over a period of _____ *(e.g., months or years)*, to commence _____ *(e.g., 30 or 60 days)* after release from imprisonment to a term of supervision; or

E ☐ Payment during the term of supervised release will commence within _____ *(e.g., 30 or 60 days)* after release from imprisonment. The court will set the payment plan based on an assessment of the defendant's ability to pay at that time; or

F ☑ Special instructions regarding the payment of criminal monetary penalties:
Any unpaid balance shall be paid at a monthly rate of not less than 10% of any income earned and/or gross income while on probation, subject to adjustment by the Court based upon ability to pay.

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during the period of imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to the clerk of the court.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☐ Joint and Several

Case Number Defendant and Co-Defendant Names *(including defendant number)*	Total Amount	Joint and Several Amount	Corresponding Payee, if appropriate

☐ The defendant shall pay the cost of prosecution.

☐ The defendant shall pay the following court cost(s):

☐ The defendant shall forfeit the defendant's interest in the following property to the United States:

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) AVAA assessment, (5) fine principal, (6) fine interest, (7) community restitution, (8) JVTA assessment, (9) penalties, and (10) costs, including cost of prosecution and court costs.

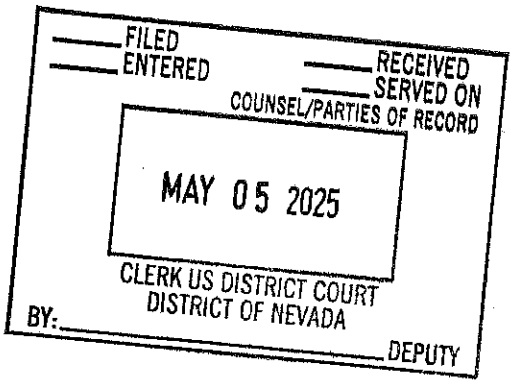
United States v. Festus Onyemaliosia Ebonka
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Restitution List

Victim:

U.S. Dept of Health & Human Services
Centers of Medicare and Medicaid Services
7500 Security Boulevard
Mailstop C3-11-03
Baltimore MD 21244

Amount:

$6,519.69



FILED
SEP 0 4 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**Case No. 19-012-CS-S** **FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER**

This matter came before the Nevada State Board of Pharmacy (Board) at its regularly scheduled meeting on Wednesday, September 4, 2024. Brett Kandt, Esq., prosecuted the case before the Board. Respondent Festus Ebonka, APRN, Certificate of Registration No. CS23430, was represented by counsel, Libo Agwara, Esq. The Board heard the case and, based on the evidence presented, the Board makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

The Board finds that probative evidence exists in the record to establish each of the following facts by a preponderance of the evidence:

1. The Board has jurisdiction over this matter and this Respondent because, at the time of the events herein, Respondent Festus Ebonka, APRN, held a controlled substance registration, Certificate of Registration No. CS23430, issued by the Board.

2. Respondent pre-signed two (2) controlled substance prescriptions that were issued to patients by his staff - on February 28, 2017, for patient J.J., and on March 2, 2017, for patient D.R. - while he was engaged in overseas travel outside of the United States from February 25 to March 11, 2017.

3. Board staff incurred at least $4,268.097 in attorney's fees and recoverable costs investigating and prosecuting this administrative action. The attorney's fees are reasonable based upon legal counsel's professional qualities, the nature of this administrative enforcement action, the work performed, and the result as evidenced by this Order.

CONCLUSIONS OF LAW

Based on the forgoing findings of fact, the Board concludes as a matter of law:

1. The Board has jurisdiction over this matter and Respondent because, at the time of the events herein, Respondent held a controlled substance registration issued by the Board.

2. The applicable law in this matter is as follows:

A. It is unlawful for a practitioner to prescribe a controlled substance except as authorized by law. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR §§ 1306.03-1306.05; NRS 453.226(1); NRS 453.321(1)(a); NRS 453.381(1); NRS 639.100(1); NRS 639.235(1); NRS 639.2353.

B. Falsifying a prescription for a controlled substance and the possession of signed prescription blanks are felony offenses. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1)(f), (h) and (i).

C. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

D. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

E. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or

revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

F. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(11).

G. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(12).

H. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

3. Respondent is GUILTY on Count One of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1), 21 CFR § 1306.04(a) and/or 21 CFR § 1306.05(a), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

4. Respondent is GUILTY on Count Two of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1) (f), (h) and (i), NRS 453.381(1), NRS 453.401(l)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2353, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

5. Respondent is NOT GUILTY on Count Three of the Accusation.

6. Respondent is GUILTY on Count Four of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

7. Respondent is GUILTY on Count Five of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(4).

8. Respondent is GUILTY on Count Six of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

ORDER

THEREFORE, THE BOARD HEREBY ORDERS AS FOLLOWS:

1. The certificate of registration of Respondent Festus Ebonka, APRN, Certificate of Registration No. CS23430, is revoked pursuant to NRS 453.241(1)(b). The revocation is stayed, and Respondent is placed on probation for a period of three (3) years pursuant to NRS 639.255(1)(b) subject to the following conditions:

A. Pursuant to NRS 622.400, Respondent shall pay Four Thousand Two Hundred Sixty-Eight Dollars and Ninety-Seven Cents ($4,268.97) to partially reimburse the Board

for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by due and payable by September 4, 2025;

B. Respondent shall complete two (2) hours of training from Board staff on Nevada Prescription Monitoring Program (PMP) compliance by September 4, 2025;

C. Respondent shall complete two (2) hours of continuing education (CE) on ethics by September 4, 2025; and

D. Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. CS23430 will be fully restored.

2. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay and immediately revoke Respondent's Certificate of Registration No. CS23430, and impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

3. This Order constitutes a final decision in a contested case and a public record pursuant to NRS 639.255(5), and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

4. This Order is effective immediately.

IT IS SO ORDERED.

Entered this 4th day of September, 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

FILED
JAN 2 5 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**Case No. 19-012-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Festus Ebonka, APRN, held a controlled substance registration, Certificate of Registration No. CS23430, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent pre-signed controlled substance prescriptions that were issued to patients by his staff while he was engaged in overseas travel. Respondent traveled outside of the United States on the following dates: July 14, 2016 – July 25, 2016; February 25, 2017 – March 11, 2017; September 27, 2017 – October 2, 2017; December 22, 2017 – December 28, 2017; and November 9, 2018 – November 30, 2018. Prescriber records and prescriptions document one-hundred and twenty-six (126) controlled substance prescriptions authorized by Respondent during these periods.

3. Respondent caused other practitioners who treated his patients to use his National Provider Identifier (NPI) while he was outside of the country to falsely bill Medicaid and other

commercial health insurance plans for services that Respondent did not personally provide, and received reimbursement for those services.

APPLICABLE LAW

4. It is unlawful for a practitioner to prescribe a controlled substance except as authorized by law. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR §§ 1306.03-1306.05; NRS 453.226(1); NRS 453.321(1)(a); NRS 453.381(1); NRS 639.100(1); NRS 639.235(1); NRS 639.2355.

5. Falsifying a prescription for a controlled substance and the possession of signed prescription blanks are felony offenses. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1)(f), (h) and (i).

6. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

7. Medicaid fraud is a felony offense. 18 U.S.C. § 1347; 42 U.S.C.A. § 1320a-7b; NRS 422.540(1).

8. Insurance fraud is a felony offense. NRS 686A.2815; NRS 686A.291.

9. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

10. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

11. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(11).

12. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(12).

13. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violation of Federal Controlled Substances Act – Issuing Fraudulent Controlled Substance Prescriptions

14. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in Paragraph 2 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1), 21 CFR § 1306.04(a) and/or 21 CFR § 1306.05(a), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

COUNT TWO

Violations of State Law – Issuing Fraudulent Controlled Substance Prescriptions

15. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in Paragraph 2 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1) (f), (h) and (i), NRS 453.381(1), NRS

453.401(l)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2355, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

COUNT THREE

Violations of Federal and State Law – Medicaid Fraud/Insurance Fraud

16. By falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 18 U.S.C. § 1347, 42 U.S.C.A. § 1320a-7b, NRS 422.540(1), NRS 686A.2815 and/or NRS 686A.291, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11) and/or (12).

COUNT FOUR

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

17. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in paragraph 2 herein, and by falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3 herein, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT FIVE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

18. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in paragraph 2 herein, and by falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3

herein, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(4).

COUNT SIX

Commission of Acts that Render Registration Inconsistent with the Public Interest

19. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in paragraph 2 herein, and by falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3 herein, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 25th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

ELECTRONICALLY SERVED
9/19/2025 2:06 PM

Electronically Filed
09/19/2025 2:05 PM
CLERK OF THE COURT

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DISTRICT COURT OF

CLARK COUNTY, NEVADA

FESTUS EBONKA, APRN, Petitioner, vs. NEVADA STATE BOARD OF PHARMACY, Respondent.	Case No. A-24-902608-J Dept. No. 29

ORDER DENYING PETITION FOR JUDICIAL REVIEW

This matter having come before this court on September 11, 2025, on Petitioner's Petition for Judicial Review; Liborius Agwara, Esq., appearing on behalf of Petitioner Festus Ebonka, APRN ("Ebonka") and Brett Kandt, Esq. appearing on behalf of the Respondent Nevada State Board of Pharmacy ("Board"); the Court having reviewed the papers and pleadings on file herein, having heard the arguments of counsel, and with good cause appearing, the Court hereby finds, concludes, and orders as follows:

Case Number: A-24-902608-J

FINDINGS OF FACT

The Notice of Intended Action and Accusation together with the Statement to Respondent and Notice of Hearing was filed and served on Ebonka on or about January 25, 2024, and originally noticed for a hearing on March 6, 2024. AR[1] 0001-0009. Ebonka filed an Answer and Notice of Defense on or about February 21, 2024. AR 0010-0011.

The Board held an evidentiary hearing on September 4, 2024. *See* Reporter's Transcript on file herein, AR 0377-0518. As stipulated by the parties, the entire case file was admitted into evidence. AR 0012-0369; AR 0381:20-0383:5. Based on the evidence presented, the Board after extensive deliberation made findings of fact, conclusions of law, and entered an order on September 4, 2024, imposing discipline on Ebonka, including a stayed revocation of his controlled substance registration, Certificate of Registration No. CS23430 (Order). AR 0370-0376; AR 0483:18-0517:14.

CONCLUSIONS OF LAW

The standard for judicial review is set forth in NRS 223B.135(3):

> The court shall not substitute its judgment for that of the agency as to the weight of evidence on a question of fact. The court may remand or affirm the final decision or set it aside in whole or in part if substantial rights of the petitioner have been prejudiced because the final decision of the agency is:
>
> (a) In violation of constitutional or statutory provisions;
> (b) In excess of the statutory authority of the agency;
> (c) Made upon unlawful procedure;
> (d) Affected by other error of law;
> (e) Clearly erroneous in view of the reliable, probative and substantial evidence on the whole record; or
> (f) Arbitrary or capricious or characterized by abuse of discretion.

See Nassiri v. Chiropractic Physicians' Bd., 130 Nev. 245, 249, 327 P.3d 487, 490 (2014).

---

[1] "AR" refers to the Administrative Record on file herein.

Ebonka only addresses questions of fact in the Memorandum of Points and Authorities in Support of Petition for Judicial Review. Specifically, Ebonka only focused on one issue for the Petition:

> 1. The Board's finding that Petitioner pre-signed two prescription scripts prior to his overseas trips was clearly erroneous in light of the reliable, probative and substantial evidence on the whole record, and therefore, was arbitrary, capricious and constitute[s] an abuse of discretion.

(Pet. at 5:15-20.)

This is fact specific. And as stated above, the Nevada Supreme Court, and the relevant statute are clear:

> The court shall not substitute its judgment for that of the agency as to the weight of evidence on a question of fact.

See Nassiri, 130 Nev. at 249, 327 P.3d at 490 (quoting 223B.135).

The Controlled Substances Act imposes strict liability on registrants to provide effective controls and procedures to guard against theft and diversion, which includes the duty to safeguard prescribing credentials from unauthorized use. *See* 21 CFR 1301.71(a).

There was substantial evidence elicited which supports the Board's finding that Ebonka pre-signed controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, in violation of 21 CFR § 1306.05(a).

The Board's determination was based on uncontroverted direct evidence in the form of the two written prescriptions together with Ebonka's own admissions, which conclusively established that the prescriptions were issued under his name and DEA registration number, on prescriptions pads from his office, while he was out of the country, to patients for whom he had previously prescribed the same schedule II controlled substances.

The only claims Ebonka made in his defense were that he did not sign the prescriptions, would never pre-sign a controlled substance prescription, and that they must be forgeries. The Board did not find Ebonka's alibi credible, and upon comparing the four samples of his signature on his written responses to the Board investigation with the signatures on the prescriptions, reasonably concluded that the signatures were in fact his.

This Court cannot overturn the Board's decision solely based upon Ebonka's dispute of the Board's findings. The Board had two versions of a story before it and did not believe Ebonka's version. This Court cannot overturn the Board's decision on this basis.

Ebonka raises several arguments for the first time in reply. This is inappropriate. Arguments may not be raised for the first time in a reply brief. *See Weaver v. State, Dep't of Motor Vehicles*, 121 Nev. 494, 502, 117 P.3d 193, 198-99 (2005) (arguments raised for the first time in an appellant's reply brief need not be considered); *see also Francis v. Wynn Las Vegas, LLC*, 127 Nev. 657, 671 n.7, 262 P.3d 705, 715 n.7 (2011) (same); *see also Khoury v. Seastrand*, 132 Nev. 520, 530 n.2, 377 P.3d 81, 88 n.2 (2016) (citing NRAP 28(c) and concluding that an issue raised for the first time in a reply brief was waived); *Hung v. Berhad*, 138 Nev. 547, 550 n.2, 513 P.3d 1285, 1288 n.2 (Nev. App. 2022) (the general rule [is] that arguments raised for the first time in [a] reply brief are deemed waived). As the factual arguments were the only focus of the opening brief that is all that is considered by the Court. The remaining arguments on other issues are waived.

ORDER

The Petition for Judicial Review is DENIED.

The Judgment of the Board is AFFIRMED.

IT IS SO ORDERED ~~this ___ day of _____, 2025.~~

Dated this 19th day of September, 2025

Jacob A. Reynolds

HONORABLE JACOB A. REYNOLDS

19F 9E6 BA98 0C4B
Jacob A. Reynolds
District Court Judge

Respectfully submitted by:

/s/ Brett Kandt

Brett Kandt, Esq. (Bar No. 5384)
General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy – Ste. 206
Reno NV 89521
Attorney for Respondent

Approved as to form and content by:

Liborius Agwara, Esq. (Bar No. 7576)
Law Office of Libo Agwara, Ltd.
2785 E. Desert Inn Road - Ste. 270
Las Vegas, NV 89121
Attorney for Petitioner

CSERV

DISTRICT COURT
CLARK COUNTY, NEVADA

Festus Ebonka, APRN, Petitioner(s) vs. Nevada State Board of Pharmacy, Respondent(s)	CASE NO: A-24-902608-J DEPT. NO. Department 29

AUTOMATED CERTIFICATE OF SERVICE

This automated certificate of service was generated by the Eighth Judicial District Court. The foregoing Order was served via the court's electronic eFile system to all recipients registered for e-Service on the above entitled case as listed below:

Service Date: 9/19/2025

Law Office	agwaralaw@yahoo.com
Liborius Agwara	libolaw@yahoo.com
Liborius Agwara	libolaw@yahoo.com
WM Kandt	bkandt@pharmacy.nv.gov

STATE OF NEVADA

JOE LOMBARDO
Governor

DR. KRISTOPHER SANCHEZ
Director

PERRY FAIGIN
NIKKI HAAG
MARCEL F. SCHAERER
Deputy Directors

CATHY DINAUER
Executive Director

DEPARTMENT OF BUSINESS AND INDUSTRY
OFFICE OF NEVADA BOARDS, COMMISSIONS AND COUNCILS STANDARDS

NEVADA STATE BOARD OF NURSING

October 8, 2025

Nevada State Board of Pharmacy
Attn: Brett Kandt
bkandt@pharmacy.nv.gov

Re: Public record request, Festus Ebonka

To whom it may concern:

Please be advised that we have received your public records request. We have reviewed our records. We have attached the documents responsive to your public record request.

If you have any questions, please do not hesitate to contact my office.

Sincerely,

Kimberly Arguello
General Counsel
702-668-4534
karguello@nsbn.state.nv.us
Enclosures

ORIGINAL

BEFORE THE NEVADA STATE BOARD OF NURSING

IN THE MATTER OF FESTUS EBONKA ADVANCED PRACTICE REGISTERED NURSE NEVADA LICENSE NO. APRN000902 RESPONDENT	COMPLAINT AND NOTICE OF HEARING CASE NO. 2024100049

The Nevada State Board of Nursing (Board), by and through counsel, Kimberly A. Arguello, hereby notifies Respondent FESTUS EBONKA (Respondent) of an administrative hearing, which is to be held pursuant to Chapters 233B and 632 of the Nevada Revised Statutes and Chapter 632 of the Nevada Administrative Code. The purpose of the hearing is to consider the allegations stated below and to determine if the Respondent should be subject to an administrative penalty as set forth in NRS 632.347 and/or NRS 632.325 and/or NAC 632.926-.927, if the stated allegations are proven at the hearing by the evidence presented.

Respondent was at the time of the allegations stated below, licensed as an Advanced Practice Registered Nurse in the State of Nevada, and is, therefore, subject to the jurisdiction of the Board and the provisions of NRS Chapter 632 and NAC Chapter 632.

IT IS HEREBY ALLEGED AND CHARGED AS FOLLOWS:

I.

On or about June 15, 2006, Respondent was granted a permanent Advanced Practice Registered Nurse's license (APRN) in the State of Nevada.

On or about May 5, 2025, before the United States District Court, District of Nevada, Respondent, after a plea of guilty, was adjudicated guilty of one count of Conversion of Government Property, a violation of 18 U.S.C. Section 641.

II.

The foregoing conduct constitutes grounds for disciplinary action pursuant to NRS 632.347(1)(b) unprofessional conduct, because Respondent is guilty of any offense (2) related to the qualifications, functions or duties of a licensee or holder of a certificate, in which case the record of conviction is conclusive evidence thereof.

Based on the foregoing:

PLEASE TAKE NOTICE, that a disciplinary hearing has been set to consider this Administrative Complaint against the above-named Respondent in accordance with Chapters 233B and 632 of the Nevada Revised Statutes and Chapter 632 of the Nevada Administrative Code.

THE HEARING WILL TAKE PLACE on **Thursday, September 18, 2025, commencing at 09:00 a.m.,** or as soon thereafter as the Board is able to hear the matter, at the **Office of the Nevada State Board of Nursing, 6005 Plumas Street, Room 101, Reno, NV 89519.** This case and other matters are scheduled to be heard by the Board.

This Nevada State Board of Nursing meeting will also be held virtually via Microsoft Teams. The link to the Teams meeting is:

To join by VIDEO/TELECONFERENCE

https://teams.microsoft.com/l/meetup-join/19%3ameeting_ZjY3MDc5MTUtODRmNi00NWI2LWJlNjMtN2YwMTBhZTZhMDU5%40thread.v2/0?context=%7b%22Tid%22%3a%22e4a340e6-b89e-4e68-8eaa-1544d2703980%22%2c%22Oid%22%3a%2243df6cf6-38b0-4aad-b524-d5e9ab50ece4%22%7d

To join by meeting ID through Microsoft Teams:

Meeting ID: 283 625 547 899 7

Passcode: Tj6Dj9Tf

To join by telephone:

Audio Conference Number: +1 775-321-6111

Phone Conference ID: 704 745 453#

This case and other matters are scheduled to be heard by the Board.

PURSUANT TO NRS 632.350, Respondent may request, in writing, that the Board furnish copies of communications, reports, and affidavits in its possession, regarding the above-referenced matter.

As the Respondent, you are specifically informed that you have the right to appear, either in person at the physical address listed above, or virtually, at the log-in address listed above, and be heard in your defense, either personally or through counsel of your choice. You have the right to respond and to present relevant evidence and argument on all issues involved. You have the right to call and examine witnesses, introduce exhibits, and cross-examine opposing witnesses on any matter relevant to the issues involved.

You have the right to request that the Board issue subpoenas to compel witnesses to testify and/or evidence to be offered on your behalf. In making this request, you may be required to demonstrate the relevancy of the witness' testimony and/or evidence.

The purpose of the hearing is to determine if the Respondent has violated NRS 632.347(1)(b), and if the allegations contained herein are substantially proven by the evidence presented to further determine what administrative penalty is to be assessed against the Respondent, if any, pursuant to NRS 632.347 and/or NRS 632.325 and/or NAC 632.926-.927.

Should the Respondent fail to appear at the hearing, a decision may still be reached by the Board. As the Respondent, you are further advised that you may be charged with cost associated with the hearing pursuant to NRS 622.400.

Pursuant to NRS 233B.121(5), informal disposition of this case may be made by stipulation, agreed settlement, consent order, or default. Any attempt to negotiate this case

should be made through Kimberly A. Arguello, General Counsel, Nevada State Board of Nursing.

Pursuant to NRS 241.033(2)(b), the Nevada State Board of Nursing may, without further notice, take administrative action against your license and/or certificate to practice within the State of Nevada if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health.

DATED this 7th day of August 2025.

By: _____

KIMBERLY A. ARGUELLO, ESQ.
General Counsel
Nevada State Board of Nursing
4220 S. Maryland Parkway, Suite B300
Las Vegas, Nevada 89119
(702) 668-4534

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Nursing, and that on this 22nd day of August 2025, I served a copy of the foregoing COMPLAINT AND NOTICE OF HEARING, by placing said document in the U.S. Mail by first class mail and by the U.S. Mail, certified, return receipt requested and postage prepaid, addressed to:

Festus Ebonka
[redacted]

By Email to: [redacted]

Corina Jimenez
Executive Assistant
Nevada State Board of Nursing

ORIGINAL

BEFORE THE NEVADA STATE BOARD OF NURSING

IN THE MATTER OF FESTUS EBONKA ADVANCED PRACTICE REGISTERED NURSE NEVADA LICENSE NO. APRN000902 RESPONDENT	FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER. CASE NO. 2024100049

On Thursday, September 18, 2025, a hearing was held in the above matter before the Nevada State Board of Nursing ("Board") in compliance with the provisions of Chapters 233B and 632 of the Nevada Revised Statutes (NRS) and Chapter 632 of the Nevada Administrative Code (NAC).

Respondent FE TUS EBONKA appeared at the hearing in proper person. The Nevada State Board of Nursing appeared through counsel, Kimberly A. Arguello, Esq.

At the hearing, documents were admitted into evidence and sworn testimony was provided. The Board made the following Findings of Fact, Conclusions of Law, and Order:

FINDINGS OF FACT

The Board, based upon evidence presented during the Hearing, finds that there is a preponderance of evidence in the record to establish each of the following findings of fact:

1. At least twenty-one (21) working days prior to the date of the hearing, Respondent had been noticed of the hearing by certified mail and by first class mail, which notice was mailed to Respondent's last known residential address.

2. The Board had jurisdiction over the matter, and the Board could proceed to make a determination in the matter.

3. On June 15, 2006, Respondent was granted a permanent Advanced Practice Registered Nurse's license (APRN) in the State of Nevada.

4. On May 5, 2025, before the United States District Court, District of Nevada, Respondent, after a plea of guilty, was adjudicated guilty of one count of Conversion of Government Property, a violation of 18 U.S.C. Section 641.

CONCLUSIONS OF LAW

Based upon the above Findings of Fact, the Board hereby finds by a preponderance of the evidence the following violation of law:

Respondent is in violation of NRS 632.347(1)(b) unprofessional conduct, because Respondent is guilty of any offense (2) related to the qualifications, functions or duties of a licensee or holder of a certificate, in which case the record of conviction is conclusive evidence thereof.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law and good cause appearing, therefore,

IT IS ORDERED that Respondent EBONKA's Nevada APRN license No. APRN000902 is Suspended. The suspension of Respondent's Nevada APRN license No. APRN000902 shall be for a term of 6 months. Additionally, Respondent shall provide proof to Board staff of the completion of a 30 hour Continuing Education course on Ethics within 6 months.

This Order shall become part of Respondent's permanent record, be published on the Board's list of disciplinary actions, and be reported to the appropriate data banks.

This Order shall become effective on 9th of November 2025.

DATED this 6th day of October 2025.

NEVADA STATE BOARD OF NURSING

By: _____

CHERYL A. MAES, Ph.D., APRN, FNP-BC
Board President

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Nursing, and that on this 6th day of October 2025, I served a copy of the foregoing FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER, by placing said document in the U.S. Mail by first class mail and by the U.S. Mail, certified, return receipt requested and postage prepaid, addressed to:

Festus Ebonka
[redacted]

By Email to: [redacted]

Corina Jimenez
Executive Assistant
Nevada State Board of Nursing

JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

October 9, 2025

VIA U.S. CERTIFIED MAIL AND ELECTRONIC MAIL TO: libolaw@yahoo.com & agwa-ralaw@yahoo.com

Festus Ebonka, APRN
c/o Liborius Agwara, Esq.
2785 E. Desert Inn Road, Ste. 270
Las Vegas, NV 89121

Re: Notice of Suspension of Registration No. CS23430 (Case Nos. 19-012-CS-S/25-215-CS-S)

Dear Mr. Ebonka:

The Nevada State Board of Pharmacy (Board) has been notified that the Nevada State Board of Nursing (NSBN) entered an order on October 6, 2025, suspending your License No. APRN000902 for 6 months effective November 9, 2025. Pursuant to NRS 639.2107, when the suspension of your License No. APRN000902 takes effect on November 9, 2025, this will operate as an immediate suspension of your Certificate of Registration No. CS23430 with the Board.

Once the suspension of your Certificate of Registration No. CS23430 takes effect you may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense any controlled substance or dangerous drug until you petition the Board for reinstatement pursuant to NRS 639.2565 and the Board reinstates your registration. Your PMP account will also suspended pursuant to NAC 453.078. You may request a hearing before the Board to contest the suspension of your registration by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

This will also confirm that through your counsel you are stipulating to a continuance of the hearing noticed for October 15, 2025, in Case No. 25-215-CS-S, during your suspension period; the hearing will be re-noticed for March 4, 2026. Please be advised that the district court entered an order in Case No. A-24-902608-J denying your petition for judicial review and affirming the Board's order entered September 4, 2024, in Case No. 19-012-CS-S; any failure to comply with that order will result in the issuance of an order to show cause pursuant to NAC 639.965.

Regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

5C

FILED
JAN 9 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RENOWN PHARMACY,** **Pharmacy License No. PH04283, and** **OLIVER SWAFFORD, RPH,** **Certificate of Registration No. 17452,** **Respondents.**	**CASE NOS. 25-139-PH-N** **25-139-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Oliver Swafford, RPh (Swafford), Certificate of Registration No. 17452, was a pharmacist registered with the Board, and Respondent Renown Pharmacy, Pharmacy License No. PH04283, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Swafford was employed as managing pharmacist of Renown Pharmacy at the time of the events alleged herein.

3. On or about January 14, 2025, in the course of attempting to dispense both prescription no. 2-490336 for prednisone 5mg tablets and prescription no. 2-490896 famotidine 40mg/5ml suspension to the father of patient S.J., a minor, at Renown Pharmacy, Swafford erroneously dispensed prescription no. 2-C484783 for buprenorphine and naloxone 12mg film

intended for patient D.J. instead of prescription no. 2-490336 for prednisone 5mg tablets. Swafford did not conduct a barcode scan of either prescription before dispensing, and no counseling was performed for either prescription although requested by the father of the five-year-old patient.

4. The father of patient S.J. administered the erroneously dispensed prescription no. 2-C484783 for buprenorphine and naloxone 12mg film to S.J.; the patient suffered a significant negative outcome and required intervention and treatment by a medical facility for an opioid overdose.

COUNT ONE

Unprofessional Conduct – Error in Dispensing Prescription

(Respondent Swafford)

5. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). Unprofessional conduct also includes a registrant performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

6. Swafford engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when he erroneously dispensed prescription no. 2-C484783 for buprenorphine and naloxone 12mg film intended for patient D.J. instead of prescription no. 2-490336 for prednisone 5mg tablets intended for patient S.J., resulting in patient harm, and failed to conduct a barcode scan of either prescription before dispensing, as alleged in paragraph 3 herein, and is therefore subject to discipline pursuant to NRS 639.210(4).

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COUNT TWO

Failure to Provide Medication Counseling to Patient/Unprofessional Conduct
(Respondent Swafford)

7. A pharmacist shall provide medication counseling to a patient when dispensing a prescription that has not been previously dispensed to the patient from that pharmacy and shall review a patient's record before dispensing a prescription to determine its therapeutic appropriateness. NRS 639.266; NAC 639.707(1) and (4). Unprofessional conduct includes a registrant performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

8. Respondent Swafford violated NRS 639.266 and/or NAC 639.707(1) and/or (4) and/or engaged in unprofessional conduct as defined in NAC 639.945(1)(i) when he failed to provide medication counseling to the father of patient S.J. for the prescriptions as requested, as alleged in paragraph 3 herein, and is therefore subject to discipline pursuant to NRS 639.210(4) and (12).

COUNT THREE

Pharmacy/Pharmacy Owner Responsibility
(Respondent Renown Pharmacy)

9. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

10. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Respondent Renown Pharmacy is responsible for those violations, including all errors and omissions of Respondent Swafford as alleged herein, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these Respondents.

Signed this 9th day of January 2026.

Yenh Long, Pharm.D.,
Deputy Executive Secretary of the Nevada State Board of Pharmacy, for and on behalf of J. David Wuest, R.Ph., Executive Secretary of the Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RENOWN PHARMACY,** **Pharmacy License No. PH04283,** **Respondent.**	**Case No. 25-139-PH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 15, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of January 2026.

Yenh Long, Pharm.D.,
Deputy Executive Secretary of the Nevada State Board of Pharmacy, for and on behalf of J. David Wuest, R.Ph., Executive Secretary of the Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RENOWN PHARMACY,** **Pharmacy License No. PH04283,** **Respondent.**	**Case No. 25-139-PH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR
Renown Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of January 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Renown Regional Medical Center
c/o Renown Pharmacy - Pringle
75 Pringle Way – 1st floor
Reno, NV 89502

Oliver Swafford, RPh
[redacted]
Reno, NV [redacted]

CVS Pharmacy #9840
c/o Oliver Swafford, RPh
8005 S Virginia St
Reno, NV 89511

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RENOWN PHARMACY,** **Pharmacy License No. PH04283, and** **OLIVER SWAFFORD, RPH,** **Certificate of Registration No. 17452,** **Respondents.**	**CASE NOS. 25-139-PH-N** **25-139-RPH-N** **STIPULATION AND ORDER** **[RENOWN PHARMACY ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Renown Pharmacy, Pharmacy License No. PH04283, by and through counsel, Marie Ellerton, Esq., **HEREBY STIPULATE AND AGREE THAT:**

1. On or about January 12, 2026, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing. Respondent is entering this Stipulation in lieu of filing an Answer and Notice of Defense to the Accusation.

2. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

3. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

4. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. As of the time of entering into this Stipulation and Order the allegations in the Accusation remain unproven. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. Respondent Oliver Swafford, RPh (Swafford), Certificate of Registration No. 17452 engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when he erroneously dispensed prescription no. 2-C484783 for buprenorphine and naloxone 12mg film intended for minor patient D.J. instead of prescription no. 2-490336 for prednisone 5mg tablets intended for patient S.J., resulting in patient harm, and failed to conduct a barcode scan of either prescription before dispensing;

B. Swafford violated NRS 639.266 and/or NAC 639.707(1) and/or (4) and/or engaged in unprofessional conduct as defined in NAC 639.945(1)(i) when he failed to provide medication counseling to the father of minor patient S.J. for the prescriptions as requested; and

C. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Renown Pharmacy is responsible for those violations, including all errors and omissions of Swafford, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

Board staff acknowledges that Respondent is not admitting that the charges as alleged in the Accusation have merit and Respondent is agreeing to resolve the matter to avoid the costs of

hearing and any potential litigation. Respondent asserts that they have evidence, witnesses, experts and defenses to the allegations in the Accusation , but for the purpose of resolving the matter and for no other purpose, Respondent waives the presentation of evidence, witnesses, experts, and defenses in order to effectuate this Stipulation and Order.

6. Those violations are plead with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

7. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Renown Pharmacy, Pharmacy License No. PH04283, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Renown Pharmacy shall pay a fine of Ten Thousand Dollars ($10,000.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by June 1, 2026; and

B. Pursuant to NRS 622.400, Renown Pharmacy shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by June 1, 2026.

8. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.

9. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on April 15, 2026. Respondent will appear in person or through counsel at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

10. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

11. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 13th day of February 2026

RENOWN PHARMACY
Pharmacy License No. PH04283

Signed this ___ day of _____ 2026

BRETT KANDT
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 13th day of February 2026

MARIE ELLERTON, ESQ.
Counsel for Respondent

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Renown Pharmacy, Pharmacy License No. PH04283, in Case No. 25-139-PH-N, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of April 2026.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RENOWN PHARMACY,** **Pharmacy License No. PH04283, and** **OLIVER SWAFFORD, RPH,** **Certificate of Registration No. 17452,** **Respondents.**	**CASE NOS. 25-139-PH-N** **25-139-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Oliver Swafford, RPh (Swafford), Certificate of Registration No. 17452, was a pharmacist registered with the Board, and Respondent Renown Pharmacy, Pharmacy License No. PH04283, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Swafford was employed as managing pharmacist of Renown Pharmacy at the time of the events alleged herein.

3. On or about January 14, 2025, in the course of attempting to dispense both prescription no. 2-490336 for prednisone 5mg tablets and prescription no. 2-490896 famotidine 40mg/5ml suspension to the father of patient S.J., a minor, at Renown Pharmacy, Swafford erroneously dispensed prescription no. 2-C484783 for buprenorphine and naloxone 12mg film

intended for patient D.J. instead of prescription no. 2-490336 for prednisone 5mg tablets. Swafford did not conduct a barcode scan of either prescription before dispensing, and no counseling was performed for either prescription although requested by the father of the five-year-old patient.

4. The father of patient S.J. administered the erroneously dispensed prescription no. 2-C484783 for buprenorphine and naloxone 12mg film to S.J.; the patient suffered a significant negative outcome and required intervention and treatment by a medical facility for an opioid overdose.

COUNT ONE

Unprofessional Conduct – Error in Dispensing Prescription

(Respondent Swafford)

5. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). Unprofessional conduct also includes a registrant performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

6. Swafford engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when he erroneously dispensed prescription no. 2-C484783 for buprenorphine and naloxone 12mg film intended for patient D.J. instead of prescription no. 2-490336 for prednisone 5mg tablets intended for patient S.J., resulting in patient harm, and failed to conduct a barcode scan of either prescription before dispensing, as alleged in paragraph 3 herein, and is therefore subject to discipline pursuant to NRS 639.210(4).

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COUNT TWO

Failure to Provide Medication Counseling to Patient/Unprofessional Conduct
(Respondent Swafford)

7. A pharmacist shall provide medication counseling to a patient when dispensing a prescription that has not been previously dispensed to the patient from that pharmacy and shall review a patient's record before dispensing a prescription to determine its therapeutic appropriateness. NRS 639.266; NAC 639.707(1) and (4). Unprofessional conduct includes a registrant performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

8. Respondent Swafford violated NRS 639.266 and/or NAC 639.707(1) and/or (4) and/or engaged in unprofessional conduct as defined in NAC 639.945(1)(i) when he failed to provide medication counseling to the father of patient S.J. for the prescriptions as requested, as alleged in paragraph 3 herein, and is therefore subject to discipline pursuant to NRS 639.210(4) and (12).

COUNT THREE

Pharmacy/Pharmacy Owner Responsibility
(Respondent Renown Pharmacy)

9. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

10. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Respondent Renown Pharmacy is responsible for those violations, including all errors and omissions of Respondent Swafford as alleged herein, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these Respondents.

Signed this 9th day of January 2026.

Yenh Long, Pharm.D.,
Deputy Executive Secretary of the Nevada State Board of Pharmacy, for and on behalf of J. David Wuest, R.Ph., Executive Secretary of the Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **OLIVER SWAFFORD, RPH,** **Certificate of Registration No. 17452,** **Respondent.**	**Case No. 25-139-RPH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 15, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of January 2026.

Yenh Long, Pharm.D.,
Deputy Executive Secretary of the Nevada State Board of Pharmacy, for and on behalf of J. David Wuest, R.Ph., Executive Secretary of the Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **OLIVER SWAFFORD, RPH,** **Certificate of Registration No. 17452,** **Respondent.**	**Case No. 25-139-RPH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

Oliver Swafford, RPh

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of January 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Renown Regional Medical Center
c/o Renown Pharmacy - Pringle
75 Pringle Way – 1st floor
Reno, NV 89502

Oliver Swafford, RPh
[redacted]
Reno, NV [redacted]

CVS Pharmacy #9840
c/o Oliver Swafford, RPh
8005 S Virginia St
Reno, NV 89511

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RENOWN PHARMACY,** **Pharmacy License No. PH04283, and** **OLIVER SWAFFORD, RPH,** **Certificate of Registration No. 17452,** **Respondents.**	**CASE NOS. 25-139-PH-N** **25-139-RPH-N** **STIPULATION AND ORDER** **[SWAFFORD ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Oliver Swafford, RPh (Swafford), Certificate of Registration No. 17452, by and through counsel, William J. Stilling, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. On or about January 12, 2026, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing. Respondent is entering this Stipulation in lieu of filing an Answer and Notice of Defense to the Accusation.

2. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

3. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

4. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. Respondent Oliver Swafford, RPh (Swafford), Certificate of Registration No. 17452 engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when he erroneously dispensed prescription no. 2-C484783 for buprenorphine and naloxone 12mg film intended for minor patient D.J. instead of prescription no. 2-490336 for prednisone 5mg tablets intended for patient S.J., resulting in patient harm;

B. Swafford violated NRS 639.266 and/or NAC 639.707(1) and/or (4) and/or engaged in unprofessional conduct as defined in NAC 639.945(1)(i) when he failed to provide medication counseling to the father of minor patient S.J. for the prescriptions as required; and

C. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Respondent Renown Pharmacy, Pharmacy License No. PH04283, is also responsible for those violations, including all errors and omissions of Swafford, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

6. Those violations are plead with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

7. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Swafford stipulate to the following

penalties. Respondent Oliver Swafford, RPh, Certificate of Registration No. 17452, is placed on probation for a period of one (1) year pursuant to NRS 639.255(1)(b) subject to the following conditions:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Swafford shall pay a fine of Two Thousand Dollars ($2,000.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by June 1, 2026;

B. Pursuant to NRS 622.400, Swafford shall pay Five Hundred Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by June 1, 2026; and

C. Respondent shall comply with all federal and state statutes and regulations regarding the practice of pharmacy, and have no additional charges filed against him while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. 17452 will be fully restored.

8. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.

9. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on April 15, 2026.

Respondent will appear in person or through counsel at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

10. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

11. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of _____ 2026

OLIVER SWAFFORD, RPH
Certificate of Registration No. 17452

Signed this ___ day of _____ 2026

BRETT KANDT
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this ___ day of _____ 2026

WILLIAM J. STILLING, ESQ.
Counsel for Respondent

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Oliver Swafford, RPh, Certificate of Registration No. 17452, in Case No. 25-139-RPH-N, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of April 2026.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARTIN JAMES FARRELL, RPH, Certificate of Registration No. 22316,** **Respondent.**	**Case No. 25-233-RPH-O** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this Respondent because, at the time of the events alleged herein, Respondent Martin James Farrell, RPh, Certificate of Registration No. 22316, was a pharmacist registered with the Board.

FACTUAL ALLEGATIONS

2. On or about April 29, 2025, the Pennsylvania State Board of Pharmacy (PABOP) and Respondent entered a consent agreement and order in Case No. 24-54-017144, imposing discipline on Respondent's PABOP License No. RP447897 to practice pharmacy for cause.

3. In PABOP Case No. 24-54-017144, Respondent admitted to altering certificates of analysis for endotoxin level and sterility tests for equine glucosamine injections, misrepresenting to U.S. Food and Drug Administration (FDA) inspectors that the levels were within acceptable ranges.

APPLICABLE LAW

4. It is illegal to knowingly and willfully make false or fraudulent statement, including without limitation, a material omission, misrepresentation, or use of a fraudulent document, to a federal agency such as the FDA. 18 U.S.C. § 1001.

5. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

6. Performing any duties as the holder of a pharmacist registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

7. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

COUNT ONE

Violation of Federal Law – False Statement to Federal Agency

8. By altering certificates of analysis for endotoxin level and sterility tests for equine glucosamine injections and misrepresenting to FDA inspectors that the levels were within acceptable ranges, as alleged herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 18 U.S.C. § 1001, and is subject to discipline pursuant to NRS 639.210(11).

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COUNT TWO

Unprofessional Conduct –Fraudulent/Deceitful Practice/Transaction

9. By altering certificates of analysis for endotoxin level and sterility tests for equine glucosamine injections and misrepresenting to FDA inspectors that the levels were within acceptable ranges, as alleged herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 639.210(4).

COUNT THREE

Unprofessional Conduct - Incompetent, Unskillful or Negligent Performance of Duties

10. By his conduct as alleged herein, Respondent has performed his duties as the holder of a pharmacist registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 639.210(4).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 10th day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENTS

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARTIN JAMES FARRELL, RPH,** **Certificate of Registration No. 22316,** **Respondent.**	**Case No. 25-233-RPH-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 15, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 20th day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARTIN JAMES FARRELL, RPH,** **Certificate of Registration No. 22316,** **Respondent.**	**Case No. 25-233-RPH-O** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

Martin James Farrell, RPh

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 20th day of February 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Martin James Farrell, RPh
[redacted]
Havertown, PA [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

DEPARTMENT OF STATE

Bureau of Professional and Occupational Affairs
Legal Office – Prosecution Division
P.O. Box 69521
Harrisburg, PA 17106-9521
www.dos.pa.gov

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Martin James Farrell, RPh
[redacted]
Havertown, PA [redacted]

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COMMONWEALTH OF PENNSYLVANIA
OFFICE OF GENERAL COUNSEL

Nathan C. Giunta
Prosecuting Attorney

ngiunta@pa.gov
Prosecution Division

April 29, 2025

Martin James Farrell, RPh
[redacted]
Havertown, PA [redacted]

RE: *Commonwealth of Pennsylvania, Bureau of Professional and Occupational Affairs v. Martin James Farrell, RPh*, Case No. 24-54-017144

Dear Mr Farrell:

Enclosed is a copy of a Consent Agreement and Order approved and adopted by the State Board of Pharmacy at its meeting on April 29, 2025. Accordingly, this case is now closed.

Thank you for your cooperation with the resolution of this matter.

Sincerely,

//s// Nathan C. Giunta

Nathan C. Giunta
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State

NCG/sv

Enclosure: Consent Agreement

COPY

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**	
vs.	**Case No. 24-54-017144**
Martin James Farrell, RPh, **Respondent**	

CONSENT AGREEMENT AND ORDER

PARTIES

The Commonwealth of Pennsylvania, Department of State, Bureau of Professional and Occupational Affairs ("Commonwealth") and **Martin James Farrell, RPh** ("Respondent") stipulate as follows in settlement of the above-captioned case.

APPLICABLE LAW

1. This matter is before the State Board of Pharmacy ("Board") pursuant to the Pharmacy Act, act of September 27, 1961, P.L. 1700, No. 699 ("Act"), *as amended*, 63 P.S. §§ 390-1 to 390-13; and/or 63 Pa.C.S. Chapter 31 ("Chapter 31"), 63 Pa.C.S. §§ 3101-3118.

LICENSURE STATUS

2. At all relevant and material times, Respondent held the following license to practice as a pharmacist in the Commonwealth of Pennsylvania: license no. RP447897, which was originally issued on July 26, 2013, and which is currently set to expire on September 30, 2026.

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STIPULATED FACTS

3. Respondent admits the following:

a. Absent additional Board action, Respondent's license may be continually renewed or reactivated upon the filing of the required documentation and payment of the applicable fees.

b. Respondent's address is: 308 Shelbourne Road, Havertown, PA 19083.

c. The Respondent was hired by Boothwyn Pharmacy in March of 2021 as a staff pharmacist.

d. The Respondent became the Pharmacist in Charge (PIC) in October of 2023.

e. The Respondent, as the PIC, was responsible for supervising several compounding pharmacists.

f. The Respondent and several other compounding pharmacists would receive certificates of analysis from different laboratory contractors.

g. The certificates contained endotoxin level and sterility tests for various products including equine glucosamine injections.

h. The Respondent, along with the pharmacist he supervised, would be responsible for reviewing the certificates of analysis to confirm the levels were within the acceptable ranges.

i. The Respondent was responsible to initiate the Boothwyn Pharmacy protocol each time the Respondent received out of specification test results.

j. Boothwyn's protocols required the following:

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(1) Respondent was to notify the President and Vice President of the out of specification results.

(2) Respondent was to notify/ contact any customer who received product from the out of specification batch.

k. The Respondent received these protocols when he was hired by Boothwyn Pharmacy.

l. In April and May of 2024, the Respondent received several out of specification certificates of analysis for equine glucosamine injections that were analyzed by ARL Laboratory for Boothwyn Pharmacy.

m. The Respondent documented, in call logs, that he contacted customers who received these batches of medication.

n. In September of 2024, the United States Food and Drug Administration (FDA) conducted an inspection of Boothwyn Pharmacy.

o. During the inspection the FDA inspectors requested certificates of analysis from the Respondent for the equine glucosamine injections.

p. The FDA inspectors informed the Vice President of Boothwyn Pharmacy that the Respondent submitted three (3) questionable certificates of analysis.

q. Following a review of the certificates of analysis, compared to the originals, it was discovered that the endotoxin levels were changed before being provided to the FDA inspectors.

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r. On or about November 13, 2024, the Respondent was interviewed by Professional Compliance Investigator Michael Mannetta (PCI Mannetta) and stated the following:

(1) In April and May of 2024, several of the Respondent's supervisees received out of specification endotoxin test results for equine glucosamine injections.

(2) The Respondent informed the supervisees he would take care of the matter; however, the Respondent did not initiate the escalation protocol required by Boothwyn Pharmacy.

(3) PCI Mannetta asked the Respondent why the escalation protocol was not initiated and the Respondent stated that he did not believe it was a fair test and the laboratories used endotoxin levels for humans, rather than horses, as the standard.

(4) The Respondent stated that he discussed endotoxin levels with several customers in the past and all reported that horses experienced no negative side effects from slightly elevated endotoxin levels.

(5) PCI Mannetta asked the Respondent about why and how he altered the certificated of analysis for the FDA inspection.

(6) The Respondent stated he used Adobe and altered the endotoxin levels to make it appear the results were within specifications.

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(7) The Respondent also generated a false call log to make it appear he provided notice to customers when he was notified that the original test results were out of specification.

MITIGATION

4. Respondent offers the following in mitigation, which the Commonwealth neither admits nor denies:

a. See Attachment "A"

AUTHORITY OF THE BOARD

5. The Board is authorized to suspend or revoke, or otherwise restrict Respondent's license under sections 5(a and/or b) & (8) of the Act, 63 P.S. §§ 390-5(a and/or b) & 390-8; impose a civil penalty upon Respondent under section 8(15.1) of the Act, 63 P.S. § 390-8(15.1), or 63 Pa.C.S. § 3108(b)(4); and/or impose the costs of investigation upon Respondent under 63 Pa.C.S. § 3108(b)(5).

SUMMARY OF DISCIPLINE

6. The following encapsulates the discipline as set forth in the Proposed Order:

- Respondent shall pay a **CIVIL PENALTY** of **$17,500.00**.
- Respondent's license will be placed on **PROBATION FOR 6 MONTHS**.
- Respondent will complete 12 hours of **CONTINUING EDUCATION** on the topics of Ethics / Record Keeping / Patient Safety.

PROPOSED ORDER



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7. The parties, intending to be legally bound, consent to the issuance of the following Order in settlement of this matter:

a. **VIOLATIONS**: Respondent violated the Act at section 5(a)(12) of the Act, 63 P.S. § 390-5(a)(12), in that Respondent failed to conform to, the standards

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of acceptable and prevailing pharmacy practice, by manipulating endotoxin test results on documents that were provided to FDA inspectors during an inspection.

b. **CIVIL PENALTY:** Respondent shall pay a civil penalty of seventeen thousand five hundred dollars ($17,500.00) as follows:

(1) Payment of the civil penalty is subject to the following terms:

(2) The full civil penalty shall be tendered to the prosecution division of the Department of State with the executed consent agreement;

(3) The civil penalty shall be paid by certified check, cashier's check, attorney's check, or money order issued by a usual, customary, and reputable issuer (e.g. U.S. Postal Money Order, Western Union Money Order, etc.);

(4) Payment shall be valid for a period of at least 180 days and shall be made payable to the "Commonwealth of Pennsylvania"; and

(5) Respondent agrees that payment shall only be made by one of the methods indicated and shall not be made by uncertified personal or corporate check.



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c. **SUSPENSION:** All licenses, registrations, certificates, approvals, permits or any other authorizations issued by the Board (hereinafter referred to collectively as "authorizations to practice the profession") to Respondent are hereby **SUSPENDED** for a period of six (6) months.

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d. During any period of active suspension, Respondent shall surrender Respondent's wall certificate, biennial renewal certificate, and wallet card (or affidavit of their loss or destruction) by mailing them to:

Nathan C. Giunta Prosecuting Attorney Bureau of Professional and Occupational Affairs P.O. Box 69521 Harrisburg, PA 17106-9521

Upon the effective date of the Consent Agreement, and during any period of active suspension, Respondent shall cease and desist from practicing as a pharmacist in the Commonwealth of Pennsylvania and shall not hold out or otherwise indicate that Respondent is a Board licensee in any matter during any period of active suspension.

e. **PROBATION:** The **SUSPENSION** of Respondent's authorizations to practice the profession shall be **IMMEDIATELY STAYED IN FAVOR OF PROBATION**, subject to the following terms and conditions:

f. **GENERAL TERMS OF PROBATION:**

(1) Respondent shall abide by and obey all federal and state laws, including, but not limited to, statutes, rules and regulations.

(2) The filing of criminal charges, other than summary traffic violations, or the initiation of a professional disciplinary matter against Respondent shall constitute a violation of this Order.

(3) The address for Respondent's Department of State, Bureau of Enforcement and Investigation (BEI) Probation Compliance Officer is:

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Probation Compliance Officer
Bureau of Enforcement and Investigation
P.O. Box 2649
Harrisburg, PA 17105-2649
717-783-7228

(4) Unless otherwise directed, Respondent, Respondent's professional employer, and any other person needing or required to make reports under this Order concerning Respondent's practice and contact information, shall cause those reports, data or other information to be provided to the probation compliance officer.

(5) Respondent shall notify the probation compliance officer, in writing, within twenty (20) days of the following:

(i) the filing of criminal charges;

(ii) the disposition of any criminal charge including, but not limited to, a conviction, an admission of guilt, a nolo contendere plea, the imposition of probation without verdict, a disposition in lieu of trial or entry into an Accelerated Rehabilitative Disposition (ARD) program;

(iii) the initiation of a professional disciplinary matter or any disciplinary action imposed by the professional licensing authority of any state or jurisdiction; and

(iv) any other legal action (civil or administrative) pertaining to the practice of the profession at issue.

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(6) Respondent shall notify the probation compliance office, in writing, within (20) twenty days of the Board's adoption of this Consent Agreement, of any actions set forth in the preceding paragraph that occurred within one (1) year prior to the Board's adoption of this Consent Agreement.

(7) Respondent shall cooperate with the Commonwealth and the BEI, in the monitoring, supervision, and investigation of Respondent's compliance with the terms and conditions of this Order.

(8) Respondent shall cause to be submitted at Respondent's own expense written reports, records, and verifications of actions that may be required by the Commonwealth and BEI.

(9) Respondent shall:

(i) provide written notice to the probation compliance officer of the name(s) and address(es) of the place(s) at which Respondent will practice within seventy-two (72) hours of the Board's adoption of this Consent Agreement;



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(ii) provide written notice to the probation compliance officer, within seventy-two (72) hours of any change in the name(s) and address(es) of the place(s) at which Respondent will practice;

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(iii) provide written notice to the probation compliance officer, within seventy-two (72) hours of a change in Respondent's home address or telephone number; and

(iv) electronically update the Board's records within seventy-two (72) hours of a change of Respondent's address and telephone number on file with the Board.

(10) If self-employed, Respondent shall submit a written verification of self-employment, along with substantiating documentation, to the probation compliance officer within fifteen (15) days of adoption of this Consent Agreement by the Board or within fifteen (15) days of becoming self-employed.

(11) Respondent consents to the release by the Commonwealth or BEI of any information or data produced as a result of this probation to any professional employer or prospective professional employer.

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(12) Respondent shall not falsify, misrepresent, or make material omission of any information submitted pursuant to this Order.

(13) Respondent's failure to fully cooperate and successfully comply with the terms and conditions of probation shall be deemed a violation of this Order.

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(14) Respondent shall make a written request for reinstatement to non-probationary status at the end of the minimum probationary period to:

Board Counsel State Board of Pharmacy P.O. Box 69523 Harrisburg, PA 17106-9523

(15) Reinstatement may be subject to administrative requirements.

(16) Reinstatement to non-probationary status shall be subject to the Board's determination that Respondent has complied with all terms and conditions of the probation imposed by this Order. The Board reserves the right to schedule a hearing to determine Respondent's compliance.

g. **REMEDIAL EDUCATION**: Prior to the expiration of the probationary period, Respondent shall attend and successfully complete at least twelve (12) hours of remedial education on the topic(s) of Ethics/ Record Keeping / Patient Safety. Respondent shall comply with the following terms and conditions pertaining to completion of the remedial education:



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(1) The remedial education required by this Order shall be in compliance with either the initial education or the continuing education regulations of the Board;

(2) If any remedial education course requires Respondent to take an examination, Respondent must pass the examination(s);

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(3) The remedial education required by this Order shall be successfully completed by October 31, 2025;

(4) Respondent shall submit acceptable proof of successful completion of the remedial education to the Board's Executive Secretary **prior to applying for reinstatement of Respondent's license to unrestricted status**;

(5) Acceptable proof of completion of the remedial education shall consist of an official school transcript or a certificate, printout or letter prepared by the provider indicating successful completion of the course(s). Such proof shall contain course titles, completion dates, final grade (if graded), and number of class hours or credits awarded;

(6) **Respondent shall note the case number of this matter on any documentation submitted to the Executive Secretary.** The address for the Board's Executive Secretary is:



COPY

Sara Trimmer & Christina Townley, Executive Secretary State Board of Pharmacy 2525 N 7th St PO Box 2649 Harrisburg, PA 17105-2649

(7) The remedial education required by this Order shall be in addition to any continuing education requirements for the renewal of any license, registration, certificate, approval, authorization, or permit issued by the Board (hereinafter referred to collectively as "authorizations to practice the profession");

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(8) Respondent may not utilize the remedial education required by this Order to satisfy any initial or continuing education requirement for Respondent's authorizations to practice the profession;

(9) Following the successful completion of the remedial education required by this Order, Respondent shall be subject to a non-random audit of continuing education upon the next renewal or reactivation of Respondent's authorizations to practice the profession; and

(10) Respondent shall bear the responsibility of all costs incurred in complying with the terms of this Order, including production of records.

h. Respondent shall bear the responsibility of all costs incurred by Respondent in complying with the terms of this Order, including production of records;



COF

MOP
5-9-25

i. **VIOLATION OF PROBATIONARY ORDER DUE TO FAILURE TO PROVIDE PROOF OF SUCCESSFUL COMPLETION OF REMEDIAL EDUCATION:** If Respondent fails to submit acceptable proof of successful completion of the Remedial Education by the end of the probationary period as required by this Consent Agreement, Respondent's license to practice as a pharmacist and any and all authorizations to practice the profession issued by the Board and held by Respondent shall be **IMMEDIATELY AND INDEFINITELY SUSPENDED**, without further hearing, until such time as Respondent does provide

DOS Prothonotary
May 01 2025

the Board's Executive Secretaries with acceptable proof of successful completion of the Remedial Education as required by this Consent Agreement.

j. **VIOLATION(S) OF PROBATION FOR REASONS OTHER THAN FAILURE TO TIMELY COMPLETE REMEDIAL EDUCATION:** Notification of a violation of the terms or conditions of this Consent Agreement and Order shall result in the **IMMEDIATE VACATING** of the stay order, **TERMINATION** of the period of probation, and **ACTIVATION** of the entire period of suspension of Respondent's authorizations to practice the profession in the Commonwealth of Pennsylvania as follows:

(1) The prosecuting attorney for the Commonwealth shall file with the Board a Petition which alleges that Respondent has violated any terms or conditions of this Consent Agreement and Order other than failure to complete the Ordered remedial education in a timely manner;



(2) Upon a probable cause determination that Respondent has violated any of the terms or conditions of this Consent Agreement and Order, the Board shall, without holding a formal hearing, issue a preliminary order vacating the stay of the suspension in this matter, terminating the period of probation and activating the entire period of suspension of Respondent's authorizations to practice the profession, without credit for any period of suspension stayed in favor of probation;

DOS Prothonotary
May 01 2025
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(3) Notification of the Board's Preliminary Order shall be mailed to Respondent within three (3) days of its issuance by certified mail and first-class mail postage prepaid, sent to the last registered address on file with the Board. If service by mail is unsuccessful, the Commonwealth is authorized to attempt service by personal service and/or publication of legal notice in a newspaper of general circulation in the county of Respondent's last known address.

(4) Within twenty (20) days of mailing of the notification of the Board's action, Respondent may answer the Commonwealth's Petition and request that a formal hearing be convened concerning Respondent's alleged violation of probation, in which Respondent may seek relief from the Preliminary Order activating the suspension. **The answer shall be set forth in numbered paragraphs corresponding to the numbered paragraphs of the Petition. Respondent shall admit or deny each of the allegations set forth in the paragraphs in the Petition**. Any answer submitted in this matter must be filed with the



003 Prothonotary
May 01 2025
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Prothonotary for the Department of State via one of the following methods:

By E-mail:	**By Mail:**	**By Facsimile:**
ra-prothonotary@pa.gov	Prothonotary Department of State 2400 Thea Dr PO Box 60130 Harrisburg, PA 17106-0130	(717)772-1892

(5) **Respondent shall send a copy of the answer, request for hearing, and all subsequent filings in the matter to the prosecuting attorney for the Commonwealth named in the Petition;**

(6) If a request for a formal hearing is received from Respondent, the Board shall convene a formal hearing within forty-five (45) days from the date of the Board's receipt of Respondent's request for a formal hearing;

(7) If Respondent files an answer and request for a hearing within the twenty (20) day period, the Preliminary Order activating the suspension shall remain in effect unless and until the Board issues a determination favorable to Respondent after holding the formal hearing;



(8) The facts and averments in paragraphs 2 & 3 and findings of the Board in paragraph 7(a) of this Consent Agreement and Order shall be deemed admitted and uncontested for purposes of the hearing;

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May 01 2025
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(9) If the Board after such hearing makes a determination adverse to Respondent, the Board will issue a Final Order activating the suspension of Respondent's license and imposing any additional disciplinary measures it deems appropriate;

(10) If a request for a formal hearing is not received from Respondent within the prescribed twenty (20) day period, the Board's Preliminary Order shall become a Final Order twenty (20) days after the date of its mailing;

(11) If the stay is terminated, Respondent shall still comply with all terms and conditions of probation during the active suspension, other than those terms and conditions pertaining to the active practice of the profession. Continued failure by Respondent to comply with the unaffected terms and conditions of probation shall result in further disciplinary action against Respondent;

k. Respondent's failure to fully comply with any terms of this Order may also constitute grounds for additional disciplinary action.

l. **VIOLATION(S) OF PROBATION**: Notification of a violation of the terms or conditions of this Consent Agreement and Order shall result in the **IMMEDIATE VACATING** of the stay order, **TERMINATION** of the period of probation, and **ACTIVATION** of the entire period of suspension of Respondent's authorizations to practice the profession in the Commonwealth of Pennsylvania as follows:

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DOS Prothonotary
May 01 2025
4063

(1) The prosecuting attorney for the Commonwealth shall file with the Board a Petition which alleges that Respondent has violated any terms or conditions of this Consent Agreement and Order other than failure to complete the Ordered remedial education in a timely manner;

(2) Upon a probable cause determination that Respondent has violated any of the terms or conditions of this Consent Agreement and Order, the Board shall, without holding a formal hearing, issue a preliminary order vacating the stay of the suspension in this matter, terminating the period of probation and activating the entire period of suspension of Respondent's authorizations to practice the profession, without credit for any period of suspension stayed in favor of probation;

(3) Notification of the Board's Preliminary Order shall be mailed to Respondent within three (3) days of its issuance by certified mail and first-class mail, postage prepaid, sent to the last registered address on file with the Board. If service by mail is unsuccessful, the Commonwealth is authorized to attempt service by personal service and/or publication of legal notice in a newspaper of general circulation in the county of Respondent's last known address.

COPY

(4) Within twenty (20) days of mailing of the notification of the Board's action, Respondent may answer the Commonwealth's

DOS Prothonotary
May 01 2025
4064

Petition and request that a formal hearing be convened concerning Respondent's alleged violation of probation, in which Respondent may seek relief from the Preliminary Order activating the suspension. **The answer shall be set forth in numbered paragraphs corresponding to the numbered paragraphs of the Petition. Respondent shall admit or deny each of the allegations set forth in the paragraphs in the Petition.** Any answer submitted in this matter must be filed with the Prothonotary for the Department of State via one of the following methods:

By E-Mail:	**By Mail**	**By Facsimile:**
ra-prothonotary@pa.gov	Prothonotary Department of State 2400 Thea Dr PO Box 60130 Harrisburg, PA 17106-0130	(717)772-1892



COPY

(5) Respondent shall send a copy of the answer, request for hearing, and all subsequent filings in the matter to the prosecuting attorney for the Commonwealth named in the Petition;

(6) If a request for a formal hearing is received from Respondent, the Board shall convene a formal hearing within forty-five (45) days from the date of the Board's receipt of Respondent's request for a formal hearing;

(7) If Respondent files an answer and request for a hearing within the twenty (20) day period, the Preliminary Order activating

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the suspension shall remain in effect unless and until the Board issues a determination favorable to Respondent after holding the formal hearing;

(8) The facts and averments in paragraphs 2and 3 and findings of the Board in paragraph 7(a) of this Consent Agreement and Order shall be deemed admitted and uncontested for purposes of the hearing;

(9) If the Board after such hearing makes a determination adverse to Respondent, the Board will issue a Final Order activating the suspension of Respondent's license and imposing any additional disciplinary measures it deems appropriate;

(10) If a request for a formal hearing is not received from Respondent within the prescribed twenty (20) day period, the Board's Preliminary Order shall become a Final Order twenty (20) days after the date of its mailing;

(11) If the stay is terminated, Respondent shall still comply with all terms and conditions of probation during the active suspension, other than those terms and conditions pertaining to the active practice of the profession. Continued failure by Respondent to comply with the unaffected terms and conditions of probation shall result in further disciplinary action against Respondent;

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m. Respondent's failure to fully comply with any terms of this Order may also constitute grounds for additional disciplinary action.

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n. This Order constitutes disciplinary action by the Board. This Order will be reported to other licensing authorities and any applicable national licensing databank as a disciplinary action.

o. This case shall be deemed settled and discontinued upon the Board issuing an order adopting this Consent Agreement.

ADMISSIBILITY OF CONSENT AGREEMENT IN FUTURE PROCEEDINGS

8. Respondent agrees that this Consent Agreement and Order shall be admitted into evidence, without objection, in any proceeding before the Department of State.

ACKNOWLEDGMENT OF NOTICE AND WAIVER OF HEARING

9. Respondent acknowledges receipt of an Order to Show Cause in this matter. Respondent knowingly and voluntarily waives the right to an administrative hearing in this matter and the following rights related to that hearing: to be represented by counsel; to present witnesses and testimony in defense or in mitigation of any sanction that may be imposed for a violation; to cross-examine witnesses and to challenge evidence presented by the Commonwealth; to present legal arguments by means of a brief; and to take an appeal from any adverse final decision.

ACKNOWLEDGMENT OF RIGHT TO ATTORNEY

10. Respondent acknowledges the right to consult with and be represented by private legal counsel of Respondent's choosing and at Respondent's expense when reviewing, considering and accepting the terms of this Consent Agreement. To the extent that Respondent is not represented by legal counsel, Respondent has knowingly elected to proceed without the assistance of legal counsel.



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WAIVER OF CLAIMS

11. Should the Board vote not to adopt the Order proposed in this Consent Agreement, the presentation and consideration of this Consent Agreement shall not prejudice the Board or any of

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May 01 2025
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its members from further participation in the adjudication of this matter. Respondent expressly waives the right to raise any claims or issues, including any and all constitutional claims or issues, which may arise or have arisen during the review, presentation and deliberation of this Consent Agreement. These claims or issues include, but are not limited to, bias, the commingling of prosecutorial and adjudicative functions by the Board or its counsel, and the Board, in its discretion, recommending a different sanction based upon the facts set forth in the Consent Agreement. If a hearing is subsequently held, neither this Consent Agreement nor the proposed terms of settlement may be admitted into evidence and any facts, averments, and allegations contained in the Consent Agreement must be proven at a hearing unless otherwise separately stipulated.

LIMITS ON MODIFICATION OF ORDER

12. Respondent agrees not to seek modification of the Order adopting and implementing this Consent Agreement without first obtaining the express written permission from the prosecution division. Any modification is at the sole discretion of the Board.

AGREEMENT NOT BINDING UNTIL APPROVED

13. This Consent Agreement is between the Commonwealth and Respondent. The Office of General Counsel has approved this Consent Agreement as to form and legality. The disciplinary provisions of this Consent Agreement do not take effect unless and until the Board issues an order adopting this Consent Agreement.

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ENTIRE AGREEMENT

14. This Consent Agreement contains the entire agreement between the parties. There are no other terms, obligations, covenants, representations, statements, or conditions, oral or otherwise, of any kind whatsoever concerning this agreement.

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AGREEMENT DOES NOT PREVENT FUTURE DISCIPLINE

15. Nothing in this Order shall preclude the prosecution division of the Department of State from filing charges, or the Board from imposing disciplinary or corrective measures, for violations or facts not contained in this Consent Agreement.

VERIFICATION OF FACTS AND STATEMENTS

16. Respondent verifies that the facts and statements set forth in this Consent Agreement are true and correct to the best of Respondent's knowledge, information and belief. Respondent understands that statements in this Consent Agreement are made subject to the criminal penalties of 18 Pa.C.S.A. §4904 relating to unsworn falsification to authorities.

/s/ Nathan C. Giunta
Nathan C. Giunta
Prosecuting Attorney

DATED: 4/9/2025

Martin James Farrell, RPh
Respondent

DATED: 03-27-2025

(24-54-017144)

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5-4-25

DOS Prothonotary:
May 01 2025
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BOOTHWYN PHARMACY

Attachment A

November 14, 2024

Subject: Role Reassignment and Disciplinary Action Following Recent Investigation Findings

Dear Martin,

Following a thorough investigation conducted in collaboration with both the U.S. Food and Drug Administration (FDA) and the Pennsylvania Board of Pharmacy, which concluded on November 13, 2024, Boothwyn Pharmacy has identified serious concerns regarding your actions related to document integrity. Specifically, this investigation revealed that your actions jeopardized the integrity of compounded medications at Boothwyn Pharmacy and compromised the ethical and professional standards our establishment upholds.

The findings disclosed multiple violations of Boothwyn Pharmacy's Standard Operating Procedures (SOP) for the evaluation of Out-of-Specification (OOS) results, SOP QA.CAPA.016.001 Variance & OOS Investigations, as well as non-compliance with the Boothwyn Pharmacy Handbook Section 3.6-Personal Code of Conduct page 31 and 32, which clearly outlines the required procedures for escalating concerns. These protocols are essential to ensure the accountability and integrity of our pharmacy operations.

The gravity of this matter cannot be understated. Altering documentation and failing to adhere to escalation protocols represent severe breaches of professional conduct. Such actions undermine the trust placed in Boothwyn Pharmacy by regulatory agencies, our clients, and the broader healthcare community.

As a result of these findings, effective immediately, you will be relieved of your position as Pharmacist in Charge and reassigned to the role of Administrative Pharmacist. In this capacity, you will focus on administrative tasks and formula management while working closely with Ali Zerafati, who will assume the role of Pharmacist in Charge. This transition aims to uphold the operational integrity of Boothwyn Pharmacy and ensure compliance with all applicable regulations moving forward.

Additionally, as part of your reassignment:

- You will undergo a 90-day probationary period, during which you will not engage in activities involving sensitive documents or records that could impact on the integrity of our compounds, results, or reputation.
- You are required to complete 20 hours of coursework in ethics, with a focus on FDA regulations and ethical practices in pharmacy, within this probationary period. Failure to comply with this requirement will result in termination of employment. Human Resources will set up the modules.

DOS Prothonotary
May 01 2025

BOOTHWYN PHARMACY

- You will be required to schedule and attend a bi-weekly appointment with our Human Resources Director to assess your progress with these directives.
- Any future violations related to document integrity or ethical breaches will lead to immediate termination.

This decision reflects Boothwyn Pharmacy's commitment to professional integrity and adherence to regulatory standards. We expect your full cooperation and dedication in adhering to these terms as we work to restore and uphold the trust of our clients and regulatory partners.

Sincerely,

John Howell

John Howell, Executive Vice President of Operations
Boothwyn Pharmacy

Cc: Louis Micolucci, CEO; Arthur Dustman, COO and President



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DOS Prothonotary
May 01 2025

CPE Monitor Statement

Printed: 03/19/2025 03:47:48 PM

Participant Name:
Martin James Farrell

NABP e-Profile ID: 650055

Provider Information:
VCU Health Continuing Education

Activity Information

Activity Title: The Ethical, Legal, and Regulatory Foundations of Pharmacy Compounding

Activity Date: 11/18/2024

ACPE UAN: JA4008237-0000-23-051-H07-P

Topic Designator: Compounding

Contact Hours (CEU): 15.00 (1.500)

Live Hours: 0.00

Home Hours: 15.00

Activity Type: Knowledge-based



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Clerk's Prothonotary
May 01 2025

CPE Monitor Statement

Printed: 03/27/2025 01:08:48 PM

Participant Name:

Martin James Farrell

NABP e-Profile ID: 650055

Provider Information:

National Pharmacy Technician Association (NPTA)

Activity Information

Activity Title: Ethics and Law in Pharmacy Practice

Activity Date: 11/14/2024

ACPE UAN: 0384-9999-23-064-H03-P

Topic Designator: Law Related to Pharmacy Practice

Contact Hours (CEU): 2.00 (0.200)

Live Hours: 0.00

Home Hours: 2.00

Activity Type: Knowledge-based

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D03 Prothonotary
May 01 2025

CPE Monitor Statement

Printed: 03/19/2025 03:47:52 PM

Participant Name:
Martin James Farrell

NABP e-Profile ID: 650055

Provider Information:
American College of Apothecaries, Inc.

Activity Information

Activity Title: Priority of Pharmacy Ethics in Healthcare

Activity Date: 11/18/2024

ACPE UAN: 0201-9999-22-035-H04-P

Topic Designator: Pharmacy Administration

Contact Hours (CEU): 1.00 (0.100)

Live Hours: 0.00

Home Hours: 1.00

Activity Type: Knowledge-based

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FCC Prothonotary
May 01 2025

CPE Monitor Statement

Printed: 03/19/2025 03:47:55 PM

Participant Name:
Martin James Farrell

NABP e-Profile ID: 650055

Provider Information:
NBLS, Inc.

Activity Information

Activity Title: FWA Prevention and General Compliance in the Pharmacy

Activity Date: 12/23/2024

ACPE UAN: 0664-0000-24-006-H03-P

Topic Designator: Law Related to Pharmacy Practice

Contact Hours (CEU): 1.00 (0.100)

Live Hours: 0.00

Home Hours: 1.00

Activity Type: Knowledge-based

COPY

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Prothonotary
May 01 2025

CPE Monitor Statement

Printed: 03/19/2025 03:48:01 PM

Participant Name:
Martin James Farrell

NABP e-Profile ID: 650055

Provider Information:
NBLS, Inc.

Activity Information

Activity Title: HIPAA Compliance for the Pharmacy (2024)

Activity Date: 12/23/2024

ACPE UAN: 0664-0000-23-021-H03-P

Topic Designator: Law Related to Pharmacy Practice

Contact Hours (CEU): 1.00 (0.100)

Live Hours: 0.00

Home Hours: 1.00

Activity Type: Knowledge-based

COPY

MCR 5446

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Filed Prothonotary
May 01 2025

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**	
vs.	**Case No.** **24-54-017144**
Martin James Farrell, RPh, **Respondent**	

ORDER

AND NOW, this 29th day of April 2025, the **STATE BOARD OF PHARMACY** ("Board") approves and adopts the foregoing Consent Agreement and incorporates the terms of paragraph 7, which shall constitute the Board's Order and is now issued in resolution of this matter.

This Order shall take effect immediately.

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

Arion R Claggett

ARION R. CLAGGETT
ACTING COMMISSIONER

BY ORDER:
STATE BOARD OF PHARMACY

CHRISTINE ROUSSEL, PHARM.D., R.PH.
CHAIRPERSON

For the Board: Sean C. Barrett, Esquire

For the Commonwealth: Nathan C. Giunta, Esquire
Prosecution Division
PO Box 69521
Harrisburg, PA 17106-9521

Respondent: Martin James Farrell, RPh
[redacted]
Havertown, PA [redacted]

Date of mailing: 5/1/2025

Farrell24541714dcsa021524ord.docx

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

In the Matter of the	**:**	
Petition for Reinstatement to	**:**	**Case No. 26-54-001563**
Unrestricted Status of the License of	**:**	
Martin James Farrell, R.Ph.,	**:**	
Petitioner	**:**	

FINAL ORDER REINSTATING LICENSE TO UNRESTRICTED STATUS

AND NOW, this 4th day of February, 2026, the State Board of Pharmacy ("Board"), upon consideration of the Petition for Reinstatement filed by Martin James Farrell, R.Ph. ("Petitioner"), in which Petitioner seeks reinstatement from the probationary status imposed by the April 29, 2025 Consent Agreement and Order at case number 24-54-017144, which suspended Petitioner's license and authorizations to practice the profession for a period of six months, with the suspension immediately stayed in favor of probation, having completed all terms and conditions set forth in the Consent Agreement and Order of April 29, 2025 to the satisfaction of the Board, and noting that the Commonwealth's prosecuting attorney does not oppose reinstatement, the Board hereby **ORDERS** that Petitioner's **PROBATION IS TERMINATED** and Petitioner's license to practice as a Pharmacist, License No. RP447897, and any other authorizations to practice the profession, are hereby **REINSTATED** to **UNRESTRICTED, NON-PROBATIONARY** status.

This Order shall take effect immediately.

BY ORDER:

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

ARION R. CLAGGETT
ACTING COMMISSIONER

STATE BOARD OF PHARMACY

CHRISTINE ROUSSEL, PHARM.D., R.PH.
CHAIRPERSON

Petitioner:
9489.0090.0027.6644.1951.53

Martin James Farrell, R.Ph.
[redacted]
Havertown, PA [redacted]
Via Email: [redacted]@gmail.com

For the Commonwealth: Nathan Giunta, Esquire

Board Counsel: Sean C. Barrett, Esquire

Date of Mailing: February 4, 2026

COMMONWEALTH OF PENNSYLVANIA
GOVERNOR'S OFFICE OF GENERAL COUNSEL

Sean C. Barrett
Assistant Counsel

seabarrett@pa.gov
Counsel Division

February 4, 2026

Via Certified and First-Class Mail

Martin James Farrell, R.Ph.
[redacted]
Havertown, PA [redacted]
Via Email: [redacted]@gmail.com

Via Interoffice Mail

Nathan Giunta, Esquire
P.O. Box 69521
Harrisburg, PA 17106-9521

RE: Final Order Reinstating License to Unrestricted Status:
In the Matter of the Petition for Reinstatement to Unrestricted Status of the License of Martin James Farrell, R.Ph.
Case No. 26-54-001563

Dear Mr. Farrell:

Enclosed please find a final order reinstating license to unrestricted status being issued this date.

Sincerely,

Sean C. Barrett, Counsel
State Board of Pharmacy

SCB/wc
Enclosure

cc: Sara Trimmer, Board Administrator
State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARTIN JAMES FARRELL, RPH,** **Certificate of Registration No. 22316,** **Respondent.**	**Case No. 25-233-RPH-O** **STIPULATION AND ORDER**

J. David Wuest, in his capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Martin James Farrell, RPh, Certificate of Registration No. 22316, by and through counsel, Lyn E. Beggs, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. On or about February 20. 2026, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing. Respondent is entering this Stipulation in lieu of filing an Answer and Notice of Defense to the Accusation.

2. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

3. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

4. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights

to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. On or about April 29, 2025, the Pennsylvania State Board of Pharmacy (PABOP) and Respondent entered a consent agreement and order in Case No. 24-54-017144, imposing discipline on Respondent's PABOP License No. RP447897 to practice pharmacy for cause, wherein Respondent admitted to altering certificates of analysis for endotoxin level and sterility tests for equine glucosamine injections, misrepresenting to U.S. Food and Drug Administration (FDA) inspectors that the levels were within acceptable ranges; and

B. By altering certificates of analysis for endotoxin level and sterility tests for equine glucosamine injections and misrepresenting to FDA inspectors that the levels were within acceptable ranges, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 18 U.S.C. § 1001, and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h) and (i).

6. Those violations are pled with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

7. On or about February 4, 2026, PABOP entered a final order in Case No. 24-54-017144, terminating Respondent's probation and reinstating Respondent’s PABOP License No. RP447897 to practice pharmacy to unrestricted status.

8. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Martin James Farrell, RPh, Certificate of Registration No. 22316, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(b), Respondent is placed on probation for one (1) year;

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of One Thousand Dollars ($1,000.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by May 15, 2026; and

C. Respondent shall comply with all federal and state statutes and regulations regarding the practice of pharmacy and controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. 22316 will be fully restored.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on April 15, 2026. Respondent will appear in person or through counsel at the meeting to answer questions from the Board

Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of _____ 2026

MARTIN JAMES FARRELL, RPH
Certificate of Registration No. 22316

Signed this ___ day of _____ 2026

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this ___ day of _____ 2026

LYN E. BEGGS, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Martin James Farrell, RPh, Certificate of Registration No. 22316, in Case No. 25-233-RPH-N and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of April 2026.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 29 day of March 2026

MARTIN JAMES FARRELL, RPH
Certificate of Registration No. 22316

Signed this ___ day of _____ 2026

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 30 day of March 2026

LYN E. BEGGS, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Martin James Farrell, RPh, Certificate of Registration No. 22316, in Case No. 25-233-RPH-N and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of April 2026.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #8792,** **Pharmacy License No. PH00637, and** **JOSHUA LEE, RPH,** **Certificate of Registration No. 24163,** **Respondents.**	**CASE NOS. 25-247-PH-N** **25-247-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Joshua Lee, RPh (Lee), Certificate of Registration No. 24163, was a pharmacist registered with the Board, and Respondent CVS Pharmacy #8792, Pharmacy License No. PH00637, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Edward Annor-Korang, RPh (Annor-Korang), Certificate of Registration No. IN05735, was an intern pharmacist registered with the Board, employed as an intern pharmacist by Respondent CVS Pharmacy #8792 and acting under the direct and immediate supervision of Respondent Lee at the time of the events alleged herein.

3. On or about June 9, 2025, in the course of attempting to dispense prescription no. 2038248 to patient A.T., venlafaxine HCl ER 150mg extended release capsules, Annor-Korang

erroneously dispensed prescription no. 2044303, trazodone HCl 50mg tablets, intended for patient M.L.

4. A.T. ingested the erroneously dispensed prescription no. 2044303 and suffered a significant negative outcome.

COUNT ONE
Unprofessional Conduct – Error in Dispensing Prescription/ Supervising Pharmacist Responsibility
(Respondent Lee)

5. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). Unprofessional conduct also includes a registrant performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

6. A registered pharmacist who has accepted responsibility for the supervision and training of an intern pharmacist is responsible for all acts performed by the intern pharmacist working under his or her supervision. NAC 639.268.

7. As the supervising pharmacist for Annor-Korang, Respondent Lee is responsible all errors and omissions of Annor-Korang alleged herein, including without limitation Annor-Korang's unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when erroneously dispensing prescription no. 2044303 as alleged in paragraph 3, and Respondent Lee is therefore subject to discipline pursuant to NAC 639.268 and NRS 639.210.

COUNT TWO
Pharmacy/Pharmacy Owner Responsibility
(Respondent CVS Pharmacy #8792)

8. Any violation of any of the provisions of NRS Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

9. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent CVS Pharmacy #8792 is responsible for those violations, including all errors and omissions of Respondent Lee and/or Annor-Korang, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these Respondents.

Signed this 20th day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #8792,** **Pharmacy License No. PH00637,** **Respondent.**	**Case No. 25-247-PH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 15, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 25 day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #8792,** **Pharmacy License No. PH00637,** **Respondent.**	**Case No. 25-247-PH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

AUTHORIZED REPRESENTATIVE FOR CVS PHARMACY #8792

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 20th day of February 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

CVS Pharmacy #8792
680 N McCarran Blvd.
Sparks, NV 89431

CVS Pharmacy #8792
c/o Brian J. Convery, Esq.
1 CVS Drive, Mail Code 2325
Woonsocket, RI 02895

And via courtesy email to: brian.convery@cvshealth.com

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #8792,** **Pharmacy License No. PH00637, and** **JOSHUA LEE, RPH,** **Certificate of Registration No. 24163,** **Respondents.**	**CASE NOS. 25-247-PH-N** **25-247-RPH-N** **STIPULATION AND ORDER** **[CVS PHARMACY #8792 ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent CVS Pharmacy #8792, Pharmacy License No. PH00637, **HEREBY STIPULATE AND AGREE THAT**:

1. On or about February 20, 2026, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing. Respondent is entering this Stipulation in lieu of filing an Answer and Notice of Defense to the Accusation.

2. Respondent is fully aware of the right to seek the advice of counsel in this matter prior to entering into this Stipulation.

3. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

4. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Respondent does not contest the allegations in the Accusation, but acknowledge that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. Edward Annor-Korang, RPh (Annor-Korang), Certificate of Registration No. IN05735, was an intern pharmacist, employed as an intern pharmacist by Respondent CVS Pharmacy #8792 and acting under the direct and immediate supervision of Respondent Joshua Lee, RPh (Lee), Certificate of Registration No. 24163;

B. As the supervising pharmacist for Annor-Korang, Respondent Lee is responsible all errors and omissions of Annor-Korang alleged herein, including without limitation Annor-Korang's unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when erroneously dispensing prescription no. 2044303, and Respondent Lee is therefore subject to discipline pursuant to NAC 639.268; and

C. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent CVS Pharmacy #8792 is responsible for those violations, including all errors and omissions of Respondent Lee and/or Annor-Korang, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

6. Those violations are plead with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

7. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent CVS Pharmacy #8792, Pharmacy License No. PH00637, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), CVS Pharmacy #8792 shall pay a fine of Two Thousand Dollars ($2,000.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by June 1, 2026; and

B. Pursuant to NRS 622.400, CVS Pharmacy #8792 shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by June 1, 2026.

8. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent consistent with the provisions of NRS Chapter 639.

9. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on April 15, 2026. Respondent will appear in person at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

10. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

11. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondents agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of _____ 2026

_____

CVS PHARMACY #8792
Pharmacy License No. PH00637

Signed this ___ day of _____ 2026

_____

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent CVS Pharmacy #8792, Pharmacy License No. PH00637, in Case No. 25-247-PH-N, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of April 2026.

_____
Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #8792,** **Pharmacy License No. PH00637, and** **JOSHUA LEE, RPH,** **Certificate of Registration No. 24163,** **Respondents.**	**CASE NOS. 25-247-PH-N** **25-247-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Joshua Lee, RPh (Lee), Certificate of Registration No. 24163, was a pharmacist registered with the Board, and Respondent CVS Pharmacy #8792, Pharmacy License No. PH00637, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Edward Annor-Korang, RPh (Annor-Korang), Certificate of Registration No. IN05735, was an intern pharmacist registered with the Board, employed as an intern pharmacist by Respondent CVS Pharmacy #8792 and acting under the direct and immediate supervision of Respondent Lee at the time of the events alleged herein.

3. On or about June 9, 2025, in the course of attempting to dispense prescription no. 2038248 to patient A.T., venlafaxine HCl ER 150mg extended release capsules, Annor-Korang

erroneously dispensed prescription no. 2044303, trazodone HCI 50mg tablets, intended for patient M.L.

4. A.T. ingested the erroneously dispensed prescription no. 2044303 and suffered a significant negative outcome.

COUNT ONE

Unprofessional Conduct – Error in Dispensing Prescription/ Supervising Pharmacist Responsibility

(Respondent Lee)

5. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). Unprofessional conduct also includes a registrant performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

6. A registered pharmacist who has accepted responsibility for the supervision and training of an intern pharmacist is responsible for all acts performed by the intern pharmacist working under his or her supervision. NAC 639.268.

7. As the supervising pharmacist for Annor-Korang, Respondent Lee is responsible all errors and omissions of Annor-Korang alleged herein, including without limitation Annor-Korang's unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when erroneously dispensing prescription no. 2044303 as alleged in paragraph 3, and Respondent Lee is therefore subject to discipline pursuant to NAC 639.268 and NRS 639.210.

COUNT TWO

Pharmacy/Pharmacy Owner Responsibility

(Respondent CVS Pharmacy #8792)

8. Any violation of any of the provisions of NRS Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

9. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent CVS Pharmacy #8792 is responsible for those violations, including all errors and omissions of Respondent Lee and/or Annor-Korang, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these Respondents.

Signed this 20th day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOSHUA LEE, RPH,** **Certificate of Registration No. 24163,** **Respondent.**	**Case No. 25-247-RPH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. A **hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 15, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26th day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOSHUA LEE, RPH,** **Certificate of Registration No. 24163,** **Respondent.**	**Case No. 25-247-RPH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

JOSHUA LEE, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 20th day of February 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Joshua Lee, RPH
[redacted]
Sparks, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #8792,** **Pharmacy License No. PH00637, and** **JOSHUA LEE, RPH,** **Certificate of Registration No. 24163,** **Respondents.**	**CASE NOS. 25-247-PH-N** **25-247-RPH-N** **STIPULATION AND ORDER** **[RESPONDENT LEE ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Joshua Lee, RPh (Lee), Certificate of Registration No. 24163, **HEREBY STIPULATE AND AGREE THAT**:

1. On or about February 20, 2026, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing. Respondent is entering this Stipulation in lieu of filing an Answer and Notice of Defense to the Accusation.

2. Respondent is fully aware of the right to seek the advice of counsel in this matter prior to entering into this Stipulation.

3. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

4. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Respondent does not contest the allegations in the Accusation, but acknowledge that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. Edward Annor-Korang, RPh (Annor-Korang), Certificate of Registration No. IN05735, was an intern pharmacist, employed as an intern pharmacist by Respondent CVS Pharmacy #8792, Pharmacy License No. PH00637, and acting under the direct and immediate supervision of Respondent Lee;

B. As the supervising pharmacist for Annor-Korang, Respondent Lee is responsible all errors and omissions of Annor-Korang alleged herein, including without limitation Annor-Korang's unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when erroneously dispensing prescription no. 2044303, and Respondent Lee is therefore subject to discipline pursuant to NAC 639.268; and

C. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent CVS Pharmacy #8792 is responsible for those violations, including all errors and omissions of Respondent Lee and/or Annor-Korang, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

6. Those violations are plead with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

7. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Joshua Lee, RPh, Certificate of Registration No. 24163, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Lee shall pay a fine of One Thousand Dollars ($1,000.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by June 1, 2026; and

B. Pursuant to NRS 622.400, Lee shall pay Five Hundred Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by June 1, 2026.

8. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent consistent with the provisions of NRS Chapter 639.

9. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on April 15, 2026. Respondent will appear in person at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

10. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

11. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of _____ 2026

_____

JOSHUA LEE, RPH
Certificate of Registration No. 24163

Signed this ___ day of _____ 2026

_____

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Joshua Lee, RPh, Certificate of Registration No. 24163, in Case No. 25-247-RPH-N, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of April 2026.

_____
Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

5H

FILED
FEB 2 0 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RAYMOND BRADBURY GRABER, D.D.S., Certificate of Registration No. CS27126,** **Respondent.**	**CASE NO. 23-340-CS-N** **ORDER TO SHOW CAUSE**

1. The Nevada State Board of Pharmacy (Board) approved a Stipulation and Order dated October 11, 2023 ("Order"), whereby the Board imposed professional discipline upon Respondent Raymond Bradbury Graber ("Respondent"), D.D.S., Certificate of Registration No. CS27126. The Board imposed discipline upon Respondent because Respondent entered a guilty plea in Carson City Justice Court to a misdemeanor drug offense, he contemporaneously admitted to a substance abuse order that predated his guilty plea in Carson City Justice Court, and he thereafter failed to report his guilty plea and/or substance abuse disorder to the Board when he renewed his certificate of registration to prescribe controlled substances.

2. For the conduct described above, the Board placed Respondent on probation for a period of five (5) years from the entry of the Order. As a condition of probation, the Board ordered Respondent to complete substance abuse counseling and provide the Board with proof of progress and completion.

3. Respondent did not renew his certificate of registration when it came due for renewal on November 1, 2024, and he did not continue with substance abuse counseling as required by the terms of the Order.

4. Respondent's privilege to prescribe controlled substances in Nevada is subject to review by the Board and may be revoked or suspended for conduct that renders registration under NRS 453.231 inconsistent with the public interest. *See* NRS 453.236; NRS 453.241.

5. Having failed to complete substance abuse counseling as required by the terms of the Order, Respondent committed an act or omission that renders registration under NRS 453.231 inconsistent with the public interest. Accordingly, pursuant to NAC 639.965, Respondent shall appear before the Board at the first available meeting to demonstrate why he should not be subject to further disciplinary action.

NOW, THEREFORE, IT IS HEREBY ORDERED that Respondent Raymond Bradbury Graber, D.D.S., Certificate of Registration No. CS27126, shall appear before the Board and show cause, if any, why his certificate of registration should not be revoked retroactively to October 31, 2024, or otherwise forfeited as of that date, and his failure to complete probation reported to the National Practitioner Data Bank.

NOTICE TO RESPONDENT

You have the right to dispute the allegations of noncompliance as set forth above. NRS 233B.127(3); NAC 639.968.

The Board has scheduled your hearing on this matter for Wednesday, April 15, 2026 at 9:00 a.m. or soon thereafter. The hearing will occur at the Hyatt Place, 1790 E Plumb Ln. Reno, Nevada 89502. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

ENTERED this 20th day of FEBRUARY, 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 20th day of February 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Raymond Graber
[redacted]
Reno, NV [redacted]

Raymond Graber
[redacted]
Carson City, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
FEB 2 0 2026
NEVADA STATE BOARD OF PHARMACY

MAILED
2/20/26

Certified - $9.15 /each
Standard - $1.90 /each

Raymond Graber
[redacted]
Reno, NV [redacted]
23-340-CS-N. OSC

9489 0178 9820 3045 1636 05

Raymond Graber
[redacted]
Carson City, NV [redacted]
23-340-CS-N. OSC

9489 0178 9820 3045 1635 99

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FAQs >

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Tracking Number:

9489017898203045163605

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Latest Update

Your item was delivered to an individual at the address at 2:01 pm on February 23, 2026 in RENO, NV 89509.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Feedback

Delivered
Delivered, Left with Individual
RENO, NV 89509
February 23, 2026, 2:01 pm

In Transit to Next Facility
February 22, 2026

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER
February 21, 2026, 1:26 pm

Accepted at USPS Origin Facility
RENO, NV 89521
February 21, 2026, 12:11 pm

Pre-Shipment, USPS Awaiting Item
February 21, 2026

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4122

What Do USPS Tracking Statuses Mean? (https://faq.usps.com/s/article/Where-is-my-package)

Text & Email Updates

Return Receipt Electronic

USPS Tracking Plus®

Product Information

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Remove ×

Tracking Number:

9489017898203045163599

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Latest Update

Your item was returned to the sender on March 28, 2026 at 2:37 pm in RENO, NV 89521 because it could not be delivered as addressed.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Alert

Return to Sender
RENO, NV 89521
March 28, 2026, 2:37 pm

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER
March 27, 2026, 2:21 pm

Arrived at USPS Regional Origin Facility
SACRAMENTO CA DISTRIBUTION CENTER
March 26, 2026, 8:48 pm

Unclaimed/Being Returned to Sender

4123

CARSON CITY, NV 89701
March 17, 2026, 10:09 am

Reminder to Schedule Redelivery of your item

March 1, 2026

Notice Left (No Authorized Recipient Available)

CARSON CITY, NV 89706
February 24, 2026, 2:49 pm

In Transit to Next Facility

February 23, 2026

Arrived at USPS Regional Facility

RENO NV DISTRIBUTION CENTER
February 22, 2026, 1:14 pm

Accepted at USPS Origin Facility

RENO, NV 89521
February 22, 2026, 11:59 am

Pre-Shipment, USPS Awaiting Item

February 21, 2026

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FAQs

4124

FILED
OCT 11 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RAYMOND BRADBURY GRABER, D.D.S., Certificate of Registration No. CS27126** **Respondent.**	**CASE NO. 23-340-CS-N** **FIRST AMENDED STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through its General Counsel, Peter K. Keegan, Esq., and Respondent Raymond Bradbury Graber, D.D.S. Certificate of Registration No. CS27126 ("Respondent Graber"), by and through counsel, Lyn E. Beggs, Esq. **HEREBY STIPULATE AND AGREE AS FOLLOWS:**

1. On or about September 12, 2023, Board Staff properly served Respondent Graber, by and through counsel Lyn E. Beggs, Esq., with the Notice of Intended Action and Accusation ("Accusation") on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. In lieu of filing an answer and notice of defense in this matter, Respondent Graber submits this Stipulation and Order for the Board's consideration.

3. Respondent Graber is fully aware of the right to seek the advice of legal counsel and has done so prior to entered into this Stipulation.

4. Respondent Graber is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B ("Nevada Administrative Procedure Act"), NRS Chapter 622A ("Administrative Procedure Before Certain Regulatory Bodies"), and NRS Chapter 639 ("Nevada Pharmacy Act").

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent Graber has failed to comply with the provisions of paragraphs below, Respondent Graber hereby freely and voluntarily waives the right to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B ("Nevada Administrative Procedure Act"), NRS Chapter 622A ("Administrative Procedure Before Certain Regulatory Bodies"), and NRS Chapter 639 ("Nevada Pharmacy Act").

JURISDICTION

6. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Graber and this matter because, because at the time of the events alleged herein Respondent Graber held a Nevada controlled substance registration, Certificate of Registration No. CS27126 issued by the Board.

FACTUAL ALLEGATIONS

7. On or about April 11, 2018, the Board initially issued Respondent Graber a Certificate of Registration to Dispense Controlled Substances, Certificate of Registration No. CS27126.

8. Respondent Graber holds a current DEA registration which expires on September 30, 2023.

9. On or about August 27, 2022, Respondent Graber was arrested for possession of 3.15 grams of cocaine, at or near 5650 South Carson Street, Carson City, State of Nevada.

10. On or about October 31, 2022, Respondent Graber's Certificate of Registration No. CS27126 lapsed and was assigned non-renewed status by the Board.

11. On or about November 4, 2022, Respondent Graber was charged with a violation of NRS 454.351, a misdemeanor, for possession of any drug which may not lawfully be introduced into interstate commerce under the Federal Food, Drug and Cosmetic Act.

12. On or about January 11, 2023, Respondent Graber entered a guilty plea to a misdemeanor violation of NRS 454.351 and his sentencing was deferred for one year to allow for completion of a drug diversion program.

13. On or about February 15, 2023, Respondent Graber submitted a late renewal application for Certificate of Registration No. CS27126.

14. Respondent Graber failed to report his January 11, 2023, misdemeanor plea of guilty to a violation of NRS 454.351, within 30 days to the Board.

15. Respondent Graber had a controlled substance abuse disorder prior to his arrest on August 27, 2022.

APPLICABLE LAW

16. Any person within this State who possesses, procures, obtains, produces, derives, manufactures, sells, offers for sale, gives away or otherwise furnishes any drug which may not be lawfully introduced into interstate commerce under the Federal Food, Drug and Cosmetic Act is guilty of a misdemeanor. NRS 454.351.

17. The holder of any certificate, license, or permit issued by the Board shall report to the Executive Secretary any conviction not later than 30 days after the conviction and provide any documentation of the conviction required by the Executive Secretary. The term "conviction" means a conviction for any crime, other than a misdemeanor traffic violation that does not involve the use of alcohol of a controlled substance, and includes: (a) final judgement; (b) plea of guilty or nolo contender; (c) plea pursuant to *North Carolina v. Alford*, 400 U.S. 25 (1970); or (d) guilty verdict following a bench trial or jury trial, regardless of whether a sentence is suspended or deferred, a final judgement of conviction has been entered or there are any pending appeals. Approved Regulation of the State Board of Pharmacy, LCB File No. R051-22, September 28, 2022.

18. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has

committed an act that would render registration inconsistent with the public interest. NRS 453.231(1)(h); NRS 453.236(1)(e) and NRS 453.241(1).

19. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

20. The Board may suspend or revoke any license or registration issued pursuant to NRS Chapter 639, and deny the application of any person for a certificate, license, registration, or permit, if the holder of applicant has a substance abuse disorder. NRS 639.210(5).

21. Violating any provision of the Federal Food, Drug and Cosmetic Act is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

22. Violating, attempting to violate, assisting, or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

23. Administrative proceedings brought by the Board against a respondent pursuant to NRS Chapter 453, to deny, suspend or revoke a registration must be initiated, conducted and concluded pursuant to the provisions of NRS 639.241 to NRS 639.257, and upon a finding of guilt against the respondent, the Board shall suspend the right of the registrant to use his or her registration or a schedule thereof; or revoke the registration of a schedule thereof. NRS 453.241.

24. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation alleged in an accusation for which the holder is found guilty. NRS 639.255(1)(f) and (3); NAC 639.955.

25. This Accusation constitutes a public record pursuant to NRS 622.330 and any discipline imposed by the Board shall be reported to the National Practitioner Data Bank as required by federal law. Title 42 USC § 1396r–2; 45 CFR Part 60.

COUNT ONE
Failure to timely Report Conviction

By failing to report Respondent's guilty plea to the misdemeanor charge of NRS 454.351 within 30 days, Respondent violated Approved Regulation of the State Board of Pharmacy, LCB File No. R051-22, September 28, 2022. By failing to timely report his guilty plea, Respondent committed an act that renders his continued registration to dispense controlled substances in Nevada inconsistent with the public interest. Respondent is therefore subject to discipline pursuant to NRS 453.231(1)(h) and/or NRS 453.236(1)(e) and/or NRS 453.241(1) and/or NRS 639.255(1)(f) and (3).

COUNT TWO
Violation of the Federal Food, Drug, and Cosmetic Act

By pleading guilty to a violation of the Federal Food, Drug and Cosmetic Act for possession of 3.15 grams of cocaine and admitting to an existing substance abuse disorder prior to his arrest on August 27, 2022, Respondent Graber is subject to discipline pursuant to NRS 639.210(5) and/or (11) and/or (12), and/or NRS 639.255(1)(f) and (3).

CULPABILITY

26. Respondent Graber admits the truth of each and every factual allegation.

27. Respondent Graber admits Count Two of the alleged violations of law.

28. Count One of the alleged violations of law contained in the Accusation is dismissed.

DISCIPLINARY ORDER

29. In consideration of the foregoing admissions and stipulations, and to save the time and expense of litigating the alleged violation(s) of law before the Board, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following **Disciplinary Order:**

A. Respondent Graber's Certificate of Registration to Dispense Controlled Substances, Certificate of Registration No. CS27126 is hereby suspended for a period of five (5)

years but the suspension is stayed immediately, and Respondent Graber is placed on probation for the duration of the stayed suspension subject to the following terms:

i. Respondent Graber shall maintain attendance in a substance abuse counseling program with random urinalysis;

ii. Respondent Graber's counselor shall submit quarterly reports directly to the Board detailing Respondent Graber's progress, attendance, and urinalysis results;

iii. Upon receipt of records demonstrating substance abuse counseling attendance and negative urinalysis attributed to Respondent Graber's deferred misdemeanor sentencing for violation of NRS 454.351, Respondent Graber shall receive credit toward the five (5) year probationary period; and

iv. Upon successful completion of the five (5) year stayed suspension, Respondent shall reappear before the Board to have the probationary conditions removed from his Certificate of Registration to Dispense Controlled Substances.;

B. Respondent Graber shall pay a fine of Two Thousand Dollars ($2,000.00) for the violations, by *cashier's check* or *certified check* or *money order* made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521 within thirty (30) days of the effective date of this Order;

C. Respondent Graber shall pay Five Hundred Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, by *cashier's check* or *certified check* or *money order* made payable to **"Nevada State Board of Pharmacy,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521 within thirty (30) days of the effective date of this Order;

D. Respondent Graber acknowledges this Stipulation and Order constitutes a public record of discipline that is reportable to the National Practitioner Data Bank.

30. Any failure by Respondent Graber to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent Graber to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent Graber, the Board may impose additional discipline upon Respondent Graber consistent with the provisions of NRS Chapter 453 and/or Chapter 639.

31. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 11, 2023. Respondent Graber will appear in-person and/or counsel at the meeting to answer questions from the Board Members. The Board Members may discuss and deliberate regarding this Stipulation, even if Respondent Graber is not present at the meeting.

32. The Board has discretion to accept this Stipulation, but it is not obligated to do so.

33. If the Board rejects any part or all this Stipulation, the parties agree that a full hearing on the merits of this matter may be heard by the Board – unless the parties reach an alternative agreement on the record which is approved by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

34. Subject to the approval of this Stipulation by the Board, the Board and Respondent Graber agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

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Respondent Graber has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 17 day of October 2023.

Raymond Bradbury Graber, D.D.S.
Certificate of Registration No. CS27126

APPROVED AS TO FORM AND CONTENT
this 17 day of October 2023.

LAW OFFICES OF LYN E. BEGGS, PLLC

Lyn E. Beggs, Esq.
Nevada Bar No. 6248
316 California Ave. #863
Reno, Nevada 89509
Counsel for Respondent Graber

APPROVED AS TO FORM AND CONTENT
this 18 day of October 2023.

NEVADA STATE BOARD OF PHARMACY

Peter Keegan, Esq.
General Counsel
Nevada Bar No. 12237
985 Damonte Ranch Pkwy. Suite 206
Reno, Nevada 89521
775-850-1440

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing First Amended Stipulation as its decision as to Respondent Raymond Bradbury Graber, D.D.S., Certificate of Registration No. 27126, in Case No. 23-340-RPH-N and hereby orders that the terms of the foregoing First Amended Stipulation be made effective immediately upon execution below.

IT IS SO ORDERED.

Entered this 18th day of October 2023.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 26th day of October, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Lyn Beggs, Esq.
328 California Ave #3
Reno, NV 89509

SHIRLEY HUNTING

FILED
SEP 12 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

RAYMOND BRADBURY GRABER, D.D.S., Certificate of Registration No. CS27126,

Respondent.

Case No. 23-340-CS-N

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Raymond Bradbury Graber, D.D.S., ("Respondent") and this matter because, because at the time of the events alleged herein Respondent held a Nevada controlled substance registration, Certificate of Registration No. CS27126 issued by the Board.

FACTUAL ALLEGATIONS

2. On or about April 11, 2018, the Board initially issued Respondent Certificate of Registration to Dispense Controlled Substances, Certificate of Registration No. CS27126.

3. Respondent holds a current DEA registration which expires on September 30, 2023.

4. On or about August 27, 2022, Respondent was arrested for possession of 3.15 grams of cocaine, at or near 5650 South Carson Street, Carson City, State of Nevada.

5. On or about October 31, 2022, Respondent's Certificate of Registration No. CS27126 lapsed and was assigned non-renewed status by the Board.

6. On or about November 4, 2022, Respondent was charged for a violation of NRS 454.351, a misdemeanor, for possession of any drug which may not lawfully be introduced into interstate commerce under the Federal Food, Drug and Cosmetic Act.

7. On or about January 11, 2023, Respondent entered a guilty plea to a misdemeanor violation of NRS 454.351 and his sentencing was deferred for one year to allow for competition of a drug diversion program.

8. On or about February 15, 2023, Respondent submitted a late renewal application for Certificate of Registration No. CS27126.

9. Respondent failed to report his January 11, 2023, misdemeanor plea of guilty to a violation of NRS 454.351, within 30 days to the Board.

10. Respondent socially used cocaine prior to his arrest on August 27, 2022.

APPLICABLE LAW

11. Any person within this State who possesses, procures, obtains, produces, derives, manufactures, sells, offers for sale, gives away or otherwise furnishes any drug which may not be lawfully introduced into interstate commerce under the Federal Food, Drug and Cosmetic Act is guilty of a misdemeanor. NRS 454.351.

12. The holder of any certificate, license, or permit issued by the Board shall report to the Executive Secretary any conviction not later than 30 days after the conviction and provide any documentation of the conviction required by the Executive Secretary. The term "conviction" means a conviction for any crime, other than a misdemeanor traffic violation that does not involve the use of alcohol of a controlled substance, and includes: (a) final judgement; (b) plea of guilty or nolo contender; (c) plea pursuant to *North Carolina v. Alford*, 400 U.S. 25 (1970); or (d) guilty verdict following a bench trial or jury trial, regardless of whether a sentence is suspended or deferred, a final judgement of conviction has been entered or there are any pending appeals. Approved Regulation of the State Board of Pharmacy, LCB File No. R051-22, September 28, 2022.

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13. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.231(1)(h); NRS 453.236(1)(e) and NRS 453.241(1).

14. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

15. The Board may suspend or revoke any license or registration issued pursuant to NRS Chapter 639, and deny the application of any person for a certificate, license, registration or permit, if the holder of applicant has a substance abuse disorder. NRS 639.210(5).

16. Violating any provision of the Federal Food, Drug and Cosmetic Act is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

17. Violating, attempting to violate, assisting, or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

18. Administrative proceedings brought by the Board against a Respondent pursuant to NRS Chapter 453, to deny, suspend or revoke a registration must be initiated, conducted and concluded pursuant to the provisions of NRS 639.241 to NRS 639.257, and upon a finding of guilt against the Respondent, the Board shall suspend the right of the registrant to use his or her registration or a schedule thereof; or revoke the registration of a schedule thereof. NRS 453.241.

19. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation alleged in an accusation for which the holder is found guilty. NRS 639.255(1)(f) and (3); NAC 639.955.

20. This Accusation constitutes a public record pursuant to NRS 622.330 and any discipline imposed by the Board shall be reported to the National Practitioner Data Bank as required by federal law. Title 42 USC § 1396r–2; 45 CFR Part 60.

COUNT ONE
Failure to timely Report Conviction

21. By failing to report Respondent's guilty plea to the misdemeanor charge of NRS 454.351 within 30 days, Respondent violated Approved Regulation of the State Board of Pharmacy, LCB File No. R051-22, September 28, 2022. By failing to timely report his guilty plea, Respondent committed an act that renders his continued registration to dispense controlled substances in Nevada inconsistent with the public interest. Respondent is therefore subject to discipline pursuant to NRS 453.231(1)(h) and/or NRS 453.236(1)(e) and/or NRS 453.241(1) and/or NRS 639.255(1)(f) and (3).

COUNT TWO
Violation of the Federal Food, Drug, and Cosmetic Act

22. By pleading guilty to a violation of the Federal Food, Drug and Cosmetic Act for possession of 3.15 grams of cocaine and admitting to social use of cocaine prior to his arrest on August 27, 2022, Respondent is subject to discipline pursuant to NRS 639.210(5) and/or (11) and/or (12), and/or NRS 639.255(1)(f) and (3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 11th day of September 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RAYMOND BRADBURY GRABER, D.D.S., Certificate of Registration No. CS27126,** **Respondent.**	**Case No. 23-340-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 11, 2023, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and p.keegan@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 12th day of September 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RAYMOND BRADBURY GRABER, D.D.S., Certificate of Registration No. CS27126,** **Respondent.**	**Case No. 23-340-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

RAYMOND BRADBURY GRABER, D.D.S.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of September, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Lyn Beggs
328 California Ave. Ste 3
Reno, NV 89509

Darlene Nases
DARLENE NASES

Nevada State Board of Pharmacy

For licensing inquires please send an email to, pharmacylicensing@pharmacy.nv.gov (mailto:pharmacylicensing@pharmacy.nv.gov).

For current information on **disciplinary actions taken against licensees**, please send an email to teambc@pharmacy.nv.gov (mailto:teambc@pharmacy.nv.gov).

VERIFY LICENSE

Last Name	First Name	License#	License Status	License Expiration Date	City	State	Discipline	Action
GRABER	RAYMOND	CS27126	Pending Renewal Probation	10/31/2026			Yes	

License Number : CS27126

Name : GRABER, RAYMOND

License Type : Controlled Substance

License Status : Pending Renewal Probation

License Date : 04/11/2018

Discipline : Yes

Expiration Date : 10/31/2026



Drop file(s) here to upload or click here to browse and select file(s) to upload. ()

Complete Upload Reset

Document Type	Upload Date	Name	Other Name	Is Public?	Status	Uploaded By	Link	Actions
Final Orders	10/27/2023	23-340-CS-N.1stAmended.SAO.Public.Graber.pdf		true		Shirley Hunting	Download ()	

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PATRICK AWA, RPH,** **Certificate of Registration No. 20399, and** **RALEY'S PHARMACY #123,** **Pharmacy License No. PH00999,** **Respondents.**	**Case Nos. 24-366-RPH-N** **24-366-PH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Board has jurisdiction over Respondent Raley's Pharmacy #123 (Respondent Raley's) because Respondent Raley's holds a license issued by the Board pursuant to NRS 639.230, authorizing Respondent Raley's to operate a pharmacy at 176 West Goldfield Avenue in Yerington, Nevada.

2. The Board has jurisdiction over Respondent Patrick Awa (Respondent Awa) because Respondent Awa is licensed by the Board pursuant to NRS 639.120 to practice pharmacy in Nevada.

3. The Board has jurisdiction over Respondents Raley's and Awa because the allegations below relate to their professional conduct as holders of a license or registration issued by the Board.

FACTUAL ALLEGATIONS

4. Between 2022 and 2025, Respondent Raley's employed Respondent Awa at its Raley's pharmacy location in Yerington, Nevada.

5. On July 3, 2024, Respondent Awa processed and filled a new prescription for patient R.S., for antibiotic ear drops. The pharmacy's automated prescription management system identified the prescription as "Rx No. 7047361."

6. Respondent Awa dispensed Rx No. 7047361 to the patient's wife, who later complained to the Board that Respondent Awa had not offered her counseling at the pharmacy counter when she picked up her husband's ear drops.

7. The Board investigated the complaint in September 2024.

8. Respondent Raley's was unable to supply the Board's investigator with video of the moment when Respondent Awa dispensed Rx No. 7047361. Respondent Raley's was unable to supply relevant video because Respondent Raley's does not retain video footage beyond 30 days.

9. Respondent Awa told the Board's investigator that he could not recall the incident on July 3, 2024, when he allegedly failed to offer counseling concerning Rx No. 7047361.

10. Respondent Awa further stated that he had no recollection of the person to whom he dispensed Rx No.7047361.

11. The complainant, a self-described retired pharmacist, admittedly did not ask questions of Respondent Awa when she picked up her husband's ear drops.

12. At all times relevant to this accusation, Respondent Raley's maintained a computerized record-keeping system for documenting pharmacist counseling.

13. According to Respondent Awa, the system automatically defaults to "Yes" as a means of documenting whether counseling was offered to the patient. In other words, unless the pharmacist manually enters a counseling entry, the system automatically registers a positive counseling entry regardless of whether the pharmacist counsels the patient.

14. As to Rx No. 7047361, Respondent Raley's record-keeping system did not correlate the counseling entry with the prescription number, the drug name, or the date or time of the presumed counseling.

15. Respondent Raley's system did not contain any counseling comments regarding Rx No. 7047361.

16. Respondent Awa permitted the pharmacy record-keeping system to default to "Yes" regarding Rx No. 7047361. This means that he did not enter comments, his electronic initials, or any other data into the system regarding Rx No. 7047361.

APPLICABLE LAW

17. The Board may discipline a pharmacy owner whose conduct in operating a pharmacy has been unprofessional or contrary to the public interest. NRS 639.210(4); NRS 639.255; NAC 639.945; NAC 639.955.

18. The Board may discipline any person whose conduct as a pharmacist has been unprofessional or contrary to the public interest. NRS 639.210(4); NRS 639.255; NAC 639.945; NAC 639.955.

19. A person's conduct is unprofessional and/or contrary to the public interest if the person performs his or her professional duties in a negligent, incompetent or unskillful manner. NAC 639.945(1)(i).

20. Generally, a pharmacist must verbally provide a patient or a person caring for the patient with information about each prescription drug or device dispensed to the patient. NRS 639.707(1). This is always true when the patient receives a new prescription. NAC 639.707(1).

21. In this case, because the medication was dispensed pursuant to a new prescription, Patient Awa had a duty to counsel the patient's spouse when he dispensed the medication associated with Rx No. 7047361.

22. Pursuant to NAC 639.707(6), a pharmacist must, at the time that counseling is provided or refused, enter his or her initials onto a record in a computerized system used by the pharmacy to document whether counseling was offered, rejected and/or provided.

23. In this case, Patient Awa had a duty to affirmatively make an electronic record of any counseling offered, provided, or rejected in connection with Rx No. 7047361.

24. To facilitate counseling regarding a prescription, a pharmacy must maintain a detailed history of each patient's prescription drug history so that the pharmacist can evaluate it before offering counseling. NAC 639.707(4); NAC 639.708(1).

25. To ensure that counseling enhances drug therapy, the record of counseling provided to the patient should reasonably correlate with details concerning the patient's prescription drug history, including the names of the drugs prescribed and the times and dates of counseling concerning those drugs. *See* NRS 639.266(1); NAC 639.707(4) and (6); NAC 639.708(1)(b).

26. A pharmacy is responsible for the negligent acts and/or omissions of the pharmacists whom the pharmacy employs. NAC 639.230(5); NAC 639.945(3).

COUNT ONE
Unprofessional Conduct by a Pharmacy

27. Respondent Raley's had a duty to facilitate counseling by its pharmacists.

28. Respondent Raley's had a duty to maintain a record-keeping system that facilitated counseling by its pharmacists, thereby enhancing drug therapy.

29. As alleged above, Respondent Raley's implemented a record-keeping system that automatically registered a positive counseling entry regardless of whether the pharmacist had counseled the patient.

30. As alleged above, Respondent Raley's implemented a record-keeping system that failed to correlate individual counseling entries with corresponding prescription numbers, drug names, and the dates and times of counseling.

31. By implementing a system that automatically registers a positive counseling entry regardless of whether the pharmacist counsels the patient, Respondent Raley's has breached its duty to facilitate counseling.

32. By implementing a record-keeping system that fails to correlate counseling entries with prescription numbers, drugs names and other identifiers concerning the medications that it dispenses to its patients, Respondent Raley's has breached its duty to enhance drug therapy through counseling.

33. By implementing a system that automatically registers a positive counseling entry regardless of whether the pharmacist counsels the patient, Respondent Raley's encourages its pharmacists to neglect their record-keeping obligations pursuant to NAC 639.707(6).

34. As a means of enhancing drug therapy through counseling, Respondent Raley's counseling records were and/or continue to be practically useless.

35. Having breached the duties described above, Respondent Raley's has performed its duties as the holder of a pharmacy license in a negligent, incompetent or unskillful manner.

36. Respondent Raley's may be disciplined by the Board for the unprofessional conduct as described above. Alternatively, Respondent Raley's may be disciplined by the Board for the unprofessional conduct of Respondent Awa as alleged in Count Two below.

COUNT TWO
Unprofessional Conduct by a Pharmacist

37. As alleged above, Respondent Awa had a duty to offer counseling to the patient or to the patient's caregiver when he dispensed the medication associated with Rx No. 7047361.

38. As alleged above, Respondent Awa had a duty to make an affirmative record of any counseling offered or provided or rejected in connection with Rx No. 7047361.

39. Respondent Awa neglected to provide counseling to the patient or to the patient's caregiver, and/or he failed to make an affirmative record of any counseling offered, provided, or rejected in connection with Rx No. 7047361.

40. Having omitted to perform either or both of the duties described above, Respondent Awa performed his duties as a pharmacist in a negligent, incompetent, or unskillful manner.

41. Respondent Awa may be disciplined by the Board for his unprofessional conduct as described above.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Patrick Awa and the pharmacy license of Respondent Raley's Pharmacy #123.

DATED this 23rd day of FEBRUARY, 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RALEY'S PHARMACY #123,** **Pharmacy License No. PH00999,** **Respondent.**	**Case No. 24-366-PH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 15, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Gregory Zunino, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 23rd day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RALEY'S PHARMACY #123,** **Pharmacy License No. PH00999,** **Respondent.**	**Case No. 24-366-PH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR RALEY'S PHARMACY #123

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of February 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Raley's Pharmacy #123
176 W Goldfield Ave.
Yerington, NV 89447

And via courtesy EMAIL: Jennifer Hall (jhall125@raleys.com)
Simon Cai (gcai@raleys.com)

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
FEB 2 3 2026
NEVADA STATE BOARD
OF PHARMACY

MAILED
2/24/26

Raley's Pharmacy #123
176 W Goldfield Ave.
Yerington, NV 89447
24-366-PH-N. NIAA

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YERINGTON, NV 89447
February 26, 2026, 10:01 am

Pre-Shipment, USPS Awaiting Item
February 25, 2026

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What Do USPS Tracking Statuses Mean? (https://faq.usps.com/s/article/Where-is-my-package)

Text & Email Updates

Return Receipt Electronic

USPS Tracking Plus®

Feedback

4159

From:	Erin Miller
To:	jhall125@raleys.com; gcai@raleys.com
Cc:	Gregory Zunino; Darlene Nases
Subject:	NVBOP Case No. 24-366-PH-N
Date:	Tuesday, February 24, 2026 2:34:51 PM
Attachments:	24-366-PH-N. NIAA. Raley"s Pharmacy #123.pdf

Hello,

The notice of intended action and accusation has been sent out via certified/regular mail. Please see attached courtesy copy for Case No. 24-366-PH-N regarding Raley's Pharmacy #123, Pharmacy License No. PH00999.

If you are to have any questions, please contact Greg Zunino (zunino@pharmacy.nv.gov).

Thank you,

Erin Miller
Administrative Assistant - Board Coordinator II
Nevada State Board of Pharmacy
Office: (775) 850-1440
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521
emiller@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

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FILED
FEB 2 3 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PATRICK AWA, RPH,** **Certificate of Registration No. 20399, and** **RALEY'S PHARMACY #123,** **Pharmacy License No. PH00999,** **Respondents.**	**Case Nos. 24-366-RPH-N** **24-366-PH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Board has jurisdiction over Respondent Raley's Pharmacy #123 (Respondent Raley's) because Respondent Raley's holds a license issued by the Board pursuant to NRS 639.230, authorizing Respondent Raley's to operate a pharmacy at 176 West Goldfield Avenue in Yerington, Nevada.

2. The Board has jurisdiction over Respondent Patrick Awa (Respondent Awa) because Respondent Awa is licensed by the Board pursuant to NRS 639.120 to practice pharmacy in Nevada.

3. The Board has jurisdiction over Respondents Raley's and Awa because the allegations below relate to their professional conduct as holders of a license or registration issued by the Board.

FACTUAL ALLEGATIONS

4. Between 2022 and 2025, Respondent Raley's employed Respondent Awa at its Raley's pharmacy location in Yerington, Nevada.

5. On July 3, 2024, Respondent Awa processed and filled a new prescription for patient R.S., for antibiotic ear drops. The pharmacy's automated prescription management system identified the prescription as "Rx No. 7047361."

6. Respondent Awa dispensed Rx No. 7047361 to the patient's wife, who later complained to the Board that Respondent Awa had not offered her counseling at the pharmacy counter when she picked up her husband's ear drops.

7. The Board investigated the complaint in September 2024.

8. Respondent Raley's was unable to supply the Board's investigator with video of the moment when Respondent Awa dispensed Rx No. 7047361. Respondent Raley's was unable to supply relevant video because Respondent Raley's does not retain video footage beyond 30 days.

9. Respondent Awa told the Board's investigator that he could not recall the incident on July 3, 2024, when he allegedly failed to offer counseling concerning Rx No. 7047361.

10. Respondent Awa further stated that he had no recollection of the person to whom he dispensed Rx No.7047361.

11. The complainant, a self-described retired pharmacist, admittedly did not ask questions of Respondent Awa when she picked up her husband's ear drops.

12. At all times relevant to this accusation, Respondent Raley's maintained a computerized record-keeping system for documenting pharmacist counseling.

13. According to Respondent Awa, the system automatically defaults to "Yes" as a means of documenting whether counseling was offered to the patient. In other words, unless the pharmacist manually enters a counseling entry, the system automatically registers a positive counseling entry regardless of whether the pharmacist counsels the patient.

14. As to Rx No. 7047361, Respondent Raley's record-keeping system did not correlate the counseling entry with the prescription number, the drug name, or the date or time of the presumed counseling.

15. Respondent Raley's system did not contain any counseling comments regarding Rx No. 7047361.

16. Respondent Awa permitted the pharmacy record-keeping system to default to "Yes" regarding Rx No. 7047361. This means that he did not enter comments, his electronic initials, or any other data into the system regarding Rx No. 7047361.

APPLICABLE LAW

17. The Board may discipline a pharmacy owner whose conduct in operating a pharmacy has been unprofessional or contrary to the public interest. NRS 639.210(4); NRS 639.255; NAC 639.945; NAC 639.955.

18. The Board may discipline any person whose conduct as a pharmacist has been unprofessional or contrary to the public interest. NRS 639.210(4); NRS 639.255; NAC 639.945; NAC 639.955.

19. A person's conduct is unprofessional and/or contrary to the public interest if the person performs his or her professional duties in a negligent, incompetent or unskillful manner. NAC 639.945(1)(i).

20. Generally, a pharmacist must verbally provide a patient or a person caring for the patient with information about each prescription drug or device dispensed to the patient. NRS 639.707(1). This is always true when the patient receives a new prescription. NAC 639.707(1).

21. In this case, because the medication was dispensed pursuant to a new prescription, Patient Awa had a duty to counsel the patient's spouse when he dispensed the medication associated with Rx No. 7047361.

22. Pursuant to NAC 639.707(6), a pharmacist must, at the time that counseling is provided or refused, enter his or her initials onto a record in a computerized system used by the pharmacy to document whether counseling was offered, rejected and/or provided.

23. In this case, Patient Awa had a duty to affirmatively make an electronic record of any counseling offered, provided, or rejected in connection with Rx No. 7047361.

24. To facilitate counseling regarding a prescription, a pharmacy must maintain a detailed history of each patient's prescription drug history so that the pharmacist can evaluate it before offering counseling. NAC 639.707(4); NAC 639.708(1).

25. To ensure that counseling enhances drug therapy, the record of counseling provided to the patient should reasonably correlate with details concerning the patient's prescription drug history, including the names of the drugs prescribed and the times and dates of counseling concerning those drugs. *See* NRS 639.266(1); NAC 639.707(4) and (6); NAC 639.708(1)(b).

26. A pharmacy is responsible for the negligent acts and/or omissions of the pharmacists whom the pharmacy employs. NAC 639.230(5); NAC 639.945(3).

COUNT ONE
Unprofessional Conduct by a Pharmacy

27. Respondent Raley's had a duty to facilitate counseling by its pharmacists.

28. Respondent Raley's had a duty to maintain a record-keeping system that facilitated counseling by its pharmacists, thereby enhancing drug therapy.

29. As alleged above, Respondent Raley's implemented a record-keeping system that automatically registered a positive counseling entry regardless of whether the pharmacist had counseled the patient.

30. As alleged above, Respondent Raley's implemented a record-keeping system that failed to correlate individual counseling entries with corresponding prescription numbers, drug names, and the dates and times of counseling.

31. By implementing a system that automatically registers a positive counseling entry regardless of whether the pharmacist counsels the patient, Respondent Raley's has breached its duty to facilitate counseling.

32. By implementing a record-keeping system that fails to correlate counseling entries with prescription numbers, drugs names and other identifiers concerning the medications that it dispenses to its patients, Respondent Raley's has breached its duty to enhance drug therapy through counseling.

33. By implementing a system that automatically registers a positive counseling entry regardless of whether the pharmacist counsels the patient, Respondent Raley's encourages its pharmacists to neglect their record-keeping obligations pursuant to NAC 639.707(6).

34. As a means of enhancing drug therapy through counseling, Respondent Raley's counseling records were and/or continue to be practically useless.

35. Having breached the duties described above, Respondent Raley's has performed its duties as the holder of a pharmacy license in a negligent, incompetent or unskillful manner.

36. Respondent Raley's may be disciplined by the Board for the unprofessional conduct as described above. Alternatively, Respondent Raley's may be disciplined by the Board for the unprofessional conduct of Respondent Awa as alleged in Count Two below.

COUNT TWO
Unprofessional Conduct by a Pharmacist

37. As alleged above, Respondent Awa had a duty to offer counseling to the patient or to the patient's caregiver when he dispensed the medication associated with Rx No. 7047361.

38. As alleged above, Respondent Awa had a duty to make an affirmative record of any counseling offered or provided or rejected in connection with Rx No. 7047361.

39. Respondent Awa neglected to provide counseling to the patient or to the patient's caregiver, and/or he failed to make an affirmative record of any counseling offered, provided, or rejected in connection with Rx No. 7047361.

40. Having omitted to perform either or both of the duties described above, Respondent Awa performed his duties as a pharmacist in a negligent, incompetent, or unskillful manner.

41. Respondent Awa may be disciplined by the Board for his unprofessional conduct as described above.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Patrick Awa and the pharmacy license of Respondent Raley's Pharmacy #123.

DATED this 21st day of FEBRUARY, 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PATRICK AWA, RPH,** **Certificate of Registration No. 20399,** **Respondent.**	**Case No. 24-366-RPH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 15, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Gregory Zunino, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 23rd day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PATRICK AWA, RPH,** **Certificate of Registration No. 20399,** **Respondent.**	**Case No. 24-366-RPH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

PATRICK AWA, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of February 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Patrick Awa, RPH
[redacted]
Yerington, NV [redacted]

Patrick Awa, RPH
c/o Raley's Pharmacy #123
176 W Goldfield Ave.
Yerington, NV 89447

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
MAR 11 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PATRICK AWA, RPH,** **Certificate of Registration No. 20399,** **Respondent.**	**Case No. 24-366-RPH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

See attached.

From:	Mr. Awa Patrick
To:	Board Coordination
Cc:	Gregory Zunino
Subject:	Response and Mitigation Statement for Case No. 24-366-RPH-N
Date:	Tuesday, March 10, 2026 4:52:43 PM
Attachments:	DEA investigator contact card from 2024 audit.pdf Email to employer regarding compliance obligations.pdf Supervisor evaluation excerpt.pdf Warning letter from the Nevada State Board of Pharmacy.pdf

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Dear Members of the Nevada State Board of Pharmacy,

I respectfully submit this response and mitigation statement regarding the complaint (Case No. 24-366-RPH-N) filed against me. I take the Board's concerns seriously and I remain committed to the highest standards of pharmacy practice and regulatory compliance.

Throughout my career I have made consistent efforts to follow pharmacy laws and professional standards in all the states that I have been privileged to serve in. I have always approached my duties with the goal of protecting patient safety and complying with state and federal regulations.

I understand the importance of proper documentation and I acknowledge the Board's concerns regarding documentation requirements. I remain committed to ensuring that all counseling and documentation obligations are met fully and consistently in my practice.

My record reflects a pattern of compliance and diligence in pharmacy practice.

In 2024, while serving as pharmacy manager in Yerington Nevada, the pharmacy underwent a DEA audit conducted by a diversion investigator from the U.S. Department of Justice Drug Enforcement Administration. During this audit, the investigator reviewed our compliance practices and commented positively on my efforts to maintain compliance with controlled substance regulations. The investigator asked me to keep up the good work and provided me with a business card following the audit, which I have attached for reference. If the Board wishes to verify the audit findings, the DEA Reno Resident Office should have records of the inspection and its conclusions.

Pharmacy technician Sandra Zavala (Tel: [redacted]) was present during the audit and heard the investigator comment on my compliance efforts. She would be able to confirm this if the Board wished to contact her.

In addition, documentation from my prior employment in Minnesota reflects that my supervisors recognized my commitment to regulatory compliance. In that evaluation my supervisor stated that I "follow the law by the books and that I consistently acted in an ethical and compliant manner." This statement reflects the approach I have consistently taken in my professional practice. You will find these statements on page 5 of the document I am submitting with the file name, "Supervisor evaluation excerpt."

I also previously communicated with my employer emphasizing my obligation to comply with pharmacy law and regulatory requirements. In that communication I expressed my position that legal requirements must be followed even when company policies may differ or when I get overwhelmed by the company's expected metrics. This communication further reflects my longstanding commitment to lawful and ethical pharmacy practice. The commutation submitted under file name "Email to employer regarding compliance obligations" was sent to the Raleys Pharmacy supervisors the same month the incidence in this allegation occurred and should serve as a description of the mindset I had then and ever. I no longer work with Raleys and cannot tell if they still have a copy of this communication on their server but my technicians, including Sandra Zavala, named above were availed of this commutation and they all joined me to anxiously wait for the reply or outcome that never came.

The warning letter I received from the Board in May 2025 advised me to be cautious regarding documentation obligations. The incident referenced in the current complaint occurred prior to that warning letter. Since receiving that notice, I have been even more attentive to documentation procedures and compliance requirements.

I respectfully ask the Board to consider these facts as mitigating circumstances. My professional history demonstrates a consistent effort to comply with pharmacy laws and regulations, and there is no intention on my part to disregard regulatory obligations.

I remain fully committed to practicing pharmacy in accordance with Nevada law and to maintaining the trust placed in pharmacists by patients, employers, and regulators. The statements I submitted during the investigation and now constitute my truth. I will trust and hope that you did your own investigation and will make a decision based on the truth that you found and I plead that you do so not without the entity of my own truth and mindset here submitted.

Thank you for your time and consideration.

Respectfully submitted,

Patrick Awa

Pharmacist License No. 20399

Attachments:

DEA investigator contact card from 2024 audit

Supervisor evaluation excerpt

Email to employer regarding compliance obligations

Warning letter from the Nevada State Board of Pharmacy



U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Au'Driann Schroeder
Diversion Investigator
Drug Enforcement Administration

Reno Resident Office
8790 Double Diamond Parkway
Reno, NV 89521

Telephone: 775-221-5709
Office: 571-362-2466
Email: AuDriann.H.Schroeder@dea.gov

New message

Inbox 2
Unread
Starred

Sent
Drafts 4
Scheduled

Trash
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Folders
New Folder
Drafts
NDSU
ourpaddy
SMS GIRLS
Synced Messages
USBank 22
VIM
Walgreens emails

Storage

← Back

patient safe

No internet connection.

Our Paddy Patrick
To: Our · Sun, Jul 21, 2024 at 5:32 PM

Greetings

I have had time to review the outcome of the meeting and the plan of action and I think that it is important to remind you on how we got here.

We had two technicians last summer. I took a two weeks' vacation in October. While I was away, one of the technicians, Sandra called out because her son was sick. It became difficult for the covering pharmacist and the lone technician to get the work done. It only took a week for that technician to get burned out to put in her quit notice before I returned. I came back on a Wednesday and met prescriptions that were received on Monday in the que.

I had to re-strategize to find a way out. In situations like that, prioritizing is usually the key. I told Sandra that we have to prioritize the compliance on the Federal law, state law and patient safety and that we will close the pharmacy the day I feel that we were not able to meet these challenges. I reminded her about this several times so much that she thought that I was kidding but I was serious about that.

When the board of pharmacy came in last November, the board representative told us that the cashier is not allowed to put drugs on the shelves.

To comply with the law and abide by the company policy, it has consistently been determined that we needed 88 technician hours per week to get that work done. Having only Sandra meant that I was only able to access 45% of the required technician hours. Sandra has gone above and beyond to ensure that we survive as a pharmacy. On her own accord, she sacrificed the 15-minute breaks accorded to her to stay and work. Sandra did not take a single 15 minutes break through the time that she was here and left less than a week to her delivery date. I cannot humanly look her in the eyes and say anything than reminding her that she has been doing a greet job.

On my part, I have worked for several days without a technician. I worked some days until 8:00 pm to ensure that we don't fall behind. The days that I worked without a technician, I had to put drugs away after closing at 6:30 pm. As we struggled through this, I kept on checking on the weekly evaluations and asking myself "have we become the worse performing pharmacy in the chain yet?" Would we have received a plan of action on the days that I worked alone and had to put drugs away after 6:30 pm?

There is one think I can assure you of. I have reviewed the plan of action with the technician and we made a commitment to do our best to comply. Be rest assured that we will not bend the state/federal law in order to meet these requirements with 45% of the workforce. We will also not knowingly compromise patient safety. Any further sacrifice by the technicians will be voluntary and not mandated under me.

I do understand that there is a pharmacist that can hurriedly compromise the law and patient safety in order to appear 100% compliant to the company policy. I am unfortunately not that pharmacist.

Thanks

Patrick Awa

Reply Forward

Starred Contact

GIG Spe
Everywh
[redacted]
excluded from price guarante

Annual Performance Review (FY21) for Retail Management

Review Period 9/1/2020 - 8/31/2021

REVIEWER

NICOLE MARIHART (Manager)

PATRICK AWA

Salaried Pharmacist (72 hours)
Position

[redacted]
User ID

Overview

Task Instructions

Welcome! The Annual Performance Review (APR) is a pivotal process for fostering a winning culture where people are inspired and motivated to deliver great results for our customers and stakeholders.

What to Expect:

- Self -Review: For team members, this is an opportunity to reflect on demonstration of the leadership behaviors for their role this year, bring awareness to the contributions they have made and identify opportunities for improvement and future success in the new performance year.
- Manager Review: Manager rates team member's demonstration of the Leadership Behaviors at the level that aligns to their role and is able to view any comments completed as a part of the Self-Review step. The performance goal rating (provided by Finance) will be uploaded into the system after calibration.
- Calibration: Managers will be required to get input on team member's leadership behavior ratings. This step should confirm that the manager has held or participated in a calibration AND that the rating provided is final. Managers will not be able to make changes to the rating after this point.
- Discussions & Acknowledgement: During this step, the manager will view the final overall performance rating with the performance goal rating (from Finance) included. The submission of this step closes out the process and confirms that team member and manager had a conversation around the final performance rating.

I'm ready to get started!

SCROLL DOWN and click on **GET STARTED** to proceed. Note that the sections to the left may help you navigate through the task. Once all sections have been completed, and you hit SUBMIT, the overall performance review score will be recorded.

Rate Leadership Behaviors

Directions

Performance Review for **PATRICK AWA**

This section addresses Walgreens' Purpose-Driven Leadership Behaviors – Care, Win Together and Inspire. Please rate the team member's demonstration of the Leadership Behaviors at the level that aligns to their role.

To Do:

1. Click Here to retrieve the Leadership Behavior rating scale for each level.
2. **Rate** each of the leadership behaviors using the rating scale in the drop down.
3. Click **Save and Continue** to move onto the next section or click **Save and Exit** to exit the review and come back later.
4. When you are ready to finalize the ratings, click the **Submit** button to complete this portion of the review.

Rating Scale

Score	Description
1	Not Achieving Expectations
2	Partially Achieving Expectations
3	Achieving Expectations
4	Exceeding Expectations
5	Outstanding

"Care"

Caring genuinely for everyone by connecting personally

(Please refer to the appropriate Leadership Behavior Descriptions)

Reviewer	Rating Scale
NICOLE MARIHART (Manager)	3

Comments

NICOLE MARIHART (Manager):
- puts customers first and shows them appreciation

- very professional - even with upset customers

- Takes the time to listen and asks questions

  - always open to suggestions for improvement

"Inspire"

Empowering each other to continuously raise the bar and fulfill our purpose

(Please refer to the appropriate Leadership Behavior Descriptions)

Reviewer	Rating Scale
NICOLE MARIHART (Manager)	3

Comments

NICOLE MARIHART (Manager):
- Takes ownership to learn and grow rapidly

- Embraces change

  - opportunity: work on supporting the technicians and keep a consistent work flow to provide a fast and pleasant experience for everyone on the team

"Win Together"

Winning together by collaborating to deliver our best work with simplicity and ease

(Please refer to the appropriate Leadership Behavior Descriptions)

Reviewer	Rating Scale
NICOLE MARIHART (Manager)	3

Comments

NICOLE MARIHART (Manager):
- Applies knowledge confidently to guide others

- Consistently acts in an ethical and compliant manner

  - by the book with rules and laws

Comments from another location
- Could improve time management and prioritization skills (keeping up with waiters, immunizations, F4, product verification, counseling, answering phone calls, etc.) all while still keeping up with VBPT.
- Be able to answer newer technician questions (daily tasks, SATR, smart count, OOS/PFL's, scanning the order)
Overall improvement includes: increasing speed while maintaining accuracy, F4'ing and verifying prescriptions in a timely manner, not setting problematic prescriptions aside, and staying on top of immunizations

Calibration - RATING NOT INCLUDED IN OVERALL SCORE - '1' INDICATES CALIBRATION HAS BEEN COMPLETED

Directions

Performance Review for PATRICK AWA

This is the calibration step of the Performance Review process. As part of the calibration step, District, Area and Region Leaders review ratings for fairness and consistency.

To Do:

1. Consult with District/Area/Region Leaders and Field HR partners during the calibration meeting to agree upon any rating changes that should be made. Ratings should not be changed prior to calibration meetings taking place.
2. Once you have participated in the calibration session, re-enter the task to make the calibrated adjustments. Note: You will need to click through all the sections of the review, even if you are not making adjustments.
3. Select **Yes** (below) to acknowledge that the calibration meeting has taken place.
4. Click the **Submit** button to complete the calibration step.

Have you completed the calibration step, and finalized your ratings for this team member?

Note: This step is required so you must select "Yes" and "Submit" even if you did not make calibrated adjustments. Once submitted, the step will move under your completed/expired tasks until the calibration step due date.

Reviewer	Rating Scale
NICOLE MARIHART (Manager)	1

Performance Goal Rating

Directions

Performance Review for PATRICK AWA

The **Performance Goals** section establishes one overall rating of performance against established goals.

1. The Performance Goal Rating is based on Improve Scorecard metrics, and is automatically uploaded to the system.
2. In addition to the overall rating, information regarding targets/actuals for each measure has been included. These metrics are not intended to be edited.
3. Click the **Submit** button to progress through this portion of the review.

Additional Information

Position Reviewed As See Comments Below

One overall Performance Goal Rating is automatically loaded to the review.

Reviewer	Rating Scale	Weight
NICOLE MARIHART (Manager)	3.0	100%

Comments

NICOLE MARIHART (Manager): ***Please note:*** *only those metrics applicable to your position(s) and location(s) were utilized to calculate your performance goal score, however, you may see additional metric details included for reference.*

Area #: 98 -- Position: RPH - Float -- Score: 3.0

- **Total Payroll Hours (% Variance to Budget)** -- Score: 4.1
  Target: 0.00%; Actual: -2.11%; Variance: -2.11%
  Monthly Results: Sep: 3 / Oct: 3 / Nov: 2 / Dec: 4 / Jan: 5 / Feb: 4 / Mar: 4 / Apr: 5 / May: 5 / Jun: 5 / Jul: 5 / Aug: 4
- **Total Rph Payroll Hours (% Variance to Budget)** -- Score: 3.8
  Target: 0.00%; Actual: -1.71%; Variance: -1.71%
  Monthly Results: Sep: 3 / Oct: 2 / Nov: 2 / Dec: 4 / Jan: 2 / Feb: 4 / Mar: 5 / Apr: 5 / May: 5 / Jun: 5 / Jul: 4 / Aug: 4
- **Self Service Sales** -- Score: 3
  Target: -0.78%; Actual: -0.23%; Variance: 0.55%
- **Total Script Count (90 Day & Control Adjusted)** -- Score: 3
  Target: 6.94%; Actual: 10.24%; Variance: 3.30%
- **Patient Promise (% Eligible Rx Verified By Promise Time, No Controls)** -- Score: 3
  Target: 76.18%; Actual: 76.95%; Variance: 0.77%
- **Adherence (PDC80) Period 1: 09/2020 to 12/2020** -- Score: 2
  Target: 86.66%; Actual: 86.52%; Variance: -0.14%
- **Adherence (PDC80) Period 2: 01/2021 to 08/2021** -- Score: 4
  Target: 92.88%; Actual: 92.66%; Variance: -0.22%

- **Specialty Patient Growth** -- Score: 2
  Target: 8.68%; Actual: 5.08%; Variance: -3.60%
- **Turn Around Time** -- Score: 4
  Target: 2.54; Actual: 2.13; Variance: 0.41

Summary

Overall Rating

Annual Performance Review (FY21) for Retail Management
PATRICK AWA

3.0 - Achieving Expectations

	Team Member Self-Review	Finalized Manager Review
Rate Leadership Behaviors		3.0 / 5.0
Performance Goal Rating		3.0 / 5.0
Overall		3.0 / 5.0

Governor

President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA
BOARD OF PHARMACY
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

May 12, 2025

Via Certified/Standard U.S. Mail and Email
Patrick Awa
Certificate of Registration No. 20399
[redacted]
Yerington NV [redacted]
[redacted]

Case No. 24-088-RPH-N, Warning Concerning Prescription Dispensing Practices

Dear Dr. Awa:

The Nevada State Board of Pharmacy ("Board") has reviewed a complaint submitted on behalf of patient L.D. regarding an alleged medication dispensing error at Raley's Pharmacy, located at 176 W. Goldfield Avenue in Yerington, where you serve as the managing pharmacist. According to the complaint, Raley's Pharmacy concurrently filled patient L.D.'s two prescriptions for levothyroxine--one calling for 25 mcg tablets and another calling for 50 mcg tablets. Based upon these facts alone, one could reasonably conclude that patient L.D. had received conflicting dosing instructions and/or an excessive quantity of levothyroxine, thus jeopardizing patient safety.

In your response to the Board, you confirmed that all prescriptions were filled in accordance with what was received from the prescribers and that the patient had multiple providers issuing different orders. You also indicated that L.D.'s wife requested fills of the earlier prescriptions, which contributed to some tension and miscommunication at the pharmacy. The Board's investigation concluded that the pharmacy filled the prescriptions as written and that no harm to the patient was reported.

However, as the managing pharmacist, you have an obligation to adequately document the history of any prescription received and/or filled by the pharmacy. *See* NRS 639.220; NAC 639.935. A documented history must include enough detail to permit an audit of any given prescription on the basis of pharmacy records alone. *See* NAC 639.935(1). Here, the history of the two prescriptions in question had to be partially reconstructed from memory and without the benefit of an adequately detailed record of salient events. See NAC 639.935(3)(g)(4).

Accordingly, the purpose of this letter is to caution you regarding your record-keeping responsibilities as outlined in NAC 639.935.

If you have any questions about this warning letter, or your ability to contest any of the above findings, please contact the Board's Senior General Counsel, Gregory Zunino, at 775-850-1440, ext. 124, or via email at zunino@pharmacy.nv.gov.

Sincerely,

Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PATRICK AWA, RPH,** **Certificate of Registration No. 20399, and** **RALEY'S PHARMACY #123,** **Pharmacy License No. PH00999,** **Respondents.**	**Case No. 24-366-RPH-N** **24-366-PH-N** **STIPULATION AND ORDER** **(Respondent Patrick Awa Only)**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through its Senior General Counsel, Gregory L. Zunino, and Respondent Patrick Awa ("Respondent") hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that he understands the terms of this Stipulation and Proposed Order ("Stipulation"), and he has executed it knowingly and voluntarily.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, and NRS Chapter 639, the Nevada Pharmacy Act.

5. Conditioned on the acceptance of this Stipulation by the Board and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this

Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent does not contest the allegations stated in the Accusations on file herein, and he further admits that evidence exists, and that the Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violation alleged against him in Count Two of the Accusation, to wit:

A. Between 2022 and 2025, Respondent was employed by Raley's Pharmacy #123 at its pharmacy location in Yerington, Nevada.

B. On July 3, 2024, Respondent processed and filled a new prescription for patient R.S., for antibiotic ear drops. The pharmacy's automated prescription management system identified the prescription as "Rx No. 7047361."

C. Respondent dispensed Rx No. 7047361 to the patient's wife, who later complained to the Board that Respondent had not offered her counseling at the pharmacy counter when she picked up her husband's ear drops.

D. When questioned about Rx No. 7047361, Respondent stated that he had no recollection of dispensing the prescription.

E. At the time of the incident described above, Raley's Pharmacy #123 maintained a computerized record-keeping system for documenting pharmacist counseling.

F. According to Respondent, the system automatically defaulted to "Yes" as a means of documenting whether counseling was offered to the patient.

G. The system did not contain any counseling comments regarding Rx No. 7047361, nor did it contain Respondent's electronic initials, or any other data regarding Rx No. 7047361.

H. Respondent admittedly failed to document whether he offered or provided patient counseling in connection with Rx No. 7047361.

7. To resolve this case without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following discipline:

A. Respondent shall pay a fine of **Seven Hundred Fifty and 00/100 Dollars ($750.00)**. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before May 31, 2026.

B. Respondent shall pay the sum of **Five Hundred and 00/100 Dollars ($500.00)**. to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this case. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before May 31, 2026.

C. On or before May 31, 2026, Respondent shall complete two credit hours of continuing education on the topic of pharmacy record keeping. Respondent shall supply proof of completion by sending a certificate of completion or other proof satisfactory to the Board's staff (teambc@pharamcy.nv.gov). The above credit hours shall be in addition to the credit hours that Respondent is otherwise required to complete pursuant to NAC 639.330.

8. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 24-366-RPH-N as it pertains to Respondent. However, any failure by Respondent to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing him to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in the finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

9. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on April 15, 2026, in Reno, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear at the meeting.

10. The Board may accept this Stipulation, but it has no obligation to accept this Stipulation. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all of this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the date of entry set forth below.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Date: March 18, 2026.

PATRICK AWA, RPH
Certificate of Registration No. 20399

Date: March 17, 2026

NEVADA STATE BOARD OF PHARMACY

By: /s/ Gregory L. Zunino
GREGORY L. ZUNINO
Senior General Counsel
Nevada Bar No. 4805

DECISION AND ORDER

As to Respondent Patrick Awa, in Case No. 24-366-RPH-N, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and orders that its terms and conditions be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 15th day of April 2025.

Helen Park, President
Nevada State Board of Pharmacy

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FILED
JUL 2 4 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH02018,** **and** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388,** **Respondents.**	**Case Nos. 24-370-PH-N** **24-370-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (the "Board"), files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Board has jurisdiction over Respondent PharMerica ("Respondent PharMerica"), the holder of Pharmacy License No. PH02018, because Respondent PharMerica is licensed by the Board to operate a pharmacy at 4750 Longley Lane in Reno, Nevada.

2. The Board has jurisdiction over Respondent Camilla Kim, RPh ("Respondent Kim"), the holder of Certificate of Registration No. 19388, because Respondent Kim is registered by the Board to engage in the practice of pharmacy in Nevada.

FACTUAL ALLEGATIONS

3. Respondent PharMerica operates a pharmacy in Reno, Nevada.

4. In March 2024, Respondent Kim was employed by Respondent PharMerica as a pharmacist.

5. In 2023 and 2024, Respondent PharMerica was under contract with MorningStar Senior Living of Sparks ("MorningStar"), an assisted living facility, to dispense prescription medication and provide medication management services to residents of the MorningStar facility.

6. Respondent PharMerica worked cooperatively with the nursing staff at MorningStar to store and deliver prescription medications for the residents of the MorningStar facility.

7. In 2023 and 2024, patient D.P., an 87-year-old female, resided at MorningStar, where she received medication and medication management services from Respondent PharMerica.

8. In 2023 and 2024, patient D.P. required levothyroxine for hypothyroidism.

9. Between March 2023 and March 2024, Respondent PharMerica dispensed levothyroxine to patient D.P. without interruption, according to the instructions of patient D.P.'s physician.

10. On March 6, 2024, patient D.P.'s physician issued her a new prescription for levothyroxine. The prescription directed Respondent PharMerica to dispense an initial 90-day supply of levothyroxine with two refills.

11. On its face, the above prescription sufficed to meet patient D.P.'s medical needs for 12 months.

12. Patient D.P.'s physician electronically transmitted the above prescription to Respondent PharMerica.

13. Respondent PharMerica assigned no. 343217 to the above prescription. Per standard operating procedure, PharMerica processed prescription no. 343217 at its facility in Kentucky.

14. At the facility in Kentucky, a pharmaceutical technician transferred the information from the electronic prescription to a computerized prescription management system.

15. When transferring the prescription information, the technician incorrectly entered code "X90D" related to the "duration" of medication treatment. This code suppressed the automatic refill

function on the system, thus instructing the system to terminate patient D.P.'s supply of levothyroxine after just 90 days.

16. Since patient D.P.'s levothyroxine was considered a "maintenance" medication, there should not have been a duration code associated with prescription no 343217.

17. In March 2024, before dispensing any medication under prescription no. 343217, Respondent Kim verified the prescription at PharMerica's facility in Reno.

18. When verifying the above prescription, Respondent Kim failed to notice that the duration code X90D, as described above, was inconsistent with the number of refill authorizations on the prescription itself. As noted above, this code instructed the automated system to terminate patient D.P.'s supply of levothyroxine after just 90 days.

19. In June of 2024, due to Respondent Kim's omission as described above, PharMerica failed to refill patient D.P.'s prescription for levothyroxine as directed by her physician.

20. Between June and September 2024, the nursing staff at MorningStar delivered no levothyroxine to patient D.P., and they made no inquiries of PharMerica concerning the abrupt cessation of patient D.P.'s medication treatment.

21. In August or September 2024, patient D.P.'s daughter observed that her mother's health had rapidly declined for no apparent reason. She alerted the nursing staff at MorningStar and/or patient D.P.'s physician.

22. In September 2024, Patient D.P. was admitted to the intensive care unit at Renown Hospital, where she was diagnosed with myxedema coma and cellulitis in her left leg. These medical conditions were caused by the cessation of medication treatment with levothyroxine.

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APPLICABLE LAW

23. The Board may discipline the holder of a license or registration issued by the Board if the holder engages in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

24. Unprofessional conduct includes "failing strictly to follow the instructions of the person writing, making or ordering a prescription or chart order as to its filling or refilling." NAC 639.945(1)(d).

25. Unprofessional conduct includes performing one's duties as the holder of a certificate of registration issued by the Board in an "incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

26. A pharmacist has a duty to supervise a pharmaceutical technician who performs one or more of the functions necessary to prepare a prescription. NAC 639.252. This includes the duty to verify the selection and strength of the drug, the dosage form, and the labeling of the prescription. NAC 639.252(2).

27. A pharmacist has a duty to maintain a record of each refill of a prescription. NAC 639.918.

28. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of its employees. NRS 639.230(5), NAC 639.702 and NAC 639.945(3).

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COUNT ONE
Unprofessional Conduct by a Pharmacist
(Respondent Kim)

29. As alleged above, Respondent Kim verified prescription no. 343217 for levothyroxine, including two refills. In verifying the prescription, Respondent Kim failed to notice that a pharmaceutical technician in Kentucky had incorrectly entered a duration code into PharMerica's prescription management system, thus causing the system to suppress the automatic refill function.

30. Respondent Kim had a duty to supervise the pharmaceutical technician in Kentucky who performed data entry tasks related to prescription no. 343217.

31. Respondent Kim had a duty to correct the data entry error described above.

32. Respondent Kim had a duty to strictly follow the instructions of patient D.P.'s physician as to the refilling of no. 343217.

33. Respondent Kim performed the above duties in an incompetent, unskillful or negligent manner.

34. Due to Respondent Kim's unprofessional conduct as described above, patient D.P. suffered harm.

35. For her unprofessional conduct as described above Respondent Kim is subject to professional discipline pursuant to NRS 639.210(4) and NAC 639.945.

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COUNT TWO

Employer Liability for Unprofessional Conduct
(Respondent PharMerica)

36. Respondent Kim engaged in unprofessional conduct as described above.

37. As Respondent Kim's employer at the time, Respondent PharMerica is responsible for the unprofessional conduct as described above. NRS 639.230(5), NAC 639.702 and NAC 639.945(3).

38. For said unprofessional conduct, Respondent PharMerica is subject to professional discipline pursuant to NRS 639.210(4) and NAC 639.945.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Camilla Kim and the pharmacy license of Respondent PharMerica.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH02018,** **Respondent.**	**Case No. 24-370-PH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24 day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH02018,** **Respondent.**	**Case No. 24-370-PH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR PharMerica

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

PharMerica
4750 Longley Ln #204
Reno, NV 89502

Camilla Kim, RPh
[redacted]
Reno, NV [redacted]

PharMerica
c/o Camilla Kim, RPh
4750 Longley Ln #204
Reno, NV 89502

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
AUG 29 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH0218,** **and** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388.** **Respondents.**	**Case Nos. 24-370-PH- N** **24-370-RPH-N** **RESPONDENTS' ANSWER AND NOTICE OF DEFENSE**

Respondents PharMerica and Camilla Kim, RPH, hereby file with the Nevada State Board of Pharmacy ("Board"), their Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on July 24, 2025.

ANSWER TO ACCUSATION

Jurisdiction: Paragraphs 1-2

Paragraph 1: Respondent PharMerica acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 1.

Paragraph 2: Respondent Kim acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 2.

Factual Allegations: Paragraphs 3-22

Paragraph 3: Respondent PharMerica acknowledges that it operates a pharmacy located in Reno, Nevada as set forth in Paragraph 3.

Paragraph 4: Respondent Kim acknowledges that she was employed by PharMerica in March 2024 as set forth in Paragraph 4.

Paragraph 5: Respondent PharMerica acknowledges that during the time periods set forth in Paragraph 5, it did dispense prescribed medication to residents of MorningStar Senior Living of Sparks as set forth in Paragraph 5.

Paragraph 6: Respondent PharMerica agrees with the factual assertions set forth in Paragraph 6 to the extent the PharMerica coordinated deliveries of prescribed and dispensed medication to the nursing staff of MorningStar Senior Living.

Paragraph 7: Respondent PharMerica agrees that patient D.P. did receive some medication management services in the time frame noted in Paragraph 7.

Paragraph 8: Respondents are without sufficient personal knowledge to respond to the factual assertions contained in Paragraph 8.

Paragraph 9: Respondent PharMerica agrees with the factual assertions in Paragraph 9 to the extent that patient D.P. received levothyroxine in 2023 through the end of February 2024.

Paragraph 10: Respondent PharMerica agrees with the factual assertions set forth in Paragraph 10 to the extent that a new prescription (no. 343217, the "Prescription") was issued March 6, 2024, by patient D.P.'s physician. However, the directions for the prescription were for one tablet daily for a 90-day duration with three refills, not two refills as noted in Paragraph 10 and further the prescription authorized three refills but did not direct automatic refills of the Prescription.

Paragraph 11: Respondents are without personal knowledge to substantively respond to the factual assertions set forth in Paragraph 11, however Respondents acknowledge that had the Prescription been refilled by patient D.P. as allowed, there would have been approximately twelve months of medication authorized by the physician.

Paragraph 12: Respondent PharMerica acknowledges that it received Prescription no. 343217 electronically.

Paragraph 13: Respondent PharMerica agrees with the factual assertions set forth in Paragraph 13.

Paragraph 14: Based on information and belief, Respondent PharMerica agrees that a PharMerica pharmacy technician would have transcribed the Prescription information into PharMerica's computerized prescription management system.

Paragraph 15: Respondents deny that the pharmacy technician incorrectly entered code "X90D" into the prescription management system. The technician correctly entered the Prescription and directions into the prescription management system; because the Prescription directions included a duration, the prescription management system automatically assigned the code to the Prescription. The prescription management system did not terminate D.P.'s supply of levothyroxine at the end of the initial ninety days; the Prescription was still active and simply needed to be refilled by MorningStar Senior Living.

Paragraph 16: Respondents disagree with the factual assertions contained in Paragraph 16; prescriptions, including prescriptions for "maintenance" medications, often have a duration associated with them.

Paragraph 17: Respondent Kim acknowledges that she verified Prescription no. 343217 before the Prescription was initially dispensed on March 19, 2024.

Paragraph 18: Respondent Kim denies that she failed to notice the duration code and asserts that the Prescription directions included a duration with refills to follow. Nothing indicated that the Prescription was to be automatically refilled. As noted above, the system did not "terminate" the supply of levothyroxine, the Prescription was still active and could be refilled.

Paragraph 19: Respondents deny the factual allegations set forth in Paragraph 19.

Paragraph 20: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 20.

Paragraph 21: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 21.

Paragraph 22: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 22.

Applicable Law: Paragraphs 23-28

Paragraph 23: Respondents agree that Paragraph 23 sufficiently reflects the contents of NRS 639.210(4).

Paragraph 24: Respondents agree that Paragraph 24 sufficiently reflects the contents of NAC 639.945(1)(d).

Paragraph 25: Respondents agree that Paragraph 25 sufficiently reflects the contents of NAC 639.945(1)(i).

Paragraph 26: Respondents agree that Paragraph 26 sufficiently reflects the contents of NAC 639.252(2).

Paragraph 27: Respondents agree that Paragraph 27 sufficiently reflects the contents of NAC 639.918.

Paragraph 28: Respondents agree that Paragraph 28 sufficiently reflects the contents of NRS 639.230(5), NAC 639.702, and NAC 639.945(3).

Count One (Paragraphs 29-35, Respondent Kim

Paragraph 29: Respondent Kim agrees that she verified Prescription no. 343217, which allowed three refills, not two as alleged. However, Respondent Kim denies the remaining allegations contained in Paragraph 29.

Paragraph 30: Respondent Kim does not work in the same location as the pharmacy technician who transcribed the information regarding the Prescription into the PharMerica computerized prescription management system, however Respondent Kim asserts that the technician did not incorrectly input the Prescription into the prescription management system. As described above, the prescription management system grabs the directions of the Prescription for generation of system codes. Regarding Prescription no. 343217, the physician's instructions included a duration and accordingly the system generated the appropriate code.

Paragraph 31: Respondent Kim denies the allegations contained in Paragraph 31 and contends that there was no error.

Paragraph 32: Respondent Kim agrees that she had a duty to strictly follow the instructions of the prescribing physician and that those instructions were indeed followed.

Paragraph 33: Respondent Kim denies the allegations contained in Paragraph 33.

Paragraph 34: Respondent Kim denies the allegations contained in Paragraph 34.

Paragraph 35: Paragraph 35 does not require a response from Respondent Kim.

Count Two (Paragraphs 36-38, Respondent PharMerica):

Paragraph 36: Respondent PharMerica denies the allegations contained in Paragraph 36.

Paragraph 37: Respondent PharMerica agrees it is responsible for Respondent Kim's conduct as an employed pharmacist but again denies that Respondent Kim engaged in unprofessional conduct as set forth in Paragraph 37.

Paragraph 38: Paragraph 38 does not require a substantive response from Respondent PharMerica.

NOTICE OF DEFENSE/MITIGATING INFORMATION

Respondents reserve all legal defenses available to them in this matter.

Respondents further assert that no violation of NRS or NAC Chapters 639 has occurred in this matter. The Prescription was received on March 6, 2024, electronically and was properly entered into the PharMerica computerized prescription management system by a pharmacy technician. The technician appropriately entered the information into the prescription management system, including the duration which was included on the Prescription sent electronically by patient D.P.'s physician. Per the Prescription directions, the prescription management system entered a code of "X90D"; however, that did not terminate the Prescription at the end of 90-days but rather required a refill to be requested. The Prescription, as written, did not direct automatic refills. Respondents are without knowledge of why the nursing staff at MorningStar Senior Living failed to request the refill of levothyroxine, however Respondents assert that neither Respondent PharMerica nor Respondent Kim violated NRS/NAC Chapter 639 as alleged.

Respectfully submitted this 29th of August, 2025.

Lyn E. Beggs, Esq.
Attorney for Respondents

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FILED
JUL 2 4 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH02018,** **and** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388,** **Respondents.**	**Case Nos. 24-370-PH-N** **24-370-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (the "Board"), files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Board has jurisdiction over Respondent PharMerica ("Respondent PharMerica"), the holder of Pharmacy License No. PH02018, because Respondent PharMerica is licensed by the Board to operate a pharmacy at 4750 Longley Lane in Reno, Nevada.

2. The Board has jurisdiction over Respondent Camilla Kim, RPh ("Respondent Kim"), the holder of Certificate of Registration No. 19388, because Respondent Kim is registered by the Board to engage in the practice of pharmacy in Nevada.

FACTUAL ALLEGATIONS

3. Respondent PharMerica operates a pharmacy in Reno, Nevada.

4. In March 2024, Respondent Kim was employed by Respondent PharMerica as a pharmacist.

5. In 2023 and 2024, Respondent PharMerica was under contract with MorningStar Senior Living of Sparks ("MorningStar"), an assisted living facility, to dispense prescription medication and provide medication management services to residents of the MorningStar facility.

6. Respondent PharMerica worked cooperatively with the nursing staff at MorningStar to store and deliver prescription medications for the residents of the MorningStar facility.

7. In 2023 and 2024, patient D.P., an 87-year-old female, resided at MorningStar, where she received medication and medication management services from Respondent PharMerica.

8. In 2023 and 2024, patient D.P. required levothyroxine for hypothyroidism.

9. Between March 2023 and March 2024, Respondent PharMerica dispensed levothyroxine to patient D.P. without interruption, according to the instructions of patient D.P.'s physician.

10. On March 6, 2024, patient D.P.'s physician issued her a new prescription for levothyroxine. The prescription directed Respondent PharMerica to dispense an initial 90-day supply of levothyroxine with two refills.

11. On its face, the above prescription sufficed to meet patient D.P.'s medical needs for 12 months.

12. Patient D.P.'s physician electronically transmitted the above prescription to Respondent PharMerica.

13. Respondent PharMerica assigned no. 343217 to the above prescription. Per standard operating procedure, PharMerica processed prescription no. 343217 at its facility in Kentucky.

14. At the facility in Kentucky, a pharmaceutical technician transferred the information from the electronic prescription to a computerized prescription management system.

15. When transferring the prescription information, the technician incorrectly entered code "X90D" related to the "duration" of medication treatment. This code suppressed the automatic refill

function on the system, thus instructing the system to terminate patient D.P.'s supply of levothyroxine after just 90 days.

16. Since patient D.P.'s levothyroxine was considered a "maintenance" medication, there should not have been a duration code associated with prescription no 343217.

17. In March 2024, before dispensing any medication under prescription no. 343217, Respondent Kim verified the prescription at PharMerica's facility in Reno.

18. When verifying the above prescription, Respondent Kim failed to notice that the duration code X90D, as described above, was inconsistent with the number of refill authorizations on the prescription itself. As noted above, this code instructed the automated system to terminate patient D.P.'s supply of levothyroxine after just 90 days.

19. In June of 2024, due to Respondent Kim's omission as described above, PharMerica failed to refill patient D.P.'s prescription for levothyroxine as directed by her physician.

20. Between June and September 2024, the nursing staff at MorningStar delivered no levothyroxine to patient D.P., and they made no inquiries of PharMerica concerning the abrupt cessation of patient D.P.'s medication treatment.

21. In August or September 2024, patient D.P.'s daughter observed that her mother's health had rapidly declined for no apparent reason. She alerted the nursing staff at MorningStar and/or patient D.P.'s physician.

22. In September 2024, Patient D.P. was admitted to the intensive care unit at Renown Hospital, where she was diagnosed with myxedema coma and cellulitis in her left leg. These medical conditions were caused by the cessation of medication treatment with levothyroxine.

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APPLICABLE LAW

23. The Board may discipline the holder of a license or registration issued by the Board if the holder engages in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

24. Unprofessional conduct includes "failing strictly to follow the instructions of the person writing, making or ordering a prescription or chart order as to its filling or refilling." NAC 639.945(1)(d).

25. Unprofessional conduct includes performing one's duties as the holder of a certificate of registration issued by the Board in an "incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

26. A pharmacist has a duty to supervise a pharmaceutical technician who performs one or more of the functions necessary to prepare a prescription. NAC 639.252. This includes the duty to verify the selection and strength of the drug, the dosage form, and the labeling of the prescription. NAC 639.252(2).

27. A pharmacist has a duty to maintain a record of each refill of a prescription. NAC 639.918.

28. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of its employees. NRS 639.230(5), NAC 639.702 and NAC 639.945(3).

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COUNT ONE
Unprofessional Conduct by a Pharmacist
(Respondent Kim)

29. As alleged above, Respondent Kim verified prescription no. 343217 for levothyroxine, including two refills. In verifying the prescription, Respondent Kim failed to notice that a pharmaceutical technician in Kentucky had incorrectly entered a duration code into PharMerica's prescription management system, thus causing the system to suppress the automatic refill function.

30. Respondent Kim had a duty to supervise the pharmaceutical technician in Kentucky who performed data entry tasks related to prescription no. 343217.

31. Respondent Kim had a duty to correct the data entry error described above.

32. Respondent Kim had a duty to strictly follow the instructions of patient D.P.'s physician as to the refilling of no. 343217.

33. Respondent Kim performed the above duties in an incompetent, unskillful or negligent manner.

34. Due to Respondent Kim's unprofessional conduct as described above, patient D.P. suffered harm.

35. For her unprofessional conduct as described above Respondent Kim is subject to professional discipline pursuant to NRS 639.210(4) and NAC 639.945.

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COUNT TWO
Employer Liability for Unprofessional Conduct
(Respondent PharMerica)

36. Respondent Kim engaged in unprofessional conduct as described above.

37. As Respondent Kim's employer at the time, Respondent PharMerica is responsible for the unprofessional conduct as described above. NRS 639.230(5), NAC 639.702 and NAC 639.945(3).

38. For said unprofessional conduct, Respondent PharMerica is subject to professional discipline pursuant to NRS 639.210(4) and NAC 639.945.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Camilla Kim and the pharmacy license of Respondent PharMerica.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388,** **Respondent.**	**Case No. 24-370-RPH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388,** **Respondent.**	**Case No. 24-370-RPH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Camilla Kim, RPh

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

PharMerica
4750 Longley Ln #204
Reno, NV 89502

Camilla Kim, RPh
[redacted]
Reno, NV [redacted]

PharMerica
c/o Camilla Kim, RPh
4750 Longley Ln #204
Reno, NV 89502

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATORY

FILED
AUG 29 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH0218,** **and** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388.** **Respondents.**	**Case Nos. 24-370-PH- N** **24-370-RPH-N** **RESPONDENTS' ANSWER AND NOTICE OF DEFENSE**

Respondents PharMerica and Camilla Kim, RPH, hereby file with the Nevada State Board of Pharmacy ("Board"), their Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on July 24, 2025.

ANSWER TO ACCUSATION

Jurisdiction: Paragraphs 1-2

Paragraph 1: Respondent PharMerica acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 1.

Paragraph 2: Respondent Kim acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 2.

Factual Allegations: Paragraphs 3-22

Paragraph 3: Respondent PharMerica acknowledges that it operates a pharmacy located in Reno, Nevada as set forth in Paragraph 3.

Paragraph 4: Respondent Kim acknowledges that she was employed by PharMerica in March 2024 as set forth in Paragraph 4.

Paragraph 5: Respondent PharMerica acknowledges that during the time periods set forth in Paragraph 5, it did dispense prescribed medication to residents of MorningStar Senior Living of Sparks as set forth in Paragraph 5.

Paragraph 6: Respondent PharMerica agrees with the factual assertions set forth in Paragraph 6 to the extent the PharMerica coordinated deliveries of prescribed and dispensed medication to the nursing staff of MorningStar Senior Living.

Paragraph 7: Respondent PharMerica agrees that patient D.P. did receive some medication management services in the time frame noted in Paragraph 7.

Paragraph 8: Respondents are without sufficient personal knowledge to respond to the factual assertions contained in Paragraph 8.

Paragraph 9: Respondent PharMerica agrees with the factual assertions in Paragraph 9 to the extent that patient D.P. received levothyroxine in 2023 through the end of February 2024.

Paragraph 10: Respondent PharMerica agrees with the factual assertions set forth in Paragraph 10 to the extent that a new prescription (no. 343217, the "Prescription") was issued March 6, 2024, by patient D.P.'s physician. However, the directions for the prescription were for one tablet daily for a 90-day duration with three refills, not two refills as noted in Paragraph 10 and further the prescription authorized three refills but did not direct automatic refills of the Prescription.

Paragraph 11: Respondents are without personal knowledge to substantively respond to the factual assertions set forth in Paragraph 11, however Respondents acknowledge that had the Prescription been refilled by patient D.P. as allowed, there would have been approximately twelve months of medication authorized by the physician.

Paragraph 12: Respondent PharMerica acknowledges that it received Prescription no. 343217 electronically.

Paragraph 13: Respondent PharMerica agrees with the factual assertions set forth in Paragraph 13.

Paragraph 14: Based on information and belief, Respondent PharMerica agrees that a PharMerica pharmacy technician would have transcribed the Prescription information into PharMerica's computerized prescription management system.

Paragraph 15: Respondents deny that the pharmacy technician incorrectly entered code "X90D" into the prescription management system. The technician correctly entered the Prescription and directions into the prescription management system; because the Prescription directions included a duration, the prescription management system automatically assigned the code to the Prescription. The prescription management system did not terminate D.P.'s supply of levothyroxine at the end of the initial ninety days; the Prescription was still active and simply needed to be refilled by MorningStar Senior Living.

Paragraph 16: Respondents disagree with the factual assertions contained in Paragraph 16; prescriptions, including prescriptions for "maintenance" medications, often have a duration associated with them.

Paragraph 17: Respondent Kim acknowledges that she verified Prescription no. 343217 before the Prescription was initially dispensed on March 19, 2024.

Paragraph 18: Respondent Kim denies that she failed to notice the duration code and asserts that the Prescription directions included a duration with refills to follow. Nothing indicated that the Prescription was to be automatically refilled. As noted above, the system did not "terminate" the supply of levothyroxine, the Prescription was still active and could be refilled.

Paragraph 19: Respondents deny the factual allegations set forth in Paragraph 19.

Paragraph 20: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 20.

Paragraph 21: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 21.

Paragraph 22: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 22.

Applicable Law: Paragraphs 23-28

Paragraph 23: Respondents agree that Paragraph 23 sufficiently reflects the contents of NRS 639.210(4).

Paragraph 24: Respondents agree that Paragraph 24 sufficiently reflects the contents of NAC 639.945(1)(d).

Paragraph 25: Respondents agree that Paragraph 25 sufficiently reflects the contents of NAC 639.945(1)(i).

Paragraph 26: Respondents agree that Paragraph 26 sufficiently reflects the contents of NAC 639.252(2).

Paragraph 27: Respondents agree that Paragraph 27 sufficiently reflects the contents of NAC 639.918.

Paragraph 28: Respondents agree that Paragraph 28 sufficiently reflects the contents of NRS 639.230(5), NAC 639.702, and NAC 639.945(3).

Count One (Paragraphs 29-35, Respondent Kim

Paragraph 29: Respondent Kim agrees that she verified Prescription no. 343217, which allowed three refills, not two as alleged. However, Respondent Kim denies the remaining allegations contained in Paragraph 29.

Paragraph 30: Respondent Kim does not work in the same location as the pharmacy technician who transcribed the information regarding the Prescription into the PharMerica computerized prescription management system, however Respondent Kim asserts that the technician did not incorrectly input the Prescription into the prescription management system. As described above, the prescription management system grabs the directions of the Prescription for generation of system codes. Regarding Prescription no. 343217, the physician's instructions included a duration and accordingly the system generated the appropriate code.

Paragraph 31: Respondent Kim denies the allegations contained in Paragraph 31 and contends that there was no error.

Paragraph 32: Respondent Kim agrees that she had a duty to strictly follow the instructions of the prescribing physician and that those instructions were indeed followed.

Paragraph 33: Respondent Kim denies the allegations contained in Paragraph 33.

Paragraph 34: Respondent Kim denies the allegations contained in Paragraph 34.

Paragraph 35: Paragraph 35 does not require a response from Respondent Kim.

Count Two (Paragraphs 36-38, Respondent PharMerica):

Paragraph 36: Respondent PharMerica denies the allegations contained in Paragraph 36.

Paragraph 37: Respondent PharMerica agrees it is responsible for Respondent Kim's conduct as an employed pharmacist but again denies that Respondent Kim engaged in unprofessional conduct as set forth in Paragraph 37.

Paragraph 38: Paragraph 38 does not require a substantive response from Respondent PharMerica.

NOTICE OF DEFENSE/MITIGATING INFORMATION

Respondents reserve all legal defenses available to them in this matter.

Respondents further assert that no violation of NRS or NAC Chapters 639 has occurred in this matter. The Prescription was received on March 6, 2024, electronically and was properly entered into the PharMerica computerized prescription management system by a pharmacy technician. The technician appropriately entered the information into the prescription management system, including the duration which was included on the Prescription sent electronically by patient D.P.'s physician. Per the Prescription directions, the prescription management system entered a code of "X90D"; however, that did not terminate the Prescription at the end of 90-days but rather required a refill to be requested. The Prescription, as written, did not direct automatic refills. Respondents are without knowledge of why the nursing staff at MorningStar Senior Living failed to request the refill of levothyroxine, however Respondents assert that neither Respondent PharMerica nor Respondent Kim violated NRS/NAC Chapter 639 as alleged.

Respectfully submitted this 29th of August, 2025.

Lyn E. Beggs, Esq.
Attorney for Respondents

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FILED
JUL 2 4 2025
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476,** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484, and** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos. 24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Sean Arora, M.D., ("Respondent Arora"), because Respondent Arora holds a certificate of registration issued by the Board authorizing him to prescribe controlled substances in Nevada. Respondent Arora holds certificate of registration no. CS31476, which was issued by the Board pursuant to NRS 453.226 and 453.231.

2. The Board has personal jurisdiction over Respondent Cassie Gifford, APRN, ("Respondent Gifford"), because Respondent Gifford holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent Gifford holds certificate of

registration no. PR18034, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.[1]

3. The Board has personal jurisdiction over Respondent Gabrielle McIntyre, APRN, ("Respondent McIntyre"), because Respondent McIntyre holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR17484, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.

4. The Board has personal jurisdiction over Respondent Allison Jaggard, APRN, ("Respondent Jaggard"), because Respondent Jaggard holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR171499, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850

5. The Board has jurisdiction over the subject matter of this accusation because it alleges violations involving the purchase, receipt, storage, possession, prescribing and/or dispensing of dangerous drugs and controlled substances. As used herein, "dangerous drug" has the meaning ascribed to it in NRS 454.201, and "controlled substance" means a substance listed in NAC 453.510 to NAC 453.550, inclusive, or in 21 CFR Part 1308.

FACTUAL ALLEGATIONS

6. Respondent Arora is a physician licensed by the Nevada State Board of Medical Examiners to practice medicine in Nevada. At all times alleged herein, Respondent Arora was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

7. Respondent Gifford is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent

1. Respondent Gifford formerly held certificate of registration no. CS34942, authorizing her to prescribe controlled substances. Certificate of registration no. CS34942 was not renewed when it came due for renewal on November 1, 2024.

Gifford was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

8. Respondent McIntyre is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

9. Respondent Jaggard is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

10. In 2024, Respondent Arora formed a partnership or other business relationship with We Treat, a medical consulting firm based in San Diego, California. We Treat provides consulting services and regulatory compliance advice to medical spas and wellness clinics.

11. We Treat provided consulting services and compliance advice to Youth, Inc. (Youth Inc.), the owner of a medical spa and wellness clinic located at 695 Sierra Rose Drive in Reno, Nevada.

12. We Treat developed a manual of policies, procedures and protocols for use by Youth Inc. Respondent Arora approved these policies, procedures and protocols for use by Youth Inc.

13. Between April 2024 and March 2025, Youth Inc. provided various anti-aging and wellness treatments for its patients. These included cosmetic treatments using botulinum toxin type A and dermal fillers, treatments for weight loss using compounded tirzepatide and semaglutide products, hormone replacement using injectable hormones, and treatment for erectile dysfunction using sildenafil and tadalafil.

14. Between April 2024 and March 2025, Youth Inc. did not lock or otherwise secure the dangerous drugs and/or controlled substances in its possession.

15. In early 2025, Youth Inc. was in possession of stock bottles containing sildenafil, tadalafil, and metformin hydrochloride, all dangerous drugs. Youth Inc.'s representatives claimed that

they were not planning to dispense these drugs until after they had secured a dispensing license issued by the Board.

16. We Treat arranged for Respondent Arora to serve as the "medical director" for Youth Inc., a role that Respondent Arora assumed sometime between April and August 2024.

17. Respondent Arora served as Youth Inc.'s medical director until early 2025.

18. During Respondent Arora's tenure as Youth Inc.'s medical director, Respondent Arora worked and resided in Seattle, Washington. Respondent Arora never visited Youth Inc.'s facility in Reno, Nevada.

19. Sometime between April 2024 and March 2025, Youth Inc. engaged the services of Respondent Gifford, Respondent McIntyre and Respondent Jaggard. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard rarely, if ever, visited Youth Inc.'s facility in Reno, Nevada.

20. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed a prospective patient's medical questionnaire prior to the prospective patient's initial treatment at Youth Inc. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed these medical questionnaires from a remote location and never saw or spoke to patients prior to their initial treatments at Youth Inc.

21. After reviewing medical questionnaires, and despite not ever seeing the patients in question, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the use or administration of dangerous drugs and/or controlled substances.

22. Sometime between April 2024 and March 2025, Youth Inc. employed Maddison Weiss-Frank, a registered nurse. Ms. Weiss-Frank was not an advanced practice registered nurse and was not a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

23. Ms. Weiss-Frank worked under the direction and supervision of Rachel Gonzalez, the co-owner and chief executive officer of Youth Inc. Ms. Gonzalez was not a "practitioner" as that term

is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125. On information and belief, Ms. Gonzalez has no formal medical training.

24. Because there was never a practitioner present at the location, Youth Inc.'s facility at 695 Sierra Rose Drive in Reno, Nevada, was not a location where a registered nurse could lawfully inject a neuromodulator pursuant to NRS 454.217.

25. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank treated patients using prescription drugs and/or controlled substances. Ms. Weiss-Frank did not act under the direction or supervision of a practitioner.

26. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances. Ms. Weiss-Frank did not work under the direction or supervision of a practitioner.

27. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

28. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

29. Consistent with the practice described above, Youth Inc. returned single-use vials to stock even after the vials were punctured and therefore rendered unusable for subsequent treatments.

30. As the medical director for Youth Inc., Respondent Arora periodically reviewed purchase invoices and signed for shipments of dangerous drugs and/or controlled substances.

31. As the medical director for Youth Inc., Respondent Arora periodically reviewed patient medical questionnaires and treatment records.

32. As the medical director for Youth Inc., Respondent Arora periodically reviewed Youth Inc.'s policies, procedures and protocols related to the procurement, storage, possession and administration of dangerous drugs and controlled substances.

33. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances without direction or supervision by a practitioner.

34. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank treated patients with prescription drugs and/or controlled substances despite not working under the supervision or direction of a practitioner.

35. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide .and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

36. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

37. As Youth Inc.'s medical director, Respondent Arora had a duty to understand Nevada law as it governs the receipt, possession, storage, and distribution of dangerous drugs and controlled substances.

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APPLICABLE LAW

38. It is unlawful for any person to engage in wholesale distribution, or permit to be distributed at wholesale, any drug or compound unless the person holds the appropriate certificate, license or permit issued by the Board. NRS 639.100(1).

39. To engage in wholesale distribution of any drug or compound in Nevada, a person must be licensed as a wholesaler or manufacturer, as applicable. NRS 639.100; NRS 639.233; NAC 639.593; NAC 639.6915.

40. The Board may revoke or suspend the registration of any practitioner who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapters 453, 454, 639, or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12); NRS 453.236.

41. Additionally, the Board may revoke or suspend the registration of any practitioner who is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4); NRS 453.236.

42. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner performs his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful, or negligent manner, or if the practitioner assists or abets a person not licensed to practice pharmacy in Nevada. NAC 639.945(1)(i) and (j).

43. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner prescribes or orders a dangerous drug or controlled substance for a person with whom the practitioner does not have a bona fide therapeutic relationship. NAC 639.945(1)(n).

44. "'Practice of pharmacy' includes, but is not limited to, the . . . [p]erformance or supervision of activities associated with manufacturing, compounding, labeling, dispensing and distributing of a drug, including the receipt, handling and storage of prescriptions and other confidential information relating to patients." NRS 639.0124(1)(a).

45. It is unlawful to possess, store, or administer dangerous drugs, including botulinum toxin type A and injectable dermal fillers, except as authorized by NRS 454.213.

46. It is unlawful to possess, store, or administer controlled substances, including testosterone, except as provided by NRS 453.375.

47. "Administer" means the direct application of a [dangerous drug or controlled substance] . . . whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject." NRS 453.021; NRS 454.191.

48. Pursuant to NRS 453.375, a registered nurse may not possess, store, or administer controlled substances except when working under the direction of a supervising practitioner.

49. Pursuant to NRS 454.213, a registered nurse may not possess, store, or administer dangerous drugs except at the direction of a supervising practitioner.

50. It is unlawful for a registered nurse to inject botulinum toxin type A in a patient or customer "at a location other than a medical facility, as defined in NRS 449.0151, or the office of a physician or physician assistant licensed [pursuant to applicable statutes]." NRS 454.217.

51. A person who maintains a stock of controlled substances and/or dangerous drugs must not commingle expired substances and unexpired substances in a storage area from which the substances are withdrawn from stock for administering or dispensing to patients. NAC 639.050(2).

52. A practitioner is subject to discipline if the practitioner causes or allows a dangerous drug to be dispensed in a manner not authorized by NRS 454.215 and NRS 454.301. *See* NRS 639.100; NRS 639.210(12).

53. The term "dispense" includes the prescribing by a practitioner, administering, packaging, labeling, or compounding necessary to prepare a substance for delivery to a patient. NRS 639.0065; NRS 453.056.

54. It is unlawful to furnish drugs without a prescription. NRS 454.221.

55. "Furnish" means to supply by any means, by sale or otherwise. NRS 454.006.

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COUNT ONE
Permitting Unlicensed Wholesale Distribution
(Respondent Arora)

56. As alleged above, Respondent Arora served as the medical director for Youth Inc.

57. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

58. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage purchases from unlicensed distributors such as GLP-1 Sciences, LLC. Respondent failed to implement such policies, procedures and protocols.

59. Given the facts and circumstances alleged above, Respondent Arora permitted the unlicensed wholesale distribution of compounded drug products in violation of NRS 639.100(1).

60. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

61. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT TWO
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondent Arora)

62. As alleged above, Respondent Arora served as the medical director for Youth Inc.

63. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered, received, possessed, and/or stored dangerous drugs and/or controlled substances. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

64. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of

Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

65. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the above persons from ordering, receiving, possessing, storing and/or furnishing dangerous drugs and/or controlled substances. Respondent Arora failed to implement such policies, procedures and protocols.

66. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the unlicensed practice of pharmacy.

67. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

68. Respondent Arora's acts and/or omissions as alleged above amount to conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(i) and (j).

COUNT THREE
Assisting or Abetting in Violations of NAC 639.050(2)
(Respondent Arora)

69. As alleged above, Respondent Arora served as the medical director for Youth Inc.

70. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

71. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the repeated or recurring use of punctured single-use vials. Respondent failed to implement such policies, procedures and protocols.

72. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the above violations of NAC 639.050(2).

73. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

74. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FOUR
Assisting or Abetting in Violations of NAC 639.050(2)
(Respondents Gifford, McIntyre and Jaggard)

75. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

76. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of injectable drugs contained within single-use vials.

77. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard had a duty to ensure that Youth Inc. did not make repeated or recurring uses of punctured single-use vials.

78. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that Youth Inc. did not return single-use vials to stock after the vials were punctured.

79. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard assisted or abetted in the above violations of NAC 639.050(2).

80. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

81. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FIVE
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondents Gifford, McIntyre and Jaggard)

82. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

83. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

84. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that dangerous drugs and/or controlled substances were administered under the direction or supervision of a practitioner. Dangerous drugs and/or controlled substances were not administered under the direction or supervision of a practitioner.

85. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard assisted or abetted the unlicensed practice of pharmacy by Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank.

86. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

87. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT SIX
Failure to Establish a Bona Fide Therapeutic Relationship with Patients (Respondents Gifford, McIntyre and Jaggard)

88. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

89. Respondent Gifford, Respondent McIntyre and Respondent Jaggard never saw or spoke with the above patients for whom they authorized treatments with dangerous drugs and/or controlled substances.

90. Having failed to see or speak with the above patients, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard failed to establish a bona fide therapeutic relationship with the above patients prior to authorizing their initial treatments with dangerous drugs and/or controlled substances.

91. Respondents' conduct as alleged above amounts to unprofessional conduct and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(n).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of Respondent Sean Arora, Respondent Cassie Gifford, Respondent Gabrielle McIntyre, and Respondent Allison Jaggard.

DATED this 24th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476,** **Respondent.**	**Case No. 24-509-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476,** **Respondent.**	**Case No. 24-509-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Sean Arora, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Sean Arora, MD
c/o Youth Inc
691 Sierra Rose Dr
Reno, NV 89511

Cassie Gifford, APRN
c/o Bionetics Health
5540 S Fort Apache Rd #120
Las Vegas, NV 89148

Gabrielle McIntyre, APRN
c/o Restore Hyper Wellness
1550 N Green Valley Pkwy., Ste 300
Henderson, NV 89074

Allison Jaggard, APRN
1708 Spring Green Blvd Ste 120-109
Katy, TX 77494

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
AUG 15 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484,** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos.** **24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **ANSWER AND NOTICE OF DEFENSE OF RESPONDENTS**

Respondents Sean Arora, M.D., Cassie Gifford, APRN, Gabrielle McIntyre, APRN, and Allison Jaggard, APRN, hereby file with the Nevada State Board of Pharmacy ("Board"), their Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on July 24, 2025.

ANSWER TO ACCUSATION

Jurisdiction: Paragraphs 1-5

Paragraph 1: Dr. Arora acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 1 of the Accusation to the extent that the matter pertains to controlled substances as he holds a controlled substance registration issued by the Board.

Paragraph 2: Ms. Gifford acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 2 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 3: Ms. McIntyre acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 3 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 4: Ms. Jaggard acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 4 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 5: Respondents acknowledge that the Board has jurisdiction in the matter to the extent that the matter involves dangerous drugs and controlled substances. Dr. Arora acknowledges that the Board has jurisdiction over the allegations pertaining to his acts or omissions to the extent they concern controlled substances.

Factual Allegations: Paragraphs 6-37

Paragraph 6: Dr. Arora agrees with the factual allegations as set forth in Paragraph 6.

Paragraph 7: Ms. Gifford agrees with the factual allegations as set forth in Paragraph 7.

Paragraph 8: Ms. McIntyre agrees with the factual allegations as set forth in Paragraph 8.

Paragraph 9: Ms. Jaggard agrees with the factual allegations as set forth in Paragraph 9.

Paragraph 10: Dr. Arora agrees with the factual allegations set forth in Paragraph 10 only to the extent that he entered into an independent contractor agreement with We Treat, LLC in 2024.

Paragraph 11: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 11 as to the types of services which were provided to Youth Inc. However, to the best of Respondents' knowledge, Youth Inc. did receive services from

We Treat related to medical clearances for patients, policies and protocols and compliance information.

Paragraph 12: Dr. Arora agrees with the factual allegations set forth in Paragraph 12 only to the extent that he reviewed and approved policies and protocols directly related to the provision of certain medical services. Dr. Arora was not involved, nor did he review or approve, policies and procedures related to any other matters involving Youth, Inc.

Paragraph 13: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 13.

Paragraph 14: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 14.

Paragraph 15: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 15.

Paragraph 16: Dr. Arora acknowledges that as part of his duties for We Treat, he was assigned as medical director for Youth, Inc. in approximately April 2024. Dr. Arora's duties as medical director included the review and approval of protocols for certain medical treatments performed at Youth, Inc., responding to patient specific questions from the clinic, and authorization of the ordering of certain dangerous drugs, to be done in accordance with compliance policies prepared by We Treat.

Paragraph 17: Dr. Arora agrees with the factual allegations contained in Paragraph 17 to the extent that he provided services to We Treat until January 2025, services which included acting as medical director for Youth,. Inc., which were limited to the duties set forth in the response to Paragraph 16.

Paragraph 18: Dr. Arora acknowledges that he was based in Seattle, Washington and that his duties for Youth, Inc. did not require him to be physically at Youth, Inc.'s location.

Paragraph 19: Respondent's Gifford, McIntyre, and Jaggard deny the factual allegations set forth in Paragraph 19. None of the named Respondents were engaged by Youth, Inc. to provide any services. All three Respondents were employees/independent contractors of We Treat which provided medical clearance screening of patients for Youth, Inc. through Nevada licensed practitioners.

Paragraph 20: Respondents Gifford, McIntyre, and Jaggard acknowledge that they reviewed and medically cleared patients for treatments performed at Youth, Inc. pursuant to medical protocols reviewed and approved by Dr. Arora and performed these reviews in accordance with policies and protocols developed and approved by We Treat, not Dr. Arora.

Paragraph 21: Respondents Gifford, McIntyre and Jaggard acknowledge that they medically cleared patients, if appropriate, after the review of medical information and authorized treatments to be performed pursuant to protocols approved by Dr. Arora which included standing orders for administration of certain drugs or the issuance of prescriptions pursuant to those protocols. No approved protocols for treatments authorized the administration of controlled substances at Youth, Inc.

Paragraph 22: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 22.

Paragraph 23: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 23.

Paragraph 24: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 24.

Paragraph 25: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 25.

Paragraph 26: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 26.

Paragraph 27: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 27.

Paragraph 28: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 28.

Paragraph 29: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 29.

Paragraph 30: Dr. Arora acknowledges that he would periodically review orders received for dangerous drugs and would sign, remotely for the same. Drugs were to be stored and accessed in accordance with policies and protocols developed by We Treat; Dr. Arora was not part of the development of those policies and procedures, nor was he asked to review them by We Treat. Dr. Arora denies that he ever signed off or approved of any shipments of controlled substances to Youth, Inc. and to his knowledge, no controlled substances were to be received or stored on-site at We Treat.

Paragraph 31: Dr. Arora denies the factual allegations contained in Paragraph 31, however he acknowledges that he would respond to patient specific questions posed to him and would review patient records at that time; however this occurred very rarely.

Paragraph 32: Dr. Arora denies the factual allegations contained in Paragraph 32. Dr. Arora was not responsible for the policies and procedures related to the procurement, storage, possession and/or administration of dangerous drugs or controlled substances other than approving

protocols directly related to the provision of medical services. We Treat's compliance department was solely responsible for the policies and protocols otherwise related to dangerous drugs and controlled substances.

Paragraph 33: Dr. Arora denies the allegations set forth in Paragraph 33.

Paragraph 34: Dr. Arora denies the allegations set forth in Paragraph 34.

Paragraph 35: Dr. Arora denies the allegations set forth in Paragraph 35.

Paragraph 36: Dr. Arora denies the allegations set forth in Paragraph 36.

Paragraph 37: Dr. Arora denies the allegations set forth in Paragraph 37 as he was not involved in, nor responsible for the receipt, possession storage, and distribution of dangerous drugs or controlled substances at Youth, Inc.

Applicable Law: Paragraphs 38-55

Paragraph 38-55: Respondents acknowledge that Paragraphs 38-55 accurately reflect the basic substance of the statutes and regulations cited therein.

Counts: Paragraphs 56-91

Count One (Paragraphs 56-61): Dr. Arora generally denies the allegations set forth in Count One in Paragraphs 56-61. Dr. Arora did not permit Youth, Inc. or any of its personnel to order any dangerous drugs from any manufacturer or supplier not licensed in Nevada. As discussed herein, Dr. Arora's duties for Youth, Inc. were limited to the review and authorization of protocols related to medical procedures. While Youth, Inc. was authorized to order supplies and dangerous drugs under Dr. Arora's credentials, this was to be done in accordance with policies and protocols developed and approved by We Treat's compliance department. To the best of Dr. Arora's knowledge, no client of We Treat was authorized to order or received dangerous drugs or other supplies from unlicensed suppliers/manufacturers.

Count Two (Paragraphs 62-68): Dr. Arora generally denies all allegations set forth in Count Two in Paragraphs 62-68. Further Dr. Arora asserts that a practice which orders, receives, and stores dangerous drugs is not engaging in the practice of pharmacy as alleged. If indeed this was accurate, every medical practice or facility that orders, receives and stores drugs for administration and/or dispensing, would be required to hold a pharmacy license with the Board; that is not currently a requirement and NRS 639.0124(1)(a) is inappropriately applied here.

Count Three (Paragraphs 69-74): Dr. Arora generally denies the allegations set forth in Count Three in Paragraphs 69-74. Again, as discussed herein, Dr. Arora's duties for Youth, Inc. were limited and did not include the development or approval of any protocols or procedures related to the procurement or storage of dangerous drugs. Dr. Arora's medical service protocols did not allow for the reuse of single use vials and any reuse of single use vials on the part of Youth, Inc. personnel would have been done without the knowledge of Dr. Arora and he did not aid or abet any violation of NAC 639.050(2).

Count Four (Paragraphs 75-81): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Four in Paragraphs 75-81. Respondents Gifford, McIntyre, and Jaggard, worked for We Treat, not Youth, Inc. Respondents' duties for Youth, Inc. were limited to conducting medical clearance reviews for patients and if cleared, the patient was authorized for treatment pursuant to approved medical protocols. None of the named respondents were responsible for supervising the staff of Youth, Inc. and would have had no knowledge of unauthorized reuse of single use vials by any personnel associated with Youth, Inc.

Count Five (Paragraphs 82-87): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Five in Paragraphs 75-81. The administration of dangerous drugs to patients is not the practice of pharmacy as defined by NRS 639.0124(1)(a) and

accordingly Respondents could not have aided or abetted in the violation of said statute. Again, as discussed above, should the Board take the position that the administration of a dangerous drug constitutes the practice of pharmacy, all practices and facilities at which any drug is administered would be required to hold a registration as a pharmacy with the Board which is not currently required.

Count Six (Paragraphs 88-91): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Six in Paragraphs 88-91.

NOTICE OF DEFENSE/MITIGATING INFORMATION

In regard to Respondent Arora, Dr. Arora stresses that his involvement with We Treat was limited as medical director. The term "medical director" is not defined under Nevada law and there is no legal precedent for what the duties of a medical director must consist of. Dr. Arora functioned as a medical director per the duties he had as a contractor for We Treat, LLC, which consisted solely of the review and authorization of protocols for medical services offered at practices contracted with We Treat and he was required to be available for consultations regarding specific patient questions as needed. The medical protocols authorized by Dr. Arora included standing orders for the administration of certain dangerous drugs and for the prescription of certain controlled substances. It should be noted that Dr. Arora never authorized the administration of controlled substances at Youth, Inc., or any other practice for which he provided services under We Treat and to his knowledge, no controlled substances were stored on-site at Youth, Inc.

We Treat's compliance department was responsible for the development and authorization of all other policies and protocols, including those related to the procurement, receipt, and storage of dangerous drugs. Dr. Arora was advised by We Treat that all policies and protocols were reviewed and vetted for compliance with the laws in each individual state in which We Treat had

clients. Dr. Arora had no reason to doubt the assurances made by We Treat that the policies and protocols for Youth, Inc. were in compliance with Nevada law.

In regard to Respondents Gifford, McIntyre, and Jaggard, all three were employees/contractors with We Treat during the times in question. Their duties were to provide medical clearance reviews for patients wishing to receive services at practices which were contracted with We Treat and if cleared, authorize treatment to be provide pursuant to previously approved medical protocols. Respondents had no duties related to the oversight or supervision of any practice served by We Treat. Respondents would be notified through a proprietary platform that a patient required a medical clearance evaluation at practices which received services from We Treat and would be given access to the patient records through the We Treat platform and would either clear the patient for treatment or deny treatment[1]. Each clinic had individual protocols which would be followed by Respondents. Respondents were informed by We Treat that policies related to requirements for providing medical clearance for patients was vetted by its compliance department and all protocols were in compliance with state laws; Respondents had no reason to question the representations of We Treat.

Respondent Gifford estimates that she performed very few medical clearance evaluations for Youth, Inc. through the We Treat platform. Respondent McIntyre estimates that she did approximately two medical clearance evaluations for Youth, Inc. Respondent Jaggard estimates that she did a maximum of ten to fifteen medical clearance evaluations for Youth, Inc.

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[1] We Treat practitioners only performed medical clearance evaluations for patients in states in which they were licensed.

All Respondents deny having violated NRS and/or NAC Chapters 453, 454, or 639. Further Respondents reserve all legal defenses available to them should this matter proceed to a hearing.

Respectfully submitted this 15th day of August, 2025.

Lyn E. Beggs, Esq.
Attorney for Respondents

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Registration No. CS31476,** **CASSIE GIFFORD, APRN,** **Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Registration No. PR17484, and** **ALLISON JAGGARD, APRN,** **Registration No. PR17499,** **Respondents.**	**Case No. 24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **STIPULATION AND ORDER** **(Respondent Arora Only)**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through its Senior General Counsel, Gregory L. Zunino, and Respondent Sean Arora, M.D. ("Respondent"), by and through his attorney, Lyn Beggs, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent timely responded to the Accusation by the filing of an Answer through his legal counsel.

4. Respondent acknowledges that he understands the terms of this Stipulation and Proposed Order ("Stipulation"), and he has executed it knowingly and voluntarily after consulting with counsel.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 453, the Nevada Controlled Substances Act, and NRS Chapter 639, the Nevada Pharmacy Act.

6. Conditioned on the acceptance of this Stipulation by the Board and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

7. As to Count One and Court Three of the Accusation, Respondent denies that he had the requisite knowledge of events to have committed the violations of law as stated therein. Regarding Count Two of the Accusation, Respondent disputes the characterization that he assisted or abetted in the "practice of pharmacy," but he acknowledges and admits that that Board staff prosecuting this case could present sufficient evidence at an administrative hearing, to establish a factual basis for the claim that he assisted or abetted in the unauthorized possession and administration of a dangerous drug, such that his conduct was contrary to the public interest, to wit:

A. Respondent, a physician, served as the medical director for Youth, Inc., a medical spa located at 691 Sierra Rose Drive in Reno, Nevada, through his contracted duties with We Treat, LLC.

B. During Respondent's tenure as medical director, Respondent was based in Seattle Washington, and he did not visit the spa's location at 691 Sierra Rose Drive.

C. During Respondent's tenure as medical director, Youth Inc.'s owner and/or employees stored and possessed prescription drugs at times when no practitioners[1] were physically present

[1] As used herein, "practitioner" has the meaning ascribed to it in NRS 453.126, NRS 454.00958, and NRS 639.0125.

at the spa's location at 691 Sierra Rose Drive and without the direct authorization of Respondent.

D. During Respondent's tenure as the medical director, Youth Inc.'s owner and/or employees administered injectable prescription drugs at times when no practitioners were physically present at the spa's location at 691 Sierra Rose Drive.

8. Now, therefore, to resolve the allegations stated in Count Two of the Accusation as described herein without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent accepts this Stipulation as a public reprimand.

B. Respondent agrees to pay an administrative fine of **Five Thousand and 00/100 Dollars ($5,000.00)**, payable by *cashier's check, certified check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before May 31, 2026.

C. Respondent shall pay the sum of **Five Hundred and 00/100 Dollars ($500.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this case. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before May 31, 2026.

9. Upon approval of this Stipulation by the Board, Count One and Three of the Accusation shall be dismissed.

10. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 24-509-CS-N. Any failure by Respondent to comply with the terms of this Stipulation may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing him to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If

such a hearing results in the finding of noncompliance by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639 and/or NRS Chapter 453.

11. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on April 15, 2026, in Reno, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear at the meeting.

12. The Board may accept this Stipulation, but it has no obligation to accept this Stipulation. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

13. If the Board rejects any part or all of this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hold a contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the date of entry set forth below.

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Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 30 day of March, 2026.

SEAN ARORA, M.D.
Registration No. CS31476

Signed this 30th day of March, 2026.

NEVADA STATE BOARD OF PHARMACY

By _____
GREGORY L. ZUNINO
Senior General Counsel

APPROVED AS TO FORM:

LYN BEGGS, ESQ.
Attorney for Respondent Sean Arora, M.D.

DECISION AND ORDER

As to Respondent Sean Arora, M.D., in Case No. 24-509-CS-N, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and orders that its terms and conditions be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 15th day of April, 2026.

Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476,** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484, and** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos. 24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Sean Arora, M.D., ("Respondent Arora"), because Respondent Arora holds a certificate of registration issued by the Board authorizing him to prescribe controlled substances in Nevada. Respondent Arora holds certificate of registration no. CS31476, which was issued by the Board pursuant to NRS 453.226 and 453.231.

2. The Board has personal jurisdiction over Respondent Cassie Gifford, APRN, ("Respondent Gifford"), because Respondent Gifford holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent Gifford holds certificate of

registration no. PR18034, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.[1]

3. The Board has personal jurisdiction over Respondent Gabrielle McIntyre, APRN, ("Respondent McIntyre"), because Respondent McIntyre holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR17484, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.

4. The Board has personal jurisdiction over Respondent Allison Jaggard, APRN, ("Respondent Jaggard"), because Respondent Jaggard holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR171499, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850

5. The Board has jurisdiction over the subject matter of this accusation because it alleges violations involving the purchase, receipt, storage, possession, prescribing and/or dispensing of dangerous drugs and controlled substances. As used herein, "dangerous drug" has the meaning ascribed to it in NRS 454.201, and "controlled substance" means a substance listed in NAC 453.510 to NAC 453.550, inclusive, or in 21 CFR Part 1308.

FACTUAL ALLEGATIONS

6. Respondent Arora is a physician licensed by the Nevada State Board of Medical Examiners to practice medicine in Nevada. At all times alleged herein, Respondent Arora was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

7. Respondent Gifford is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent

1. Respondent Gifford formerly held certificate of registration no. CS34942, authorizing her to prescribe controlled substances. Certificate of registration no. CS34942 was not renewed when it came due for renewal on November 1, 2024.

Gifford was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

8. Respondent McIntyre is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

9. Respondent Jaggard is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

10. In 2024, Respondent Arora formed a partnership or other business relationship with We Treat, a medical consulting firm based in San Diego, California. We Treat provides consulting services and regulatory compliance advice to medical spas and wellness clinics.

11. We Treat provided consulting services and compliance advice to Youth, Inc. (Youth Inc.), the owner of a medical spa and wellness clinic located at 695 Sierra Rose Drive in Reno, Nevada.

12. We Treat developed a manual of policies, procedures and protocols for use by Youth Inc. Respondent Arora approved these policies, procedures and protocols for use by Youth Inc.

13. Between April 2024 and March 2025, Youth Inc. provided various anti-aging and wellness treatments for its patients. These included cosmetic treatments using botulinum toxin type A and dermal fillers, treatments for weight loss using compounded tirzepatide and semaglutide products, hormone replacement using injectable hormones, and treatment for erectile dysfunction using sildenafil and tadalafil.

14. Between April 2024 and March 2025, Youth Inc. did not lock or otherwise secure the dangerous drugs and/or controlled substances in its possession.

15. In early 2025, Youth Inc. was in possession of stock bottles containing sildenafil, tadalafil, and metformin hydrochloride, all dangerous drugs. Youth Inc.'s representatives claimed that

they were not planning to dispense these drugs until after they had secured a dispensing license issued by the Board.

16. We Treat arranged for Respondent Arora to serve as the "medical director" for Youth Inc., a role that Respondent Arora assumed sometime between April and August 2024.

17. Respondent Arora served as Youth Inc.'s medical director until early 2025.

18. During Respondent Arora's tenure as Youth Inc.'s medical director, Respondent Arora worked and resided in Seattle, Washington. Respondent Arora never visited Youth Inc.'s facility in Reno, Nevada.

19. Sometime between April 2024 and March 2025, Youth Inc. engaged the services of Respondent Gifford, Respondent McIntyre and Respondent Jaggard. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard rarely, if ever, visited Youth Inc.'s facility in Reno, Nevada.

20. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed a prospective patient's medical questionnaire prior to the prospective patient's initial treatment at Youth Inc. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed these medical questionnaires from a remote location and never saw or spoke to patients prior to their initial treatments at Youth Inc.

21. After reviewing medical questionnaires, and despite not ever seeing the patients in question, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the use or administration of dangerous drugs and/or controlled substances.

22. Sometime between April 2024 and March 2025, Youth Inc. employed Maddison Weiss-Frank, a registered nurse. Ms. Weiss-Frank was not an advanced practice registered nurse and was not a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

23. Ms. Weiss-Frank worked under the direction and supervision of Rachel Gonzalez, the co-owner and chief executive officer of Youth Inc. Ms. Gonzalez was not a "practitioner" as that term

is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125. On information and belief, Ms. Gonzalez has no formal medical training.

24. Because there was never a practitioner present at the location, Youth Inc.'s facility at 695 Sierra Rose Drive in Reno, Nevada, was not a location where a registered nurse could lawfully inject a neuromodulator pursuant to NRS 454.217.

25. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank treated patients using prescription drugs and/or controlled substances. Ms. Weiss-Frank did not act under the direction or supervision of a practitioner.

26. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances. Ms. Weiss-Frank did not work under the direction or supervision of a practitioner.

27. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

28. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

29. Consistent with the practice described above, Youth Inc. returned single-use vials to stock even after the vials were punctured and therefore rendered unusable for subsequent treatments.

30. As the medical director for Youth Inc., Respondent Arora periodically reviewed purchase invoices and signed for shipments of dangerous drugs and/or controlled substances.

31. As the medical director for Youth Inc., Respondent Arora periodically reviewed patient medical questionnaires and treatment records.

32. As the medical director for Youth Inc., Respondent Arora periodically reviewed Youth Inc.'s policies, procedures and protocols related to the procurement, storage, possession and administration of dangerous drugs and controlled substances.

33. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances without direction or supervision by a practitioner.

34. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank treated patients with prescription drugs and/or controlled substances despite not working under the supervision or direction of a practitioner.

35. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

36. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

37. As Youth Inc.'s medical director, Respondent Arora had a duty to understand Nevada law as it governs the receipt, possession, storage, and distribution of dangerous drugs and controlled substances.

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APPLICABLE LAW

38. It is unlawful for any person to engage in wholesale distribution, or permit to be distributed at wholesale, any drug or compound unless the person holds the appropriate certificate, license or permit issued by the Board. NRS 639.100(1).

39. To engage in wholesale distribution of any drug or compound in Nevada, a person must be licensed as a wholesaler or manufacturer, as applicable. NRS 639.100; NRS 639.233; NAC 639.593; NAC 639.6915.

40. The Board may revoke or suspend the registration of any practitioner who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapters 453, 454, 639, or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12); NRS 453.236.

41. Additionally, the Board may revoke or suspend the registration of any practitioner who is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4); NRS 453.236.

42. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner performs his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful, or negligent manner, or if the practitioner assists or abets a person not licensed to practice pharmacy in Nevada. NAC 639.945(1)(i) and (j).

43. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner prescribes or orders a dangerous drug or controlled substance for a person with whom the practitioner does not have a bona fide therapeutic relationship. NAC 639.945(1)(n).

44. "'Practice of pharmacy' includes, but is not limited to, the . . . [p]erformance or supervision of activities associated with manufacturing, compounding, labeling, dispensing and distributing of a drug, including the receipt, handling and storage of prescriptions and other confidential information relating to patients." NRS 639.0124(1)(a).

45. It is unlawful to possess, store, or administer dangerous drugs, including botulinum toxin type A and injectable dermal fillers, except as authorized by NRS 454.213.

46. It is unlawful to possess, store, or administer controlled substances, including testosterone, except as provided by NRS 453.375.

47. "Administer" means the direct application of a [dangerous drug or controlled substance] . . . whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject." NRS 453.021; NRS 454.191.

48. Pursuant to NRS 453.375, a registered nurse may not possess, store, or administer controlled substances except when working under the direction of a supervising practitioner.

49. Pursuant to NRS 454.213, a registered nurse may not possess, store, or administer dangerous drugs except at the direction of a supervising practitioner.

50. It is unlawful for a registered nurse to inject botulinum toxin type A in a patient or customer "at a location other than a medical facility, as defined in NRS 449.0151, or the office of a physician or physician assistant licensed [pursuant to applicable statutes]." NRS 454.217.

51. A person who maintains a stock of controlled substances and/or dangerous drugs must not commingle expired substances and unexpired substances in a storage area from which the substances are withdrawn from stock for administering or dispensing to patients. NAC 639.050(2).

52. A practitioner is subject to discipline if the practitioner causes or allows a dangerous drug to be dispensed in a manner not authorized by NRS 454.215 and NRS 454.301. *See* NRS 639.100; NRS 639.210(12).

53. The term "dispense" includes the prescribing by a practitioner, administering, packaging, labeling, or compounding necessary to prepare a substance for delivery to a patient. NRS 639.0065; NRS 453.056.

54. It is unlawful to furnish drugs without a prescription. NRS 454.221.

55. "Furnish" means to supply by any means, by sale or otherwise. NRS 454.006.

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COUNT ONE
Permitting Unlicensed Wholesale Distribution
(Respondent Arora)

56. As alleged above, Respondent Arora served as the medical director for Youth Inc.

57. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

58. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage purchases from unlicensed distributors such as GLP-1 Sciences, LLC. Respondent failed to implement such policies, procedures and protocols.

59. Given the facts and circumstances alleged above, Respondent Arora permitted the unlicensed wholesale distribution of compounded drug products in violation of NRS 639.100(1).

60. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

61. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT TWO
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondent Arora)

62. As alleged above, Respondent Arora served as the medical director for Youth Inc.

63. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered, received, possessed, and/or stored dangerous drugs and/or controlled substances. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

64. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of

Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

65. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the above persons from ordering, receiving, possessing, storing and/or furnishing dangerous drugs and/or controlled substances. Respondent Arora failed to implement such policies, procedures and protocols.

66. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the unlicensed practice of pharmacy.

67. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

68. Respondent Arora's acts and/or omissions as alleged above amount to conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(i) and (j).

COUNT THREE
Assisting or Abetting in Violations of NAC 639.050(2)
(Respondent Arora)

69. As alleged above, Respondent Arora served as the medical director for Youth Inc.

70. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

71. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the repeated or recurring use of punctured single-use vials. Respondent failed to implement such policies, procedures and protocols.

72. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the above violations of NAC 639.050(2).

73. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

74. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FOUR
Assisting or Abetting in Violations of NAC 639.050(2)
(Respondents Gifford, McIntyre and Jaggard)

75. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

76. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of injectable drugs contained within single-use vials.

77. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard had a duty to ensure that Youth Inc. did not make repeated or recurring uses of punctured single-use vials.

78. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that Youth Inc. did not return single-use vials to stock after the vials were punctured.

79. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard assisted or abetted in the above violations of NAC 639.050(2).

80. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

81. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FIVE
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondents Gifford, McIntyre and Jaggard)

82. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

83. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

84. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that dangerous drugs and/or controlled substances were administered under the direction or supervision of a practitioner. Dangerous drugs and/or controlled substances were not administered under the direction or supervision of a practitioner.

85. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard assisted or abetted the unlicensed practice of pharmacy by Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank.

86. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

87. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT SIX
Failure to Establish a Bona Fide Therapeutic Relationship with Patients
(Respondents Gifford, McIntyre and Jaggard)

88. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

89. Respondent Gifford, Respondent McIntyre and Respondent Jaggard never saw or spoke with the above patients for whom they authorized treatments with dangerous drugs and/or controlled substances.

90. Having failed to see or speak with the above patients, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard failed to establish a bona fide therapeutic relationship with the above patients prior to authorizing their initial treatments with dangerous drugs and/or controlled substances.

91. Respondents' conduct as alleged above amounts to unprofessional conduct and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(n).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of Respondent Sean Arora, Respondent Cassie Gifford, Respondent Gabrielle McIntyre, and Respondent Allison Jaggard.

DATED this 24th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **Respondent.**	**Case No. 24-509-PR-A-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **Respondent.**	**Case No. 24-509-PR-A-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Cassie Gifford, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Sean Arora, MD
c/o Youth Inc
691 Sierra Rose Dr
Reno, NV 89511

Cassie Gifford, APRN
c/o Bionetics Health
5540 S Fort Apache Rd #120
Las Vegas, NV 89148

Gabrielle McIntyre, APRN
c/o Restore Hyper Wellness
1550 N Green Valley Pkwy., Ste 300
Henderson, NV 89074

Allison Jaggard, APRN
1708 Spring Green Blvd Ste 120-109
Katy, TX 77494

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
AUG 15 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484,** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos.**	**24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **ANSWER AND NOTICE OF DEFENSE OF RESPONDENTS**

Respondents Sean Arora, M.D., Cassie Gifford, APRN, Gabrielle McIntyre, APRN, and Allison Jaggard, APRN, hereby file with the Nevada State Board of Pharmacy ("Board"), their Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on July 24, 2025.

ANSWER TO ACCUSATION

Jurisdiction: Paragraphs 1-5

Paragraph 1: Dr. Arora acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 1 of the Accusation to the extent that the matter pertains to controlled substances as he holds a controlled substance registration issued by the Board.

Paragraph 2: Ms. Gifford acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 2 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 3: Ms. McIntyre acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 3 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 4: Ms. Jaggard acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 4 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 5: Respondents acknowledge that the Board has jurisdiction in the matter to the extent that the matter involves dangerous drugs and controlled substances. Dr. Arora acknowledges that the Board has jurisdiction over the allegations pertaining to his acts or omissions to the extent they concern controlled substances.

Factual Allegations: Paragraphs 6-37

Paragraph 6: Dr. Arora agrees with the factual allegations as set forth in Paragraph 6.

Paragraph 7: Ms. Gifford agrees with the factual allegations as set forth in Paragraph 7.

Paragraph 8: Ms. McIntyre agrees with the factual allegations as set forth in Paragraph 8.

Paragraph 9: Ms. Jaggard agrees with the factual allegations as set forth in Paragraph 9.

Paragraph 10: Dr. Arora agrees with the factual allegations set forth in Paragraph 10 only to the extent that he entered into an independent contractor agreement with We Treat, LLC in 2024.

Paragraph 11: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 11 as to the types of services which were provided to Youth Inc. However, to the best of Respondents' knowledge, Youth Inc. did receive services from

We Treat related to medical clearances for patients, policies and protocols and compliance information.

Paragraph 12: Dr. Arora agrees with the factual allegations set forth in Paragraph 12 only to the extent that he reviewed and approved policies and protocols directly related to the provision of certain medical services. Dr. Arora was not involved, nor did he review or approve, policies and procedures related to any other matters involving Youth, Inc.

Paragraph 13: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 13.

Paragraph 14: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 14.

Paragraph 15: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 15.

Paragraph 16: Dr. Arora acknowledges that as part of his duties for We Treat, he was assigned as medical director for Youth, Inc. in approximately April 2024. Dr. Arora's duties as medical director included the review and approval of protocols for certain medical treatments performed at Youth, Inc., responding to patient specific questions from the clinic, and authorization of the ordering of certain dangerous drugs, to be done in accordance with compliance policies prepared by We Treat.

Paragraph 17: Dr. Arora agrees with the factual allegations contained in Paragraph 17 to the extent that he provided services to We Treat until January 2025, services which included acting as medical director for Youth,. Inc., which were limited to the duties set forth in the response to Paragraph 16.

Paragraph 18: Dr. Arora acknowledges that he was based in Seattle, Washington and that his duties for Youth, Inc. did not require him to be physically at Youth, Inc.'s location.

Paragraph 19: Respondent's Gifford, McIntyre, and Jaggard deny the factual allegations set forth in Paragraph 19. None of the named Respondents were engaged by Youth, Inc. to provide any services. All three Respondents were employees/independent contractors of We Treat which provided medical clearance screening of patients for Youth, Inc. through Nevada licensed practitioners.

Paragraph 20: Respondents Gifford, McIntyre, and Jaggard acknowledge that they reviewed and medically cleared patients for treatments performed at Youth, Inc. pursuant to medical protocols reviewed and approved by Dr. Arora and performed these reviews in accordance with policies and protocols developed and approved by We Treat, not Dr. Arora.

Paragraph 21: Respondents Gifford, McIntyre and Jaggard acknowledge that they medically cleared patients, if appropriate, after the review of medical information and authorized treatments to be performed pursuant to protocols approved by Dr. Arora which included standing orders for administration of certain drugs or the issuance of prescriptions pursuant to those protocols. No approved protocols for treatments authorized the administration of controlled substances at Youth, Inc.

Paragraph 22: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 22.

Paragraph 23: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 23.

Paragraph 24: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 24.

Paragraph 25: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 25.

Paragraph 26: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 26.

Paragraph 27: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 27.

Paragraph 28: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 28.

Paragraph 29: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 29.

Paragraph 30: Dr. Arora acknowledges that he would periodically review orders received for dangerous drugs and would sign, remotely for the same. Drugs were to be stored and accessed in accordance with policies and protocols developed by We Treat; Dr. Arora was not part of the development of those policies and procedures, nor was he asked to review them by We Treat. Dr. Arora denies that he ever signed off or approved of any shipments of controlled substances to Youth, Inc. and to his knowledge, no controlled substances were to be received or stored on-site at We Treat.

Paragraph 31: Dr. Arora denies the factual allegations contained in Paragraph 31, however he acknowledges that he would respond to patient specific questions posed to him and would review patient records at that time; however this occurred very rarely.

Paragraph 32: Dr. Arora denies the factual allegations contained in Paragraph 32. Dr. Arora was not responsible for the policies and procedures related to the procurement, storage, possession and/or administration of dangerous drugs or controlled substances other than approving

protocols directly related to the provision of medical services. We Treat's compliance department was solely responsible for the policies and protocols otherwise related to dangerous drugs and controlled substances.

Paragraph 33: Dr. Arora denies the allegations set forth in Paragraph 33.

Paragraph 34: Dr. Arora denies the allegations set forth in Paragraph 34.

Paragraph 35: Dr. Arora denies the allegations set forth in Paragraph 35.

Paragraph 36: Dr. Arora denies the allegations set forth in Paragraph 36.

Paragraph 37: Dr. Arora denies the allegations set forth in Paragraph 37 as he was not involved in, nor responsible for the receipt, possession storage, and distribution of dangerous drugs or controlled substances at Youth, Inc.

Applicable Law: Paragraphs 38-55

Paragraph 38-55: Respondents acknowledge that Paragraphs 38-55 accurately reflect the basic substance of the statutes and regulations cited therein.

Counts: Paragraphs 56-91

Count One (Paragraphs 56-61): Dr. Arora generally denies the allegations set forth in Count One in Paragraphs 56-61. Dr. Arora did not permit Youth, Inc. or any of its personnel to order any dangerous drugs from any manufacturer or supplier not licensed in Nevada. As discussed herein, Dr. Arora's duties for Youth, Inc. were limited to the review and authorization of protocols related to medical procedures. While Youth, Inc. was authorized to order supplies and dangerous drugs under Dr. Arora's credentials, this was to be done in accordance with policies and protocols developed and approved by We Treat's compliance department. To the best of Dr. Arora's knowledge, no client of We Treat was authorized to order or received dangerous drugs or other supplies from unlicensed suppliers/manufacturers.

Count Two (Paragraphs 62-68): Dr. Arora generally denies all allegations set forth in Count Two in Paragraphs 62-68. Further Dr. Arora asserts that a practice which orders, receives, and stores dangerous drugs is not engaging in the practice of pharmacy as alleged. If indeed this was accurate, every medical practice or facility that orders, receives and stores drugs for administration and/or dispensing, would be required to hold a pharmacy license with the Board; that is not currently a requirement and NRS 639.0124(1)(a) is inappropriately applied here.

Count Three (Paragraphs 69-74): Dr. Arora generally denies the allegations set forth in Count Three in Paragraphs 69-74. Again, as discussed herein, Dr. Arora's duties for Youth, Inc. were limited and did not include the development or approval of any protocols or procedures related to the procurement or storage of dangerous drugs. Dr. Arora's medical service protocols did not allow for the reuse of single use vials and any reuse of single use vials on the part of Youth, Inc. personnel would have been done without the knowledge of Dr. Arora and he did not aid or abet any violation of NAC 639.050(2).

Count Four (Paragraphs 75-81): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Four in Paragraphs 75-81. Respondents Gifford, McIntyre, and Jaggard, worked for We Treat, not Youth, Inc. Respondents' duties for Youth, Inc. were limited to conducting medical clearance reviews for patients and if cleared, the patient was authorized for treatment pursuant to approved medical protocols. None of the named respondents were responsible for supervising the staff of Youth, Inc. and would have had no knowledge of unauthorized reuse of single use vials by any personnel associated with Youth, Inc.

Count Five (Paragraphs 82-87): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Five in Paragraphs 75-81. The administration of dangerous drugs to patients is not the practice of pharmacy as defined by NRS 639.0124(1)(a) and

accordingly Respondents could not have aided or abetted in the violation of said statute. Again, as discussed above, should the Board take the position that the administration of a dangerous drug constitutes the practice of pharmacy, all practices and facilities at which any drug is administered would be required to hold a registration as a pharmacy with the Board which is not currently required.

Count Six (Paragraphs 88-91): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Six in Paragraphs 88-91.

NOTICE OF DEFENSE/MITIGATING INFORMATION

In regard to Respondent Arora, Dr. Arora stresses that his involvement with We Treat was limited as medical director. The term "medical director" is not defined under Nevada law and there is no legal precedent for what the duties of a medical director must consist of. Dr. Arora functioned as a medical director per the duties he had as a contractor for We Treat, LLC, which consisted solely of the review and authorization of protocols for medical services offered at practices contracted with We Treat and he was required to be available for consultations regarding specific patient questions as needed. The medical protocols authorized by Dr. Arora included standing orders for the administration of certain dangerous drugs and for the prescription of certain controlled substances. It should be noted that Dr. Arora never authorized the administration of controlled substances at Youth, Inc., or any other practice for which he provided services under We Treat and to his knowledge, no controlled substances were stored on-site at Youth, Inc.

We Treat's compliance department was responsible for the development and authorization of all other policies and protocols, including those related to the procurement, receipt, and storage of dangerous drugs. Dr. Arora was advised by We Treat that all policies and protocols were reviewed and vetted for compliance with the laws in each individual state in which We Treat had

clients. Dr. Arora had no reason to doubt the assurances made by We Treat that the policies and protocols for Youth, Inc. were in compliance with Nevada law.

In regard to Respondents Gifford, McIntyre, and Jaggard, all three were employees/contractors with We Treat during the times in question. Their duties were to provide medical clearance reviews for patients wishing to receive services at practices which were contracted with We Treat and if cleared, authorize treatment to be provide pursuant to previously approved medical protocols. Respondents had no duties related to the oversight or supervision of any practice served by We Treat. Respondents would be notified through a proprietary platform that a patient required a medical clearance evaluation at practices which received services from We Treat and would be given access to the patient records through the We Treat platform and would either clear the patient for treatment or deny treatment[1]. Each clinic had individual protocols which would be followed by Respondents. Respondents were informed by We Treat that policies related to requirements for providing medical clearance for patients was vetted by its compliance department and all protocols were in compliance with state laws; Respondents had no reason to question the representations of We Treat.

Respondent Gifford estimates that she performed very few medical clearance evaluations for Youth, Inc. through the We Treat platform. Respondent McIntyre estimates that she did approximately two medical clearance evaluations for Youth, Inc. Respondent Jaggard estimates that she did a maximum of ten to fifteen medical clearance evaluations for Youth, Inc.

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[1] We Treat practitioners only performed medical clearance evaluations for patients in states in which they were licensed.

All Respondents deny having violated NRS and/or NAC Chapters 453, 454, or 639. Further Respondents reserve all legal defenses available to them should this matter proceed to a hearing.

Respectfully submitted this 15th day of August, 2025.

Lyn E. Beggs, Esq.
Attorney for Respondents

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FILED
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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476,** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484, and** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos. 24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Sean Arora, M.D., ("Respondent Arora"), because Respondent Arora holds a certificate of registration issued by the Board authorizing him to prescribe controlled substances in Nevada. Respondent Arora holds certificate of registration no. CS31476, which was issued by the Board pursuant to NRS 453.226 and 453.231.

2. The Board has personal jurisdiction over Respondent Cassie Gifford, APRN, ("Respondent Gifford"), because Respondent Gifford holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent Gifford holds certificate of

registration no. PR18034, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.[1]

3. The Board has personal jurisdiction over Respondent Gabrielle McIntyre, APRN, ("Respondent McIntyre"), because Respondent McIntyre holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR17484, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.

4. The Board has personal jurisdiction over Respondent Allison Jaggard, APRN, ("Respondent Jaggard"), because Respondent Jaggard holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR171499, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850

5. The Board has jurisdiction over the subject matter of this accusation because it alleges violations involving the purchase, receipt, storage, possession, prescribing and/or dispensing of dangerous drugs and controlled substances. As used herein, "dangerous drug" has the meaning ascribed to it in NRS 454.201, and "controlled substance" means a substance listed in NAC 453.510 to NAC 453.550, inclusive, or in 21 CFR Part 1308.

FACTUAL ALLEGATIONS

6. Respondent Arora is a physician licensed by the Nevada State Board of Medical Examiners to practice medicine in Nevada. At all times alleged herein, Respondent Arora was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

7. Respondent Gifford is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent

1. Respondent Gifford formerly held certificate of registration no. CS34942, authorizing her to prescribe controlled substances. Certificate of registration no. CS34942 was not renewed when it came due for renewal on November 1, 2024.

Gifford was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

8. Respondent McIntyre is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

9. Respondent Jaggard is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

10. In 2024, Respondent Arora formed a partnership or other business relationship with We Treat, a medical consulting firm based in San Diego, California. We Treat provides consulting services and regulatory compliance advice to medical spas and wellness clinics.

11. We Treat provided consulting services and compliance advice to Youth, Inc. (Youth Inc.), the owner of a medical spa and wellness clinic located at 695 Sierra Rose Drive in Reno, Nevada.

12. We Treat developed a manual of policies, procedures and protocols for use by Youth Inc. Respondent Arora approved these policies, procedures and protocols for use by Youth Inc.

13. Between April 2024 and March 2025, Youth Inc. provided various anti-aging and wellness treatments for its patients. These included cosmetic treatments using botulinum toxin type A and dermal fillers, treatments for weight loss using compounded tirzepatide and semaglutide products, hormone replacement using injectable hormones, and treatment for erectile dysfunction using sildenafil and tadalafil.

14. Between April 2024 and March 2025, Youth Inc. did not lock or otherwise secure the dangerous drugs and/or controlled substances in its possession.

15. In early 2025, Youth Inc. was in possession of stock bottles containing sildenafil, tadalafil, and metformin hydrochloride, all dangerous drugs. Youth Inc.'s representatives claimed that

they were not planning to dispense these drugs until after they had secured a dispensing license issued by the Board.

16. We Treat arranged for Respondent Arora to serve as the "medical director" for Youth Inc., a role that Respondent Arora assumed sometime between April and August 2024.

17. Respondent Arora served as Youth Inc.'s medical director until early 2025.

18. During Respondent Arora's tenure as Youth Inc.'s medical director, Respondent Arora worked and resided in Seattle, Washington. Respondent Arora never visited Youth Inc.'s facility in Reno, Nevada.

19. Sometime between April 2024 and March 2025, Youth Inc. engaged the services of Respondent Gifford, Respondent McIntyre and Respondent Jaggard. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard rarely, if ever, visited Youth Inc.'s facility in Reno, Nevada.

20. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed a prospective patient's medical questionnaire prior to the prospective patient's initial treatment at Youth Inc. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed these medical questionnaires from a remote location and never saw or spoke to patients prior to their initial treatments at Youth Inc.

21. After reviewing medical questionnaires, and despite not ever seeing the patients in question, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the use or administration of dangerous drugs and/or controlled substances.

22. Sometime between April 2024 and March 2025, Youth Inc. employed Maddison Weiss-Frank, a registered nurse. Ms. Weiss-Frank was not an advanced practice registered nurse and was not a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

23. Ms. Weiss-Frank worked under the direction and supervision of Rachel Gonzalez, the co-owner and chief executive officer of Youth Inc. Ms. Gonzalez was not a "practitioner" as that term

is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125. On information and belief, Ms. Gonzalez has no formal medical training.

24. Because there was never a practitioner present at the location, Youth Inc.'s facility at 695 Sierra Rose Drive in Reno, Nevada, was not a location where a registered nurse could lawfully inject a neuromodulator pursuant to NRS 454.217.

25. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank treated patients using prescription drugs and/or controlled substances. Ms. Weiss-Frank did not act under the direction or supervision of a practitioner.

26. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances. Ms. Weiss-Frank did not work under the direction or supervision of a practitioner.

27. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

28. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

29. Consistent with the practice described above, Youth Inc. returned single-use vials to stock even after the vials were punctured and therefore rendered unusable for subsequent treatments.

30. As the medical director for Youth Inc., Respondent Arora periodically reviewed purchase invoices and signed for shipments of dangerous drugs and/or controlled substances.

31. As the medical director for Youth Inc., Respondent Arora periodically reviewed patient medical questionnaires and treatment records.

32. As the medical director for Youth Inc., Respondent Arora periodically reviewed Youth Inc.'s policies, procedures and protocols related to the procurement, storage, possession and administration of dangerous drugs and controlled substances.

33. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances without direction or supervision by a practitioner.

34. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank treated patients with prescription drugs and/or controlled substances despite not working under the supervision or direction of a practitioner.

35. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

36. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

37. As Youth Inc.'s medical director, Respondent Arora had a duty to understand Nevada law as it governs the receipt, possession, storage, and distribution of dangerous drugs and controlled substances.

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APPLICABLE LAW

38. It is unlawful for any person to engage in wholesale distribution, or permit to be distributed at wholesale, any drug or compound unless the person holds the appropriate certificate, license or permit issued by the Board. NRS 639.100(1).

39. To engage in wholesale distribution of any drug or compound in Nevada, a person must be licensed as a wholesaler or manufacturer, as applicable. NRS 639.100; NRS 639.233; NAC 639.593; NAC 639.6915.

40. The Board may revoke or suspend the registration of any practitioner who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapters 453, 454, 639, or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12); NRS 453.236.

41. Additionally, the Board may revoke or suspend the registration of any practitioner who is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4); NRS 453.236.

42. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner performs his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful, or negligent manner, or if the practitioner assists or abets a person not licensed to practice pharmacy in Nevada. NAC 639.945(1)(i) and (j).

43. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner prescribes or orders a dangerous drug or controlled substance for a person with whom the practitioner does not have a bona fide therapeutic relationship. NAC 639.945(1)(n).

44. "'Practice of pharmacy' includes, but is not limited to, the . . . [p]erformance or supervision of activities associated with manufacturing, compounding, labeling, dispensing and distributing of a drug, including the receipt, handling and storage of prescriptions and other confidential information relating to patients." NRS 639.0124(1)(a).

45. It is unlawful to possess, store, or administer dangerous drugs, including botulinum toxin type A and injectable dermal fillers, except as authorized by NRS 454.213.

46. It is unlawful to possess, store, or administer controlled substances, including testosterone, except as provided by NRS 453.375.

47. "Administer" means the direct application of a [dangerous drug or controlled substance] . . . whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject." NRS 453.021; NRS 454.191.

48. Pursuant to NRS 453.375, a registered nurse may not possess, store, or administer controlled substances except when working under the direction of a supervising practitioner.

49. Pursuant to NRS 454.213, a registered nurse may not possess, store, or administer dangerous drugs except at the direction of a supervising practitioner.

50. It is unlawful for a registered nurse to inject botulinum toxin type A in a patient or customer "at a location other than a medical facility, as defined in NRS 449.0151, or the office of a physician or physician assistant licensed [pursuant to applicable statutes]." NRS 454.217.

51. A person who maintains a stock of controlled substances and/or dangerous drugs must not commingle expired substances and unexpired substances in a storage area from which the substances are withdrawn from stock for administering or dispensing to patients. NAC 639.050(2).

52. A practitioner is subject to discipline if the practitioner causes or allows a dangerous drug to be dispensed in a manner not authorized by NRS 454.215 and NRS 454.301. *See* NRS 639.100; NRS 639.210(12).

53. The term "dispense" includes the prescribing by a practitioner, administering, packaging, labeling, or compounding necessary to prepare a substance for delivery to a patient. NRS 639.0065; NRS 453.056.

54. It is unlawful to furnish drugs without a prescription. NRS 454.221.

55. "Furnish" means to supply by any means, by sale or otherwise. NRS 454.006.

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COUNT ONE
Permitting Unlicensed Wholesale Distribution
(Respondent Arora)

56. As alleged above, Respondent Arora served as the medical director for Youth Inc.

57. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

58. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage purchases from unlicensed distributors such as GLP-1 Sciences, LLC. Respondent failed to implement such policies, procedures and protocols.

59. Given the facts and circumstances alleged above, Respondent Arora permitted the unlicensed wholesale distribution of compounded drug products in violation of NRS 639.100(1).

60. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

61. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT TWO
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondent Arora)

62. As alleged above, Respondent Arora served as the medical director for Youth Inc.

63. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered, received, possessed, and/or stored dangerous drugs and/or controlled substances. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

64. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of

Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

65. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the above persons from ordering, receiving, possessing, storing and/or furnishing dangerous drugs and/or controlled substances. Respondent Arora failed to implement such policies, procedures and protocols.

66. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the unlicensed practice of pharmacy.

67. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

68. Respondent Arora's acts and/or omissions as alleged above amount to conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(i) and (j).

COUNT THREE
Assisting or Abetting in Violations of NAC 639.050(2)
(Respondent Arora)

69. As alleged above, Respondent Arora served as the medical director for Youth Inc.

70. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

71. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the repeated or recurring use of punctured single-use vials. Respondent failed to implement such policies, procedures and protocols.

72. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the above violations of NAC 639.050(2).

73. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

74. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FOUR
Assisting or Abetting in Violations of NAC 639.050(2)
(Respondents Gifford, McIntyre and Jaggard)

75. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

76. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of injectable drugs contained within single-use vials.

77. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard had a duty to ensure that Youth Inc. did not make repeated or recurring uses of punctured single-use vials.

78. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that Youth Inc. did not return single-use vials to stock after the vials were punctured.

79. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard assisted or abetted in the above violations of NAC 639.050(2).

80. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

81. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FIVE
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondents Gifford, McIntyre and Jaggard)

82. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

83. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

84. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that dangerous drugs and/or controlled substances were administered under the direction or supervision of a practitioner. Dangerous drugs and/or controlled substances were not administered under the direction or supervision of a practitioner.

85. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard assisted or abetted the unlicensed practice of pharmacy by Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank.

86. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

87. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT SIX
Failure to Establish a Bona Fide Therapeutic Relationship with Patients (Respondents Gifford, McIntyre and Jaggard)

88. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

89. Respondent Gifford, Respondent McIntyre and Respondent Jaggard never saw or spoke with the above patients for whom they authorized treatments with dangerous drugs and/or controlled substances.

90. Having failed to see or speak with the above patients, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard failed to establish a bona fide therapeutic relationship with the above patients prior to authorizing their initial treatments with dangerous drugs and/or controlled substances.

91. Respondents' conduct as alleged above amounts to unprofessional conduct and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(n).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of Respondent Sean Arora, Respondent Cassie Gifford, Respondent Gabrielle McIntyre, and Respondent Allison Jaggard.

DATED this 24th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484,** **Respondent.**	**Case No. 24-509-PR-B-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484,** **Respondent.**	**Case No. 24-509-PR-B-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Gabrielle McIntyre, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Sean Arora, MD
c/o Youth Inc
691 Sierra Rose Dr
Reno, NV 89511

Cassie Gifford, APRN
c/o Bionetics Health
5540 S Fort Apache Rd #120
Las Vegas, NV 89148

Gabrielle McIntyre, APRN
c/o Restore Hyper Wellness
1550 N Green Valley Pkwy., Ste 300
Henderson, NV 89074

Allison Jaggard, APRN
1708 Spring Green Blvd Ste 120-109
Katy, TX 77494

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
AUG 15 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484,** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos.** **24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **ANSWER AND NOTICE OF DEFENSE OF RESPONDENTS**

Respondents Sean Arora, M.D., Cassie Gifford, APRN, Gabrielle McIntyre, APRN, and Allison Jaggard, APRN, hereby file with the Nevada State Board of Pharmacy ("Board"), their Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on July 24, 2025.

ANSWER TO ACCUSATION

Jurisdiction: Paragraphs 1-5

Paragraph 1: Dr. Arora acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 1 of the Accusation to the extent that the matter pertains to controlled substances as he holds a controlled substance registration issued by the Board.

Paragraph 2: Ms. Gifford acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 2 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 3: Ms. McIntyre acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 3 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 4: Ms. Jaggard acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 4 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 5: Respondents acknowledge that the Board has jurisdiction in the matter to the extent that the matter involves dangerous drugs and controlled substances. Dr. Arora acknowledges that the Board has jurisdiction over the allegations pertaining to his acts or omissions to the extent they concern controlled substances.

Factual Allegations: Paragraphs 6-37

Paragraph 6: Dr. Arora agrees with the factual allegations as set forth in Paragraph 6.

Paragraph 7: Ms. Gifford agrees with the factual allegations as set forth in Paragraph 7.

Paragraph 8: Ms. McIntyre agrees with the factual allegations as set forth in Paragraph 8.

Paragraph 9: Ms. Jaggard agrees with the factual allegations as set forth in Paragraph 9.

Paragraph 10: Dr. Arora agrees with the factual allegations set forth in Paragraph 10 only to the extent that he entered into an independent contractor agreement with We Treat, LLC in 2024.

Paragraph 11: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 11 as to the types of services which were provided to Youth Inc. However, to the best of Respondents' knowledge, Youth Inc. did receive services from

We Treat related to medical clearances for patients, policies and protocols and compliance information.

Paragraph 12: Dr. Arora agrees with the factual allegations set forth in Paragraph 12 only to the extent that he reviewed and approved policies and protocols directly related to the provision of certain medical services. Dr. Arora was not involved, nor did he review or approve, policies and procedures related to any other matters involving Youth, Inc.

Paragraph 13: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 13.

Paragraph 14: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 14.

Paragraph 15: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 15.

Paragraph 16: Dr. Arora acknowledges that as part of his duties for We Treat, he was assigned as medical director for Youth, Inc. in approximately April 2024. Dr. Arora's duties as medical director included the review and approval of protocols for certain medical treatments performed at Youth, Inc., responding to patient specific questions from the clinic, and authorization of the ordering of certain dangerous drugs, to be done in accordance with compliance policies prepared by We Treat.

Paragraph 17: Dr. Arora agrees with the factual allegations contained in Paragraph 17 to the extent that he provided services to We Treat until January 2025, services which included acting as medical director for Youth,. Inc., which were limited to the duties set forth in the response to Paragraph 16.

Paragraph 18: Dr. Arora acknowledges that he was based in Seattle, Washington and that his duties for Youth, Inc. did not require him to be physically at Youth, Inc.'s location.

Paragraph 19: Respondent's Gifford, McIntyre, and Jaggard deny the factual allegations set forth in Paragraph 19. None of the named Respondents were engaged by Youth, Inc. to provide any services. All three Respondents were employees/independent contractors of We Treat which provided medical clearance screening of patients for Youth, Inc. through Nevada licensed practitioners.

Paragraph 20: Respondents Gifford, McIntyre, and Jaggard acknowledge that they reviewed and medically cleared patients for treatments performed at Youth, Inc. pursuant to medical protocols reviewed and approved by Dr. Arora and performed these reviews in accordance with policies and protocols developed and approved by We Treat, not Dr. Arora.

Paragraph 21: Respondents Gifford, McIntyre and Jaggard acknowledge that they medically cleared patients, if appropriate, after the review of medical information and authorized treatments to be performed pursuant to protocols approved by Dr. Arora which included standing orders for administration of certain drugs or the issuance of prescriptions pursuant to those protocols. No approved protocols for treatments authorized the administration of controlled substances at Youth, Inc.

Paragraph 22: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 22.

Paragraph 23: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 23.

Paragraph 24: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 24.

Paragraph 25: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 25.

Paragraph 26: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 26.

Paragraph 27: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 27.

Paragraph 28: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 28.

Paragraph 29: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 29.

Paragraph 30: Dr. Arora acknowledges that he would periodically review orders received for dangerous drugs and would sign, remotely for the same. Drugs were to be stored and accessed in accordance with policies and protocols developed by We Treat; Dr. Arora was not part of the development of those policies and procedures, nor was he asked to review them by We Treat. Dr. Arora denies that he ever signed off or approved of any shipments of controlled substances to Youth, Inc. and to his knowledge, no controlled substances were to be received or stored on-site at We Treat.

Paragraph 31: Dr. Arora denies the factual allegations contained in Paragraph 31, however he acknowledges that he would respond to patient specific questions posed to him and would review patient records at that time; however this occurred very rarely.

Paragraph 32: Dr. Arora denies the factual allegations contained in Paragraph 32. Dr. Arora was not responsible for the policies and procedures related to the procurement, storage, possession and/or administration of dangerous drugs or controlled substances other than approving

protocols directly related to the provision of medical services. We Treat's compliance department was solely responsible for the policies and protocols otherwise related to dangerous drugs and controlled substances.

Paragraph 33: Dr. Arora denies the allegations set forth in Paragraph 33.

Paragraph 34: Dr. Arora denies the allegations set forth in Paragraph 34.

Paragraph 35: Dr. Arora denies the allegations set forth in Paragraph 35.

Paragraph 36: Dr. Arora denies the allegations set forth in Paragraph 36.

Paragraph 37: Dr. Arora denies the allegations set forth in Paragraph 37 as he was not involved in, nor responsible for the receipt, possession storage, and distribution of dangerous drugs or controlled substances at Youth, Inc.

Applicable Law: Paragraphs 38-55

Paragraph 38-55: Respondents acknowledge that Paragraphs 38-55 accurately reflect the basic substance of the statutes and regulations cited therein.

Counts: Paragraphs 56-91

Count One (Paragraphs 56-61): Dr. Arora generally denies the allegations set forth in Count One in Paragraphs 56-61. Dr. Arora did not permit Youth, Inc. or any of its personnel to order any dangerous drugs from any manufacturer or supplier not licensed in Nevada. As discussed herein, Dr. Arora's duties for Youth, Inc. were limited to the review and authorization of protocols related to medical procedures. While Youth, Inc. was authorized to order supplies and dangerous drugs under Dr. Arora's credentials, this was to be done in accordance with policies and protocols developed and approved by We Treat's compliance department. To the best of Dr. Arora's knowledge, no client of We Treat was authorized to order or received dangerous drugs or other supplies from unlicensed suppliers/manufacturers.

Count Two (Paragraphs 62-68): Dr. Arora generally denies all allegations set forth in Count Two in Paragraphs 62-68. Further Dr. Arora asserts that a practice which orders, receives, and stores dangerous drugs is not engaging in the practice of pharmacy as alleged. If indeed this was accurate, every medical practice or facility that orders, receives and stores drugs for administration and/or dispensing, would be required to hold a pharmacy license with the Board; that is not currently a requirement and NRS 639.0124(1)(a) is inappropriately applied here.

Count Three (Paragraphs 69-74): Dr. Arora generally denies the allegations set forth in Count Three in Paragraphs 69-74. Again, as discussed herein, Dr. Arora's duties for Youth, Inc. were limited and did not include the development or approval of any protocols or procedures related to the procurement or storage of dangerous drugs. Dr. Arora's medical service protocols did not allow for the reuse of single use vials and any reuse of single use vials on the part of Youth, Inc. personnel would have been done without the knowledge of Dr. Arora and he did not aid or abet any violation of NAC 639.050(2).

Count Four (Paragraphs 75-81): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Four in Paragraphs 75-81. Respondents Gifford, McIntyre, and Jaggard, worked for We Treat, not Youth, Inc. Respondents' duties for Youth, Inc. were limited to conducting medical clearance reviews for patients and if cleared, the patient was authorized for treatment pursuant to approved medical protocols. None of the named respondents were responsible for supervising the staff of Youth, Inc. and would have had no knowledge of unauthorized reuse of single use vials by any personnel associated with Youth, Inc.

Count Five (Paragraphs 82-87): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Five in Paragraphs 75-81. The administration of dangerous drugs to patients is not the practice of pharmacy as defined by NRS 639.0124(1)(a) and

accordingly Respondents could not have aided or abetted in the violation of said statute. Again, as discussed above, should the Board take the position that the administration of a dangerous drug constitutes the practice of pharmacy, all practices and facilities at which any drug is administered would be required to hold a registration as a pharmacy with the Board which is not currently required.

Count Six (Paragraphs 88-91): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Six in Paragraphs 88-91.

NOTICE OF DEFENSE/MITIGATING INFORMATION

In regard to Respondent Arora, Dr. Arora stresses that his involvement with We Treat was limited as medical director. The term "medical director" is not defined under Nevada law and there is no legal precedent for what the duties of a medical director must consist of. Dr. Arora functioned as a medical director per the duties he had as a contractor for We Treat, LLC, which consisted solely of the review and authorization of protocols for medical services offered at practices contracted with We Treat and he was required to be available for consultations regarding specific patient questions as needed. The medical protocols authorized by Dr. Arora included standing orders for the administration of certain dangerous drugs and for the prescription of certain controlled substances. It should be noted that Dr. Arora never authorized the administration of controlled substances at Youth, Inc., or any other practice for which he provided services under We Treat and to his knowledge, no controlled substances were stored on-site at Youth, Inc.

We Treat's compliance department was responsible for the development and authorization of all other policies and protocols, including those related to the procurement, receipt, and storage of dangerous drugs. Dr. Arora was advised by We Treat that all policies and protocols were reviewed and vetted for compliance with the laws in each individual state in which We Treat had

clients. Dr. Arora had no reason to doubt the assurances made by We Treat that the policies and protocols for Youth, Inc. were in compliance with Nevada law.

In regard to Respondents Gifford, McIntyre, and Jaggard, all three were employees/contractors with We Treat during the times in question. Their duties were to provide medical clearance reviews for patients wishing to receive services at practices which were contracted with We Treat and if cleared, authorize treatment to be provide pursuant to previously approved medical protocols. Respondents had no duties related to the oversight or supervision of any practice served by We Treat. Respondents would be notified through a proprietary platform that a patient required a medical clearance evaluation at practices which received services from We Treat and would be given access to the patient records through the We Treat platform and would either clear the patient for treatment or deny treatment[1]. Each clinic had individual protocols which would be followed by Respondents. Respondents were informed by We Treat that policies related to requirements for providing medical clearance for patients was vetted by its compliance department and all protocols were in compliance with state laws; Respondents had no reason to question the representations of We Treat.

Respondent Gifford estimates that she performed very few medical clearance evaluations for Youth, Inc. through the We Treat platform. Respondent McIntyre estimates that she did approximately two medical clearance evaluations for Youth, Inc. Respondent Jaggard estimates that she did a maximum of ten to fifteen medical clearance evaluations for Youth, Inc.

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[1] We Treat practitioners only performed medical clearance evaluations for patients in states in which they were licensed.

All Respondents deny having violated NRS and/or NAC Chapters 453, 454, or 639. Further Respondents reserve all legal defenses available to them should this matter proceed to a hearing.

Respectfully submitted this 15th day of August, 2025.

Lyn E. Beggs, Esq.
Attorney for Respondents

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476,** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484, and** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos. 24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Sean Arora, M.D., ("Respondent Arora"), because Respondent Arora holds a certificate of registration issued by the Board authorizing him to prescribe controlled substances in Nevada. Respondent Arora holds certificate of registration no. CS31476, which was issued by the Board pursuant to NRS 453.226 and 453.231.

2. The Board has personal jurisdiction over Respondent Cassie Gifford, APRN, ("Respondent Gifford"), because Respondent Gifford holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent Gifford holds certificate of

registration no. PR18034, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.[1]

3. The Board has personal jurisdiction over Respondent Gabrielle McIntyre, APRN, ("Respondent McIntyre"), because Respondent McIntyre holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR17484, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850.

4. The Board has personal jurisdiction over Respondent Allison Jaggard, APRN, ("Respondent Jaggard"), because Respondent Jaggard holds a certificate of registration issued by the Board authorizing her to prescribe dangerous drugs in Nevada. Respondent holds certificate of registration no. PR171499, which was issued by the Board pursuant to NRS 639.2351 and NAC 639.850

5. The Board has jurisdiction over the subject matter of this accusation because it alleges violations involving the purchase, receipt, storage, possession, prescribing and/or dispensing of dangerous drugs and controlled substances. As used herein, "dangerous drug" has the meaning ascribed to it in NRS 454.201, and "controlled substance" means a substance listed in NAC 453.510 to NAC 453.550, inclusive, or in 21 CFR Part 1308.

FACTUAL ALLEGATIONS

6. Respondent Arora is a physician licensed by the Nevada State Board of Medical Examiners to practice medicine in Nevada. At all times alleged herein, Respondent Arora was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

7. Respondent Gifford is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent

1. Respondent Gifford formerly held certificate of registration no. CS34942, authorizing her to prescribe controlled substances. Certificate of registration no. CS34942 was not renewed when it came due for renewal on November 1, 2024.

Gifford was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

8. Respondent McIntyre is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

9. Respondent Jaggard is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. At all times alleged herein, Respondent McIntyre was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

10. In 2024, Respondent Arora formed a partnership or other business relationship with We Treat, a medical consulting firm based in San Diego, California. We Treat provides consulting services and regulatory compliance advice to medical spas and wellness clinics.

11. We Treat provided consulting services and compliance advice to Youth, Inc. (Youth Inc.), the owner of a medical spa and wellness clinic located at 695 Sierra Rose Drive in Reno, Nevada.

12. We Treat developed a manual of policies, procedures and protocols for use by Youth Inc. Respondent Arora approved these policies, procedures and protocols for use by Youth Inc.

13. Between April 2024 and March 2025, Youth Inc. provided various anti-aging and wellness treatments for its patients. These included cosmetic treatments using botulinum toxin type A and dermal fillers, treatments for weight loss using compounded tirzepatide and semaglutide products, hormone replacement using injectable hormones, and treatment for erectile dysfunction using sildenafil and tadalafil.

14. Between April 2024 and March 2025, Youth Inc. did not lock or otherwise secure the dangerous drugs and/or controlled substances in its possession.

15. In early 2025, Youth Inc. was in possession of stock bottles containing sildenafil, tadalafil, and metformin hydrochloride, all dangerous drugs. Youth Inc.'s representatives claimed that

they were not planning to dispense these drugs until after they had secured a dispensing license issued by the Board.

16. We Treat arranged for Respondent Arora to serve as the "medical director" for Youth Inc., a role that Respondent Arora assumed sometime between April and August 2024.

17. Respondent Arora served as Youth Inc.'s medical director until early 2025.

18. During Respondent Arora's tenure as Youth Inc.'s medical director, Respondent Arora worked and resided in Seattle, Washington. Respondent Arora never visited Youth Inc.'s facility in Reno, Nevada.

19. Sometime between April 2024 and March 2025, Youth Inc. engaged the services of Respondent Gifford, Respondent McIntyre and Respondent Jaggard. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard rarely, if ever, visited Youth Inc.'s facility in Reno, Nevada.

20. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed a prospective patient's medical questionnaire prior to the prospective patient's initial treatment at Youth Inc. Respondent Gifford, Respondent McIntyre, and Respondent Jaggard reviewed these medical questionnaires from a remote location and never saw or spoke to patients prior to their initial treatments at Youth Inc.

21. After reviewing medical questionnaires, and despite not ever seeing the patients in question, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the use or administration of dangerous drugs and/or controlled substances.

22. Sometime between April 2024 and March 2025, Youth Inc. employed Maddison Weiss-Frank, a registered nurse. Ms. Weiss-Frank was not an advanced practice registered nurse and was not a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

23. Ms. Weiss-Frank worked under the direction and supervision of Rachel Gonzalez, the co-owner and chief executive officer of Youth Inc. Ms. Gonzalez was not a "practitioner" as that term

is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125. On information and belief, Ms. Gonzalez has no formal medical training.

24. Because there was never a practitioner present at the location, Youth Inc.'s facility at 695 Sierra Rose Drive in Reno, Nevada, was not a location where a registered nurse could lawfully inject a neuromodulator pursuant to NRS 454.217.

25. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank treated patients using prescription drugs and/or controlled substances. Ms. Weiss-Frank did not act under the direction or supervision of a practitioner.

26. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances. Ms. Weiss-Frank did not work under the direction or supervision of a practitioner.

27. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

28. In adherence to the policies, procedures and protocols developed by We Treat and approved by Respondent Arora, Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

29. Consistent with the practice described above, Youth Inc. returned single-use vials to stock even after the vials were punctured and therefore rendered unusable for subsequent treatments.

30. As the medical director for Youth Inc., Respondent Arora periodically reviewed purchase invoices and signed for shipments of dangerous drugs and/or controlled substances.

31. As the medical director for Youth Inc., Respondent Arora periodically reviewed patient medical questionnaires and treatment records.

32. As the medical director for Youth Inc., Respondent Arora periodically reviewed Youth Inc.'s policies, procedures and protocols related to the procurement, storage, possession and administration of dangerous drugs and controlled substances.

33. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank received, stored, and possessed dangerous drugs and/or controlled substances without direction or supervision by a practitioner.

34. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank treated patients with prescription drugs and/or controlled substances despite not working under the supervision or direction of a practitioner.

35. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or Ms. Gonzalez ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

36. Based upon his knowledge of Youth Inc.'s records and business practices, Respondent Arora knew or should have known that Ms. Weiss-Frank and/or other employees of Youth Inc. injected multiple patients with prescription drugs and/or controlled substances contained within single-use vials.

37. As Youth Inc.'s medical director, Respondent Arora had a duty to understand Nevada law as it governs the receipt, possession, storage, and distribution of dangerous drugs and controlled substances.

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APPLICABLE LAW

38. It is unlawful for any person to engage in wholesale distribution, or permit to be distributed at wholesale, any drug or compound unless the person holds the appropriate certificate, license or permit issued by the Board. NRS 639.100(1).

39. To engage in wholesale distribution of any drug or compound in Nevada, a person must be licensed as a wholesaler or manufacturer, as applicable. NRS 639.100; NRS 639.233; NAC 639.593; NAC 639.6915.

40. The Board may revoke or suspend the registration of any practitioner who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapters 453, 454, 639, or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12); NRS 453.236.

41. Additionally, the Board may revoke or suspend the registration of any practitioner who is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4); NRS 453.236.

42. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner performs his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful, or negligent manner, or if the practitioner assists or abets a person not licensed to practice pharmacy in Nevada. NAC 639.945(1)(i) and (j).

43. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner prescribes or orders a dangerous drug or controlled substance for a person with whom the practitioner does not have a bona fide therapeutic relationship. NAC 639.945(1)(n).

44. "'Practice of pharmacy' includes, but is not limited to, the . . . [p]erformance or supervision of activities associated with manufacturing, compounding, labeling, dispensing and distributing of a drug, including the receipt, handling and storage of prescriptions and other confidential information relating to patients." NRS 639.0124(1)(a).

45. It is unlawful to possess, store, or administer dangerous drugs, including botulinum toxin type A and injectable dermal fillers, except as authorized by NRS 454.213.

46. It is unlawful to possess, store, or administer controlled substances, including testosterone, except as provided by NRS 453.375.

47. "Administer" means the direct application of a [dangerous drug or controlled substance] . . . whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject." NRS 453.021; NRS 454.191.

48. Pursuant to NRS 453.375, a registered nurse may not possess, store, or administer controlled substances except when working under the direction of a supervising practitioner.

49. Pursuant to NRS 454.213, a registered nurse may not possess, store, or administer dangerous drugs except at the direction of a supervising practitioner.

50. It is unlawful for a registered nurse to inject botulinum toxin type A in a patient or customer "at a location other than a medical facility, as defined in NRS 449.0151, or the office of a physician or physician assistant licensed [pursuant to applicable statutes]." NRS 454.217.

51. A person who maintains a stock of controlled substances and/or dangerous drugs must not commingle expired substances and unexpired substances in a storage area from which the substances are withdrawn from stock for administering or dispensing to patients. NAC 639.050(2).

52. A practitioner is subject to discipline if the practitioner causes or allows a dangerous drug to be dispensed in a manner not authorized by NRS 454.215 and NRS 454.301. *See* NRS 639.100; NRS 639.210(12).

53. The term "dispense" includes the prescribing by a practitioner, administering, packaging, labeling, or compounding necessary to prepare a substance for delivery to a patient. NRS 639.0065; NRS 453.056.

54. It is unlawful to furnish drugs without a prescription. NRS 454.221.

55. "Furnish" means to supply by any means, by sale or otherwise. NRS 454.006.

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COUNT ONE
Permitting Unlicensed Wholesale Distribution
(Respondent Arora)

56. As alleged above, Respondent Arora served as the medical director for Youth Inc.

57. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered and received compounded tirzepatide and semaglutide products from GLP-1 Sciences, LLC, a California manufacturer and/or supplier not licensed to engage in wholesale distribution in Nevada.

58. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage purchases from unlicensed distributors such as GLP-1 Sciences, LLC. Respondent failed to implement such policies, procedures and protocols.

59. Given the facts and circumstances alleged above, Respondent Arora permitted the unlicensed wholesale distribution of compounded drug products in violation of NRS 639.100(1).

60. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

61. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT TWO
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondent Arora)

62. As alleged above, Respondent Arora served as the medical director for Youth Inc.

63. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank ordered, received, possessed, and/or stored dangerous drugs and/or controlled substances. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

64. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of

Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

65. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the above persons from ordering, receiving, possessing, storing and/or furnishing dangerous drugs and/or controlled substances. Respondent Arora failed to implement such policies, procedures and protocols.

66. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the unlicensed practice of pharmacy.

67. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

68. Respondent Arora's acts and/or omissions as alleged above amount to conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(i) and (j).

COUNT THREE
Assisting or Abetting in Violations of NAC 639.050(2)
(Respondent Arora)

69. As alleged above, Respondent Arora served as the medical director for Youth Inc.

70. During Respondent Arora's tenure as medical director, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

71. As the medical director for Youth Inc., Respondent Arora had a duty to implement policies, procedures and protocols to prevent or discourage the repeated or recurring use of punctured single-use vials. Respondent failed to implement such policies, procedures and protocols.

72. Given the facts and circumstances alleged above, Respondent Arora assisted or abetted in the above violations of NAC 639.050(2).

73. Given the facts and circumstances alleged above, Respondent Arora performed his duties in an incompetent, unskillful, or negligent manner.

74. Respondent Arora's acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FOUR
Assisting or Abetting in Violations of NAC 639.050(2)
(Respondents Gifford, McIntyre and Jaggard)

75. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank injected multiple patients with drugs contained within single-use vials. After the vials were punctured, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank returned the vials to stock for subsequent use, in violation of NAC 639.050(2).

76. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of injectable drugs contained within single-use vials.

77. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard had a duty to ensure that Youth Inc. did not make repeated or recurring uses of punctured single-use vials.

78. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that Youth Inc. did not return single-use vials to stock after the vials were punctured.

79. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard assisted or abetted in the above violations of NAC 639.050(2).

80. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

81. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT FIVE
Assisting or Abetting the Unlicensed Practice of Pharmacy
(Respondents Gifford, McIntyre and Jaggard)

82. As alleged above, between April 2024 and March 2025, Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank furnished dangerous drugs and/or controlled substances to patients of Youth Inc. This amounted to the unlicensed "practice of pharmacy" as that term is defined at NRS 639.0124(1)(a).

83. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

84. Having authorized the above treatments, Respondent Gifford, Respondent McIntyre and Respondent Jaggard had a duty to ensure that dangerous drugs and/or controlled substances were administered under the direction or supervision of a practitioner. Dangerous drugs and/or controlled substances were not administered under the direction or supervision of a practitioner.

85. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard assisted or abetted the unlicensed practice of pharmacy by Youth Inc., Rachel Gonzalez, and/or Maddison Weiss-Frank.

86. Given the facts and circumstances alleged above, Respondent Gifford, Respondent McIntyre and Respondent Jaggard performed their duties in an incompetent, unskillful, or negligent manner.

87. Respondents' acts and/or omissions as alleged above amount to a violation of law and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 453.236; NAC 639.945(1)(i).

COUNT SIX
Failure to Establish a Bona Fide Therapeutic Relationship with Patients
(Respondents Gifford, McIntyre and Jaggard)

88. Between April 2024 and March 2025, as alleged above, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard authorized initial patient treatments calling for the administration of dangerous drugs and/or controlled substances.

89. Respondent Gifford, Respondent McIntyre and Respondent Jaggard never saw or spoke with the above patients for whom they authorized treatments with dangerous drugs and/or controlled substances.

90. Having failed to see or speak with the above patients, Respondent Gifford, Respondent McIntyre, and Respondent Jaggard failed to establish a bona fide therapeutic relationship with the above patients prior to authorizing their initial treatments with dangerous drugs and/or controlled substances.

91. Respondents' conduct as alleged above amounts to unprofessional conduct and/or conduct contrary to the public interest for which the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236; NAC 639.945(1)(n).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of Respondent Sean Arora, Respondent Cassie Gifford, Respondent Gabrielle McIntyre, and Respondent Allison Jaggard.

DATED this 24th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondent.**	**Case No. 24-509-PR-C-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondent.**	**Case No. 24-509-PR-C-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Allison Jaggard, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Sean Arora, MD
c/o Youth Inc
691 Sierra Rose Dr
Reno, NV 89511

Cassie Gifford, APRN
c/o Bionetics Health
5540 S Fort Apache Rd #120
Las Vegas, NV 89148

Gabrielle McIntyre, APRN
c/o Restore Hyper Wellness
1550 N Green Valley Pkwy., Ste 300
Henderson, NV 89074

Allison Jaggard, APRN
1708 Spring Green Blvd Ste 120-109
Katy, TX 77494

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 7th day of August 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Allison Jaggard, APRN c/o Allie Vitality
1708 Spring Green Blvd Ste 120-109
Katy, TX 77494

Allison Jaggard, APRN
[redacted]
Katy, TX[redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
AUG 15 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN ARORA, M.D.,** **Certificate of Registration No. CS31476** **CASSIE GIFFORD, APRN,** **Certificate of Registration Nos. CS34942 and PR18034,** **GABRIELLE MCINTYRE, APRN,** **Certificate of Registration No. PR17484,** **ALLISON JAGGARD, APRN,** **Certificate of Registration No. PR17499,** **Respondents.**	**Case Nos.** **24-509-CS-N** **24-509-PR-A-N** **24-509-PR-B-N** **24-509-PR-C-N** **ANSWER AND NOTICE OF DEFENSE OF RESPONDENTS**

Respondents Sean Arora, M.D., Cassie Gifford, APRN, Gabrielle McIntyre, APRN, and Allison Jaggard, APRN, hereby file with the Nevada State Board of Pharmacy ("Board"), their Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on July 24, 2025.

ANSWER TO ACCUSATION

Jurisdiction: Paragraphs 1-5

Paragraph 1: Dr. Arora acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 1 of the Accusation to the extent that the matter pertains to controlled substances as he holds a controlled substance registration issued by the Board.

Paragraph 2: Ms. Gifford acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 2 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 3: Ms. McIntyre acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 3 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 4: Ms. Jaggard acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 4 of the Accusation as she holds a certificate to prescribe dangerous drugs issued by the Board.

Paragraph 5: Respondents acknowledge that the Board has jurisdiction in the matter to the extent that the matter involves dangerous drugs and controlled substances. Dr. Arora acknowledges that the Board has jurisdiction over the allegations pertaining to his acts or omissions to the extent they concern controlled substances.

Factual Allegations: Paragraphs 6-37

Paragraph 6: Dr. Arora agrees with the factual allegations as set forth in Paragraph 6.

Paragraph 7: Ms. Gifford agrees with the factual allegations as set forth in Paragraph 7.

Paragraph 8: Ms. McIntyre agrees with the factual allegations as set forth in Paragraph 8.

Paragraph 9: Ms. Jaggard agrees with the factual allegations as set forth in Paragraph 9.

Paragraph 10: Dr. Arora agrees with the factual allegations set forth in Paragraph 10 only to the extent that he entered into an independent contractor agreement with We Treat, LLC in 2024.

Paragraph 11: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 11 as to the types of services which were provided to Youth Inc. However, to the best of Respondents' knowledge, Youth Inc. did receive services from

We Treat related to medical clearances for patients, policies and protocols and compliance information.

Paragraph 12: Dr. Arora agrees with the factual allegations set forth in Paragraph 12 only to the extent that he reviewed and approved policies and protocols directly related to the provision of certain medical services. Dr. Arora was not involved, nor did he review or approve, policies and procedures related to any other matters involving Youth, Inc.

Paragraph 13: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 13.

Paragraph 14: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 14.

Paragraph 15: Respondents are without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 15.

Paragraph 16: Dr. Arora acknowledges that as part of his duties for We Treat, he was assigned as medical director for Youth, Inc. in approximately April 2024. Dr. Arora's duties as medical director included the review and approval of protocols for certain medical treatments performed at Youth, Inc., responding to patient specific questions from the clinic, and authorization of the ordering of certain dangerous drugs, to be done in accordance with compliance policies prepared by We Treat.

Paragraph 17: Dr. Arora agrees with the factual allegations contained in Paragraph 17 to the extent that he provided services to We Treat until January 2025, services which included acting as medical director for Youth,. Inc., which were limited to the duties set forth in the response to Paragraph 16.

Paragraph 18: Dr. Arora acknowledges that he was based in Seattle, Washington and that his duties for Youth, Inc. did not require him to be physically at Youth, Inc.'s location.

Paragraph 19: Respondent's Gifford, McIntyre, and Jaggard deny the factual allegations set forth in Paragraph 19. None of the named Respondents were engaged by Youth, Inc. to provide any services. All three Respondents were employees/independent contractors of We Treat which provided medical clearance screening of patients for Youth, Inc. through Nevada licensed practitioners.

Paragraph 20: Respondents Gifford, McIntyre, and Jaggard acknowledge that they reviewed and medically cleared patients for treatments performed at Youth, Inc. pursuant to medical protocols reviewed and approved by Dr. Arora and performed these reviews in accordance with policies and protocols developed and approved by We Treat, not Dr. Arora.

Paragraph 21: Respondents Gifford, McIntyre and Jaggard acknowledge that they medically cleared patients, if appropriate, after the review of medical information and authorized treatments to be performed pursuant to protocols approved by Dr. Arora which included standing orders for administration of certain drugs or the issuance of prescriptions pursuant to those protocols. No approved protocols for treatments authorized the administration of controlled substances at Youth, Inc.

Paragraph 22: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 22.

Paragraph 23: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 23.

Paragraph 24: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 24.

Paragraph 25: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 25.

Paragraph 26: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 26.

Paragraph 27: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 27.

Paragraph 28: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 28.

Paragraph 29: Respondents are without sufficient personal knowledge to respond to the allegations contained in Paragraph 29.

Paragraph 30: Dr. Arora acknowledges that he would periodically review orders received for dangerous drugs and would sign, remotely for the same. Drugs were to be stored and accessed in accordance with policies and protocols developed by We Treat; Dr. Arora was not part of the development of those policies and procedures, nor was he asked to review them by We Treat. Dr. Arora denies that he ever signed off or approved of any shipments of controlled substances to Youth, Inc. and to his knowledge, no controlled substances were to be received or stored on-site at We Treat.

Paragraph 31: Dr. Arora denies the factual allegations contained in Paragraph 31, however he acknowledges that he would respond to patient specific questions posed to him and would review patient records at that time; however this occurred very rarely.

Paragraph 32: Dr. Arora denies the factual allegations contained in Paragraph 32. Dr. Arora was not responsible for the policies and procedures related to the procurement, storage, possession and/or administration of dangerous drugs or controlled substances other than approving

protocols directly related to the provision of medical services. We Treat's compliance department was solely responsible for the policies and protocols otherwise related to dangerous drugs and controlled substances.

Paragraph 33: Dr. Arora denies the allegations set forth in Paragraph 33.

Paragraph 34: Dr. Arora denies the allegations set forth in Paragraph 34.

Paragraph 35: Dr. Arora denies the allegations set forth in Paragraph 35.

Paragraph 36: Dr. Arora denies the allegations set forth in Paragraph 36.

Paragraph 37: Dr. Arora denies the allegations set forth in Paragraph 37 as he was not involved in, nor responsible for the receipt, possession storage, and distribution of dangerous drugs or controlled substances at Youth, Inc.

Applicable Law: Paragraphs 38-55

Paragraph 38-55: Respondents acknowledge that Paragraphs 38-55 accurately reflect the basic substance of the statutes and regulations cited therein.

Counts: Paragraphs 56-91

Count One (Paragraphs 56-61): Dr. Arora generally denies the allegations set forth in Count One in Paragraphs 56-61. Dr. Arora did not permit Youth, Inc. or any of its personnel to order any dangerous drugs from any manufacturer or supplier not licensed in Nevada. As discussed herein, Dr. Arora's duties for Youth, Inc. were limited to the review and authorization of protocols related to medical procedures. While Youth, Inc. was authorized to order supplies and dangerous drugs under Dr. Arora's credentials, this was to be done in accordance with policies and protocols developed and approved by We Treat's compliance department. To the best of Dr. Arora's knowledge, no client of We Treat was authorized to order or received dangerous drugs or other supplies from unlicensed suppliers/manufacturers.

Count Two (Paragraphs 62-68): Dr. Arora generally denies all allegations set forth in Count Two in Paragraphs 62-68. Further Dr. Arora asserts that a practice which orders, receives, and stores dangerous drugs is not engaging in the practice of pharmacy as alleged. If indeed this was accurate, every medical practice or facility that orders, receives and stores drugs for administration and/or dispensing, would be required to hold a pharmacy license with the Board; that is not currently a requirement and NRS 639.0124(1)(a) is inappropriately applied here.

Count Three (Paragraphs 69-74): Dr. Arora generally denies the allegations set forth in Count Three in Paragraphs 69-74. Again, as discussed herein, Dr. Arora's duties for Youth, Inc. were limited and did not include the development or approval of any protocols or procedures related to the procurement or storage of dangerous drugs. Dr. Arora's medical service protocols did not allow for the reuse of single use vials and any reuse of single use vials on the part of Youth, Inc. personnel would have been done without the knowledge of Dr. Arora and he did not aid or abet any violation of NAC 639.050(2).

Count Four (Paragraphs 75-81): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Four in Paragraphs 75-81. Respondents Gifford, McIntyre, and Jaggard, worked for We Treat, not Youth, Inc. Respondents' duties for Youth, Inc. were limited to conducting medical clearance reviews for patients and if cleared, the patient was authorized for treatment pursuant to approved medical protocols. None of the named respondents were responsible for supervising the staff of Youth, Inc. and would have had no knowledge of unauthorized reuse of single use vials by any personnel associated with Youth, Inc.

Count Five (Paragraphs 82-87): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Five in Paragraphs 75-81. The administration of dangerous drugs to patients is not the practice of pharmacy as defined by NRS 639.0124(1)(a) and

accordingly Respondents could not have aided or abetted in the violation of said statute. Again, as discussed above, should the Board take the position that the administration of a dangerous drug constitutes the practice of pharmacy, all practices and facilities at which any drug is administered would be required to hold a registration as a pharmacy with the Board which is not currently required.

Count Six (Paragraphs 88-91): Respondents Gifford, McIntyre, and Jaggard all generally deny the allegations set forth in Count Six in Paragraphs 88-91.

NOTICE OF DEFENSE/MITIGATING INFORMATION

In regard to Respondent Arora, Dr. Arora stresses that his involvement with We Treat was limited as medical director. The term "medical director" is not defined under Nevada law and there is no legal precedent for what the duties of a medical director must consist of. Dr. Arora functioned as a medical director per the duties he had as a contractor for We Treat, LLC, which consisted solely of the review and authorization of protocols for medical services offered at practices contracted with We Treat and he was required to be available for consultations regarding specific patient questions as needed. The medical protocols authorized by Dr. Arora included standing orders for the administration of certain dangerous drugs and for the prescription of certain controlled substances. It should be noted that Dr. Arora never authorized the administration of controlled substances at Youth, Inc., or any other practice for which he provided services under We Treat and to his knowledge, no controlled substances were stored on-site at Youth, Inc.

We Treat's compliance department was responsible for the development and authorization of all other policies and protocols, including those related to the procurement, receipt, and storage of dangerous drugs. Dr. Arora was advised by We Treat that all policies and protocols were reviewed and vetted for compliance with the laws in each individual state in which We Treat had

clients. Dr. Arora had no reason to doubt the assurances made by We Treat that the policies and protocols for Youth, Inc. were in compliance with Nevada law.

In regard to Respondents Gifford, McIntyre, and Jaggard, all three were employees/contractors with We Treat during the times in question. Their duties were to provide medical clearance reviews for patients wishing to receive services at practices which were contracted with We Treat and if cleared, authorize treatment to be provide pursuant to previously approved medical protocols. Respondents had no duties related to the oversight or supervision of any practice served by We Treat. Respondents would be notified through a proprietary platform that a patient required a medical clearance evaluation at practices which received services from We Treat and would be given access to the patient records through the We Treat platform and would either clear the patient for treatment or deny treatment[1]. Each clinic had individual protocols which would be followed by Respondents. Respondents were informed by We Treat that policies related to requirements for providing medical clearance for patients was vetted by its compliance department and all protocols were in compliance with state laws; Respondents had no reason to question the representations of We Treat.

Respondent Gifford estimates that she performed very few medical clearance evaluations for Youth, Inc. through the We Treat platform. Respondent McIntyre estimates that she did approximately two medical clearance evaluations for Youth, Inc. Respondent Jaggard estimates that she did a maximum of ten to fifteen medical clearance evaluations for Youth, Inc.

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[1] We Treat practitioners only performed medical clearance evaluations for patients in states in which they were licensed.

All Respondents deny having violated NRS and/or NAC Chapters 453, 454, or 639. Further Respondents reserve all legal defenses available to them should this matter proceed to a hearing.

Respectfully submitted this 15th day of August, 2025.

Lyn E. Beggs, Esq.
Attorney for Respondents

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL J. STELLMACHER, PA, Certificate of Registration No. CS21884,** **Respondent.**	**Case No. 24-364-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Michael J. Stellmacher, PA ("Respondent") held a registration issued by the Board, Certificate of Registration No. CS21884.

FACTUAL ALLEGATIONS

2. At all times relevant to this accusation, Respondent has been employed as the medical director of Premier Beauty, LLC, also known as Channel Pro, (Premier Beauty), located at 4555 S. Fort Apache Road, Suite 104, in Las Vegas, Nevada.

3. Since at least December 28, 2023 until present, Joseph Gillis ("Gillis") owned and/or operated Premier Beauty. Since at least May 9, 2024 until present, Betty Dare ("Dare") was listed as the director of Premier Beauty. Gillis and Dare are not Nevada-licensed practitioners as that term is defined in NRS 639.0125 and NRS 453.126.

4. A Board investigation on August 29, 2024 revealed that Respondent permitted Gillis and Dare to have independent access to the medication storage containing dangerous drugs, and to access those medications outside Respondent's presence without Respondent's supervision.

5. Respondent admitted that he was the medical director of Premier Beauty, but that he rarely was on site and stated that he had no patient records. Respondent was not physically on-site at Premier Beauty while Board investigators were there.

6. Respondent permitted Dare to independently access, possess, furnish, and administer dangerous drugs to patients, to provide on-site medical treatment, including the administration of dangerous drugs through injection, specifically tirzepatide, semaglutide powders, and nicotinamide adenine dinucleotide (NAD), without direct practitioner supervision, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug was medically necessary.

7. Furthermore, the investigation revealed that these dangerous drugs were purchased from OUISA Pharmacy Corp. (OUISA), located in Spring Hill, Florida; OUISA not licensed as a wholesaler by the Board. The dangerous drugs were labeled as not for patient use.

8. Respondent permitted Gillis to purchase the drug products using the National Provider Identifier (NPI) number of Dr. Jayendrakumar Amin (Amin) and had the products shipped to California. Amin is located in California and does not hold any license or registration with the Board.

9. Premier Beauty's inventory included multiple vials of various injectable drugs intended for distribution in foreign markets and not approved for distribution or use in the United States, including medytox and other forms of botulinum toxins, multivitamin injections, and glutathione injections.

10. In at least one instance, Respondent's failure to supervise Dare while she administered tirzepatide to a patient resulted in patient harm. On June 7, 2024, Dare injected patient D.S. with tirzepatide and gave D.S. three more shots to take home with her. D.S. went to the emergency room with injuries from the injection. Respondent was not on site during the injection.

11. On or about February 19, 2025, the Board issued a cease-and-desist order with a citation and fine against Premier Beauty, Gillis, and Dare for unlicensed activity. On or about February 25, 2025, the Board issued a cease-and-desist order with a citation and fine against Amin for unlicensed wholesale activity.

APPLICABLE LAW

12. No person may possess, furnish or administer a dangerous drug in Nevada without specific statutory authority to do so. NRS 454.213; NRS 454.217; NRS 454.221; NRS 454.316; NRS 454.321; NRS 454.356; NRS 639.100(1); NRS 639.1373.

13. Only those individuals permitted to do so pursuant to NRS 454.213 may possess, store, or administer dangerous drugs. Chart orders are patient-specific and medication-specific. *See* NRS 454.0041; NRS 639.004.

14. A physician assistant who is authorized to prescribe and dispense controlled substances and dangerous drugs may do so only for a legitimate medical purpose. NAC 639.280(1)(a).

15. All controlled substances and dangerous drugs in the possession of physician assistant must be kept in a locked storage area with access restricted to authorized persons. NAC 639.285(1).

16. The Board may suspend or revoke the certificate of registration of physician assistant that has failed to maintain the security of his or her drug supply. NAC 639.295(13).

17. It is unlawful to purchase, possess, sell, furnish or administer any drug product intended for distribution in foreign markets and not approved for distribution or use in the United States. 21 U.S.C. § 331; 21 U.S.C. § 355(a); NRS 454.351(1); NRS 585.490.

18. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of registration issued by the Board to a physician assistant. NRS 639.210(11); NAC 639.295(10).

19. The Board may revoke or suspend the registration of any physician assistant who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any law or regulation relating to drugs, including, without limitation, any provision of chapter 453, 454, 585 or 639 of NRS or any regulation pertaining thereto. NRS 639.210(12) NAC 639.295(16).

20. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.295(4).

21. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.295(4).

22. It is unlawful for a physician assistant to inject botulinum toxin type A in a patient or customer "at a location other than a medical facility, as defined in NRS 449.0151, or the office of a physician or physician assistant licensed [pursuant to applicable statutes]." NRS 454.217.

23. Dispensing a drug to any patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct contrary to the public pursuant to NAC 639.945(1)(n) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.295(4).

24. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

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COUNT ONE

Violations of State Law - Failure to Maintain Security of Dangerous Drugs

25. By permitting Gillis and Dare to have unrestricted access to his inventory of dangerous drugs at Premier Beauty as alleged in paragraphs 4-5 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.285(1), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.295(13) and (16) and/or NRS 639.210(12).

COUNT TWO

Violations of State Law – Unlawful Possession & Administration of Dangerous Drugs

26. By permitting an unlicensed individual to independently access, possess, furnish, and administer dangerous drugs without direct practitioner supervision, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed not determined that a dangerous drug was medically necessary, as alleged in paragraph 6 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356, NRS 639.100(1) and/or NRS 639.1373, and is subject to discipline pursuant to NAC 639.295(16 and/or NRS 639.210(12).

COUNT THREE

Violations of Federal and State Law – Using Drugs Not Approved in the United States

27. By purchasing, possessing, selling, furnishing and/or administering drug products intended for distribution in foreign markets and not approved for distribution or use in the U.S., as alleged in paragraph 9 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 331, 21 U.S.C. § 355(a), NRS 454.351(1) and/or NRS 585.490, and is subject to discipline pursuant to NAC 639.295(10) and/or NRS 639.210(11).

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COUNT FOUR

Unprofessional Conduct – Unlawful Possession & Administration of Dangerous Drugs

28. By his conduct as alleged in paragraphs 4-10 herein, Respondent performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner, aided and abetted unlicensed practice, and engaged in or aided and abetted others to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and (n), and is subject to discipline pursuant to NAC 639.295(4) and/or NRS 639.210(4).

COUNT FIVE

Commission of Acts that Render Registration Inconsistent with Public Interest

29. By his conduct as alleged in paragraphs 4-10 herein, Respondent has committed acts that render registration inconsistent with public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy impose appropriate discipline with respect to Respondent's Certificate of Registration No. CS21884.

Signed this 9th day of JUNE 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL J. STELLMACHER, PA,** **Certificate of Registration No. CS21884,** **Respondent.**	**Case No. 24-364-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, July 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** L.Tucker@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of June 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL J. STELLMACHER, PA,** **Certificate of Registration No. CS21884,** **Respondent.**	**Case No. 24-364-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Michael J. Stellmacher, PA

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 10th day of June 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Michael Stellmacher, PA
[redacted]
Fallon, NV [redacted]

Michael Stellmacher, PA
[redacted]
Pahrump, NV [redacted]

Michael Stellmacher, PA
[redacted]
Las Vegas, NV [redacted]

Forte Family Practice
c/o Michael Stellmacher, PA
9010 West Cheyenne Ave
Las Vegas, NV 89129

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL J. STELLMACHER, PA,** **Certificate of Registration No. CS21884,** **Respondent.**	**Case No. 24-364-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through its General Counsel, Laura M. Tucker, and Respondent Michael J. Stellmacher, PA. ("Respondent"), by and through his counsel, Anthony Cortez, hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that he understands the terms of this Stipulation and Proposed Order ("Stipulation"), and he has executed it knowingly and voluntarily.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 453, the Nevada Controlled Substances Act, and NRS Chapter 639, the Nevada Pharmacy Act.

5. Conditioned on the acceptance of this Stipulation by the Board and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this

Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent does not contest the allegations stated in Count One, Count Two, Count Three, Count Four, and Count Five of the Accusation, and further admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged therein, to wit:

A. Respondent, a physician assistant, served as the medical director for Premier Beauty, LLC, also known as Channel Pro, (Premier Beauty), a medical spa located at 4555 S. Fort Apache Road, Suite 104, in Las Vegas, Nevada.

B. During Respondent's tenure as medical director, Respondent rarely visited the spa's location at 4555 S. Fort Apache Road, Suite 104.

C. During Respondent's tenure as medical director, Premier Beauty's owner and/or employees stored and possessed dangerous drugs at times when Respondent was not physically present at the spa's location at 4555 S. Fort Apache Road, Suite 104.

D. During Respondent's tenure as the medical director, a Premier Beauty employee administered injectable prescription drugs at times when Respondent was not physically present at the spa's location at 4555 S. Fort Apache Road, Suite 104, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug was medically necessary.

E. During Respondent's tenure as medical director, Premier Beauty's owner and/or employees ordered and received dangerous drugs labeled as not for patient use from OUISA Pharmacy Corp., located in Spring Hill, Florida, a wholesaler not licensed to engage in wholesale distribution in Nevada.

F. During Respondent's tenure as medical director, Premier Beauty's inventory included multiple vials of various injectable drugs intended for distribution in foreign markets and not approved for distribution or use in the United States, including medytox and other forms of botulinum toxins, multivitamin injections, and glutathione injections.

7. Now, therefore, to resolve the allegations stated in Count One, Count Two, Count Three, Count Four, and Count Five of the Accusation without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent accepts this Stipulation as a public reprimand.

B. Respondent agrees to pay an administrative fine of **Two Thousand Five Hundred and 00/100 Dollars ($2,500.00)**, payable by *cashier's check, certified check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before June 30, 2026.

C. Respondent shall pay the sum of **One Thousand and 00/100 Dollars ($1,000.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this case. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before June 30, 2026.

8. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 24-364-CS-S. Any failure by Respondent to comply with the terms of this Stipulation may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing him to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in the finding of noncompliance by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639 and/or NRS Chapter 453.

9. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on April 15, 2026, in Reno, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear at the meeting.

10. The Board may accept this Stipulation, but it has no obligation to accept this Stipulation. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and

shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all of this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hold a contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the date of entry set forth below.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ____ day of ____ 2026.

_____
MICHAEL STELLMACHER, PA
Certificate of Registration No. CS21884

Signed this ____ day of _____ 2026.

NEVADA STATE BOARD OF PHARMACY

By_____
LAURA M. TUCKER, ESQ.
General Counsel

Approved as to Form and Content:

_____
ANTHONY CORTEZ, ESQ.

Attorney for Respondent Michael Stellmacher, PA

DECISION AND ORDER

As to Respondent Michael Stellmacher, PA, in Case No. 24-364-CS-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and orders that its terms and conditions be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this __ day of April 2026.

_____
Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHILIP RICH, MD,** **Certificate of Registration No. CS02308,** **Respondent.**	**Case No. 25-021-CS-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Philip Rich, MD (Respondent) held a registration issued by the Board, Certificate of Registration No. CS02308.

FACTUAL ALLEGATIONS

2. Respondent is licensed by the Nevada State Board of Medical Examiners to practice medicine. At the time of the violations alleged herein, Respondent was a "practitioner" as that term is defined at NRS 453.126(1) and 639.0125(1).

3. Since April 4, 1980 through present, Respondent has held a certificate of registration issued by the Board pursuant to NRS 453.226. This certificate of registration authorized Respondent to prescribe controlled substances. Respondent's current certificate of registration was renewed November 1, 2024, and is set to expire October 31, 2026.

4. Respondent has an established account with Nevada's Prescription Monitoring Program (PMP). The account provides Respondent with individual access to the PMP database, a

confidential source of information concerning all prescriptions written in Nevada for controlled substances.

5. Patient S.V. has had a provider/patient relationship with Respondent since 2015. Between June 2020 and June 2025, Patient S.V. received two hundred ten (210) controlled substances prescriptions from twenty-six (26) different prescribers. Respondent prescribed her approximately eighty-five (85) of the prescriptions, including refills.

6. During the relevant timeframe, the first prescription Respondent wrote for Patient S.V. was on October 27, 2021, and the last one was written on January 7, 2025. The prescriptions were for alprazolam (Xanax), zolpidem tartrate (Ambien), daridorexant (Quviviq), temazepam, and diazepam. According to Patient S.V.'s PMP patient utilization report, she was simultaneously prescribed hydrocodone, oxycodone, diazepam, pregabalin, and buprenorphine by other providers while seeing Respondent.

7. Specifically, according to Board records, Respondent wrote fifteen (15) controlled substance prescriptions for Patient S.V. between October 27, 2021 and August 30, 2022, but did not run a PMP patient utilization report on Patient S.V. to evaluate her prescription history during that timeframe or ninety (90) days prior. The first time during the relevant timeframe that Respondent ran a patient utilization report on Patient S.V. was October 5, 2022.

8. Respondent wrote thirteen (13) controlled substance prescriptions for Patient S.V. between January 30, 2023 and January 3, 2024, but did not run a patient utilization report on her during that timeframe or ninety (90) days prior.

9. Respondent wrote four (4) controlled substance prescriptions for Patient S.V. between November 1, 2024 and January 7, 2025, but did not run a patient utilization report on her during that timeframe or ninety (90) days prior. Respondent ran a patient utilization report on Patient S.V. on April 25, 2025.

10. According to the Board's records, between August 21, 2023 and August 12, 2025, Respondent never accessed the PMP database to review his own prescribing activity.

11. Between March 18, 2023 – March 18, 2025 Respondent wrote 13,759 prescriptions for controlled substances, including refills, for 818 unique patients. He conducted a total of 831 patient history queries for 634 unique patients.

APPLICABLE LAW

12. In Nevada, it is unlawful to dispense a controlled substance except as authorized by NRS Chapter 453. NRS 453.321(1)(a). "Dispense" is defined to include the act of prescribing a controlled substance. NRS 453.056.

13. Every practitioner who intends to prescribe controlled substances in Nevada must first apply for and obtain a certificate of registration from the Board. NRS 453.226(1); NRS 453.231(3). The practitioner must renew the certificate of registration on a biennial basis. *Id.* A practitioner who fails to register or renew may be subject to criminal and/or civil penalties for prescribing controlled substances without a certificate of registration. NRS 453.232; NRS 453.553; NRS 453.5531.

14. When a practitioner first obtains a certificate of registration to prescribe controlled substances, the practitioner must enroll in the PMP and complete a course of instruction concerning the use of the PMP database. NRS 453.164(5) & (6); NAC 453.065.

15. A practitioner shall, before issuing an initial prescription for a controlled substance, and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the PMP. NRS 639.23507.

16. A practitioner registered with the Board to write prescriptions for controlled substances must access his or her prescriber activity in the PMP at least once every 6 months to review prescriptions issued by the practitioner and to verify for the Board that he or she continues to have access to the PMP. NRS 453.164(7).

17. The Board may revoke or suspend the registration of any practitioner who has violated any Nevada statute or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12).

18. The Board may revoke or suspend the existing registration of any practitioner who has engaged in unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4).

19. A practitioner's conduct is deemed unprofessional and/or contrary to the public interest if the practitioner performs his or her duties in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i).

20. In addition to or in lieu of revoking or suspending a practitioner's certificate of registration due to any violation described herein, the Board may impose an administrative fine upon the practitioner. The fine may not exceed $10,000 for each offense. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct/Conduct Contrary to the Public Interest - Noncompliance with Prescription Monitoring Program

21. As alleged above, between October 27, 2021 and August 30, 2022, January 30, 2023 and January 3, 2024, and November 1, 2024 and January 7, 2025, Respondent failed to query the PMP database regarding Patient S.V.'s history of using controlled substances. The PMP database compiles a controlled substance utilization report for any practitioner who makes such a query. The controlled substance utilization report provides the practitioner with evidence as to whether a patient is doctor-shopping and/or abusing controlled substances.

22. As alleged above, between October 27, 2021 and January 7, 2025, Respondent wrote 32 prescriptions for Patient S.V. without reviewing her patient utilization report prior to issuing the prescription or during the course of treatment.

23. As alleged above, between August 21, 2023 and August 12, 2025, Respondent failed to query the PMP database regarding his own prescriber activity. The PMP database

compiles a report of prescribing activity for any practitioner who makes such a query. This allows the practitioner to evaluate whether anyone has fraudulently used the practitioner's credentials to prescribe controlled substances.

24. As alleged above, between March 18, 2023 and March 18, 2025, Respondent wrote 13,759 prescriptions for controlled substances, including refills, for 818 unique patients.

25. By failing to query the PMP database to review Patient S.V.'s utilization report prior to issuing a prescription for a controlled substance and by failing to review his own prescriber activity on a semi-annual basis, as required by NRS 453.164(7) and NRS 639.23507, Respondent performed his duties as the holder of a certificate issued by the Board in an incompetent, unskillful or negligent manner. This violation of law renders his Nevada controlled substance registration inconsistent with the public interest. As alleged above, Respondent's conduct constitutes unprofessional conduct for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 639.255(3), NAC 639.945(1)(i), NRS 453.236(1)(d) and (e), and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Philip Rich.

DATED this 23rd day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHILIP RICH, MD,** **Certificate of Registration No. CS02308,** **Respondent.**	**Case No. 25-021-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 15, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 23rd day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHILIP RICH, MD,** **Certificate of Registration No. CS02308,** **Respondent.**	**Case No. 25-021-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

Philip Rich, M.D.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of FEBRUARY 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Sierra Mountain Health
c/o Philip Rich, MD
628 N Lake St
Reno, NV 89501

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHILIP RICH, MD,** **Certificate of Registration No. CS02308,** **Respondent.**	**Case No. 25-021-CS-N** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Laura M. Tucker, Esq., and Respondent Philip Rich, M.D., Certificate of Registration No. CS02308, by and through counsel, Lyn Beggs, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. On or about February 26, 2026, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. On or about March 20, 2026, the Board's General Counsel and Respondent's Counsel agreed to a stay of the deadline for Respondent to file an Answer and Notice of Defense to the Accusation.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing,

reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. Respondent has an established account with Nevada's Prescription Monitoring Program (PMP);

B. Between October 27, 2021 and August 30, 2022, January 30, 2023 and January 3, 2024, and November 1, 2024 and January 7, 2025, Respondent failed to query the PMP database regarding Patient S.V.'s history of using controlled substances;

C. Between October 27, 2021 and January 7, 2025, Respondent wrote 32 prescriptions for Patient S.V. without reviewing her patient utilization report prior to issuing the prescription or during the course of treatment;

D. Between August 21, 2023 and August 12, 2025, Respondent failed to query the PMP database regarding his own prescriber activity;

E. Between August 21, 2023 and August 12, 2025, Respondent wrote 13,759 prescriptions for controlled substances, including refills, for 818 unique patients;

F. As a result, Respondent engaged in unprofessional conduct pursuant to NRS 639.210(4) and (12); NRS 639.255(3), NAC 639.945(1)(i), NRS 453.236(1)(d) and (e), and NRS 453.241(1).

7. Those violations are pled with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

8. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agrees to the imposition of the following penalties:

A. Respondent agrees to participate in training with Board staff on use of the PMP system within sixty (60) days of the effective date of this Order;

B. Respondent shall pay a fine of Five Thousand Dollars ($5,000.00) for the alleged violations, payable by *cashier's check* or *certified check* or *money order* made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within sixty (60) days of the effective date of this Order;

C. Respondent shall pay **One Thousand Dollars ($1,000.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, payable by *cashier's check* or *certified check* or *money order* made payable to **"Nevada State Board of Pharmacy,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within sixty (60) days of the effective date of this Order;

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on April 15, 2026. Respondent will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this

matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of _____, 2026

PHILIP RICH, MD,
Certificate of Registration No. CS02308

Signed this ___ day of _____, 2026

LAURA M. TUCKER
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this ___ day of _____, 2026

_____
LYN BEGGS, ESQ.
Attorney for Respondent Philip Rich, MD

DECISION AND ORDER

As to Philip Rich, MD, in Case No. 25-021-CS-N, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____day of April 2026.

_____
Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAURA OKI, APRN,** **Certificate of Registration No. CS24180,** **Respondent.**	**Case No. 25-112-CS-A-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Laura Oki, APRN ("Respondent") held a registration issued by the Board, Certificate of Registration No. CS24180.

FACTUAL ALLEGATIONS

2. Respondent is an advanced practice registered nurse (APRN) who has been licensed by the Nevada State Board of Nursing since December 2017. She has been registered to prescribe dangerous drugs and controlled substances since January 7, 2016.

3. As of October 8, 2025, Respondent has not been issued a license to dispense dangerous drugs with the Board as required by NRS 639.23505 and NAC 639.742.

4. From on or about April 23, 2023 until February 18, 2024, Respondent was employed as the medical director of Skin Lab, LLC, (Skin Lab), located at 5362 Sparks Blvd., in Sparks, Nevada.

5. On or about December 18, 2024 until May 31, 2025, Respondent resumed the role of medical director, and Dr. William Clearfield (Clearfield) simultaneously served as the interim

medical director to provide oversight while Respondent completed her clinicals hours to become a Board-certified family nurse practitioner. During that time, both Respondent and Clearfield were responsible for ensuring that Skin Lab complied with Nevada state and federal regulations.

6. On or about June 1, 2025 through the present, Respondent has been employed full-time as medical director of Skin Lab.

7. From on or about April 23, 2023 until February 18, 2024, and on or about December 18, 2024 through the present, Respondent also owned Sparks Women's Wellness, PLLC, which operated with Skin Lab, LLC through a management services agreement.

8. Since at least July 2023, Chanelle Sisia (Sisia) has owned and operated Skin Lab. Sisia is not a Nevada-licensed practitioner as that term is defined in NRS 639.0125 and NRS 453.126.

9. As medical director, Respondent worked with and/or occasionally supervised Cyril Casino (Casino), a registered nurse who also injected customers with botulinum toxin type A and various dermal fillers. Casino is not a Nevada-licensed practitioner as that term is defined in NRS 639.0125 and NRS 453.126.

10. Botulinum toxin type A and injectable dermal fillers are "dangerous drugs" as that term is defined at NRS 454.201.

11. On or about June 3, 2025, Board Investigator Monica Segedy (Segedy) and Inspector Mui Lee (Lee) made a site visit to Skin Lab. During the inspection, Segedy and Lee found that a refrigerator at Skin Lab contained several opened vials of dangerous drugs Botox, Dysport, and Xeomin. Each vial contained the direction "single use only." The vials were dated and initialed by Casino.

12. Skin Lab maintains the vials after initial use in the event the patient returned for a "touch up." None of the vials were marked with a patient's name.

13. Segedy and Lee also found white pouches containing pre-filled syringes of dermal fillers Restylane and Juvéderm. The pouches contained the patient's name, the date of initial treatment, and Casino's initials. Restylane and Juvéderm are single-use only injections.

14. Skin Lab maintains the syringes in the event the patient returned for a "touch up."

15. Segedy and Lee found at least one expired pouch containing a date of March 2025 along with the unopened and unexpired dangerous drugs in the refrigerator.

16. During the timeframe of the inspection and while Respondent was also medical director, Clearfield would come to Skin Lab in the morning before the other Skin Lab employees arrived for work. Clearfield would pre-draw the drugs to be administered that day and place them in the secured refrigerator in the designated drug storage room. Clearfield would then either leave the key in a desk drawer in the front reception desk or give the key to Sisia or Skin Lab employee Meghan Gibson when he left Skin Lab. All Skin Lab employees had access to the desk drawer in the front reception desk, which contained the key to the refrigerator containing the dangerous drugs. This practice continued until at least June 3, 2025 when Respondent took over as sole medical director.

17. From August 2023 and October 2024, Skin Lab dispensed hydroquinone, strengths 4% to 8%, to patients. From August 2023 and February 18, 2024, while Respondent was medical director, Skin Lab dispensed hydroquinone seventeen (17) times.

APPLICABLE LAW

18. Pursuant to NRS 639.898 and NRS 639.100(1), it is unlawful for any person to possess, store, administer and/or dispense dangerous drugs without having secured the appropriate license and/or certificate of registration from the Board.

19. Only those individuals permitted to do so pursuant to NRS 454.213 may possess, store, or administer dangerous drugs.

20. Although a practitioner may administer dangerous drugs within the scope of his or her practice, *see* NRS 454.213, a practitioner may not lawfully dispense dangerous drugs unless

the practitioner registers with the Board as a dispensing practitioner and thereafter complies with all applicable regulations governing dispensing, *see* NRS 454.215(6), NRS 639.23505, and NAC 639.742.

21. "Dispense" means the furnishing of a controlled substance or dangerous drug in any amount greater than that necessary for the present and immediate needs of the ultimate user. NAC 639.450.

22. The Board may suspend or revoke any registration if the holder or applicant: 1) has violated, attempted to violate, assisted, or abetted in the violation of or conspired to violate any of the provisions of NRS chapter 639 or any law or regulation relating to drugs; or 2) is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4) and (12).

23. Unprofessional conduct includes performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration. NAC 639.945(1)(k). Unprofessional conduct also includes performing any duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

24. All controlled substances and dangerous drugs which are in the possession of an advanced practice registered nurse must be kept in a locked storage area. NAC 639.898.

25. A practitioner who maintains a stock of controlled substances and/or dangerous drugs must not commingle expired substances and unexpired substances in a storage area from which the substances are withdrawn from inventory for administering or dispensing to patients. NAC 639.050(2); NAC 639.473.

26. The sale or delivery or holding or offering for sale any drug that is adulterated is prohibited under Nevada law. NRS 585.520(1). A drug shall be deemed adulterated if it is a drug

recognized in an official compendium and its quality or purity falls below the standard set forth in the compendium. NRS 585.380.

27. The Board may suspend or revoke the registration to dispense a controlled substance if the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to that section. NRS 453.236(1)(e). *See also* NRS 453.231(1)(h).

COUNT ONE

Violations of State Law - Failure to Maintain Security of Dangerous Drugs

28. As alleged above, Respondent permitted all employees of Skin Lab to have unrestricted access to the inventory of dangerous drugs at Skin Lab.

29. As alleged above, some of the employees who had access to the inventory of dangerous drugs were not authorized to possess dangerous drugs pursuant to NRS 454.213, did not meet the criteria of an individual permitted access pursuant to NRS 453.375, and/or had access outside of direction of Respondent or another prescribing practitioner.

30. As alleged above, Respondent failed to maintain the security of the dangerous drugs within her possession in violation of NAC 639.898.

31. Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.898 and is subject to discipline pursuant to NRS 639.210(4) and (12); NRS 453.236(1)(e); NRS 453.231(1)(h).

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COUNT TWO

Violation of State Law – Performing an Act, Task or Operation for Which Licensure is Required without the Required License

32. As alleged above, Respondent engaged in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(k) when she dispensed or allowed to be dispensed dangerous drugs without a dispensing practitioner license as required by NRS 454.215(3), NRS 639.23505, and NAC 639.742.

33. This is a violation of law for which the Board may impose administrative discipline. See NRS 639.210(4) and (12); NRS 453.236(1)(e); NRS 453.231(1)(h).

COUNT THREE

Negligence and/or Violation of State Law – Holding for Sale An Adulterated Drug

34. As alleged above, Respondent engaged in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i) when Respondent held for sale adulterated drugs in violation of NRS 585.520(1).

35. As alleged above, Respondent engaged in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i) when Respondent commingled expired substances and unexpired substances in a storage area from which the substances are withdrawn from inventory for administering or dispensing to patients in violation of NAC 639.050(2) and NAC 639.473.

36. Based upon the facts or circumstances surrounding her professional knowledge of dangerous drugs, Respondent knew or should have known that holding for sale an expired prescription drug and commingling expired and unexpired drugs was not safe.

37. By holding for sale into interstate commerce adulterated dangerous drugs, Respondent possessed adulterated drugs in violation of 21 U.S.C.A § 331 and/or NRS 454.351.

38. As alleged above, Respondent performed her duties as the holder of a registration issued by the Board in a negligent, unskillful, or incompetent manner.

39. This is a violation of law for which the Board may impose administrative discipline. *See* NRS 639.210(4) and (12); NRS 453.236(1)(e); NRS 453.231(1)(h).

COUNT FOUR

Negligence and/or Violation of State Law – Failure to Follow Manufacturer's Instructions

40. As alleged above, Respondent engaged in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i) when Respondent held for sale and administered dangerous drugs marked for "single-use" and administered them as "multi-use" drugs, contrary to the manufacturer's packaging.

41. Based upon the facts or circumstances surrounding her professional knowledge of dangerous drugs, Respondent knew or should have known that holding for sale and administering dangerous drugs marked for "single-use" and administering them as "multi-use" drugs in contradiction of the manufacturer's packaging was unsafe.

42. As alleged above, Respondent performed her duties as the holder of a registration issued by the Board in a negligent, unskillful, or incompetent manner.

43. This is a violation of law for which the Board may impose administrative discipline. *See* NRS 639.210(4) and (12); NRS 453.236(1)(e); NRS 453.231(1)(h).

WHEREFORE it is requested that the Nevada State Board of Pharmacy impose appropriate discipline with respect to Respondent's Certificate of Registration No. CS24180.

Signed this 23rd day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAURA OKI, APRN,** **Certificate of Registration No. CS24180,** **Respondent.**	**Case No. 25-112-CS-A-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 15, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 23rd day of February 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAURA OKI, APRN,** **Certificate of Registration No. CS24180,** **Respondent.**	**Case No. 25-112-CS-A-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

LAURA OKI, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of February 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Laura Oki, APRN
[redacted]
Reno, NV [redacted]

Laura Oki, APRN c/o
Sparks Women's Wellness & Skin Lab
5362 Sparks Blvd.
Sparks, NV 89436

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

c
CRAIG K. PERRY, Esq.
Nevada Bar No. 3786
CRAIG K. PERRY & ASSOCIATES
6210 N. Jones Blvd., #753907
Las Vegas, NV 89136
Telephone (702) 228-4777
Fax: (702) 943-7520
cperry@craigperry.com

Attorney for Respondent
LAURA OKI
Certificate of Registration No. CS24180

FILED
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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY Petitioner, vs. LAURA OKI, APRN, Certificate of Registration No. CS24180 Respondent.	Case No. 25-112-CS-A-N ANSWER TO NOTICE OF INTENDED ACTION AND ACCUSATION; AND NOTICE OF DEFENSE

Respondent, above named, by and through her attorney, Craig K. Perry of the law firm of Craig K. Perry & Associates, that in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, and on advice of counsel, Respondent answers as follows:

1. Respondent admits, denies and alleges, with respect to each paragraph, as follows:

As to paragraphs 1, 2, 3, 4, 5, 6, 7, 10, 14, and 32, Respondent admits the contents.

As to paragraphs 8, 11, 12, 13, 15, 16, 17, Respondent is without sufficient knowledge and therefore denies the contents.

As to paragraphs 18-27 is without sufficient legal knowledge or expertise to confirm agree with how these statutes should be interpreted and therefore denies the allegations.

As to paragraphs 9, 28-31, and 33-43, Respondent denies the allegations.

I hereby declare, under penalty of perjury, that the foregoing answer and notice of defense, and all facts therein stated, are true and correct to the best of my knowledge.

DEFENSES

1. The Respondent's failure to obtain the specific license to dispense as required by NRS 639.23505 and NAC 639.742 was the result of a scrivener's error and an honest administrative mistake. The application forms provided by the Board for "Prescribing" and "Dispensing" are substantially similar in appearance, layout, and nomenclature. Respondent, acting in good faith, downloaded and submitted the incorrect form under the reasonable, albeit mistaken, belief that it encompassed the necessary authorizations for her role.
2. At the time, I responded and attempted to for a dispensing license, Respondent already had a prescribing license from the Board. When she innocently filed the wrong form for dispensing (i.e., the application for prescribing), nobody at the Board of Pharmacy acknowledged she already possessed a prescribing license, had she been notified, she would have immediately cured the defect with the filing of the correct application.
3. At no time did Respondent willfully or intentionally violate the Nevada Nurse Practice Act or the regulations of the Nevada State Board of Pharmacy. Respondent's conduct was at all times transparent; she sought licensure openly, and the resulting deficiency was a product of procedural confusion rather than a conscious disregard for statutory requirements.
4. Respondent was employed in a limited, part-time capacity as a Medical Director, while going to school, with primary administrative and operational oversight vested in a separate, full-time Director who was given complete oversight to supervise all workers. Respondent had no actual or constructive notice of the improper access to, or dispensing of, dangerous drugs by third parties. As a part-time remote or intermittent supervisor, Respondent could not discover these other activities, which occurred outside the scope of her specific delegated duties.

5. To the extent the Board alleges improper dispensing occurred at the facility, such acts were the result of independent, intervening, and superseding actions by third parties over whom the Respondent did not exercise direct day-to-day control. Respondent cannot be held professionally liable for the clandestine or unauthorized acts of others that she neither authorized, encouraged, nor had a reasonable opportunity to prevent given her limited part-time role.
6. At all times relevant to the Accusation, to the best of Respondent's knowledge, there is no evidence of actual harm to any patient resulting from the Respondent's licensure status or her performance as a Medical Director. The technical nature of the licensing deficiency did not impact the quality of care provided or the safety of the public.
7. Respondent has an unblemished record of compliance with statutory requirements until now and has never been disciplined before.
8. Client denies any willful violation of either the Nevada Revised Statutes or Nevada Administrative Code. Any mistakes made were honest mistakes or lack of clarity from the owner of the clinic as to her responsibilities.

DATED this 17th day of March 2026.



Laura Oki
Certification of Registration No. *CS24180*
Respondent

CERTIFICATE OF SERVICE

I certify that that I am an Craig K. Perry, Esq. of Craig K. Perry & Associates, and that on this day, I served the ANSWER TO NOTICE OF INTENDED ACTION AND ACCUSATION; AND NOTICE OF DEFENSE by email to the following;

Nevada Board of Pharmacy staff: TeamBC@pharmacy.nv.gov	**Laura Tucker, Esq.** Nevada Board of Pharmacy L.tucker@pharmacy.nv.gov

Dated: 17th day of March, 2026

Craig K. Perry, Esq.
Craig K. Perry & Associates
Attorney for Laura Oki, Respondent.

eSignature Details

Signer ID:	**UfR7kfzD4PMomdky7u87nfpF**
Signed by:	Laura Oki
Sent to email:	[redacted]
IP Address:	12.200.138.170
Signed at:	Mar 17 2026, 1:22 pm PDT

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **APRIA HEALTHCARE, LLC,** **License No. MP00030,** **Respondent.**	**Case No. 25-138-MP-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Apria Healthcare, LLC (Respondent) held a license by the Board to operate as a medical products provider pursuant to NRS 639.233 and NAC 639.6942.

FACTUAL ALLEGATIONS

2. Respondent, located at 1395 Greg Street in Sparks, Nevada, has been licensed by the Board to sell medical products since 2001.

3. As a licensed medical products provider, Respondent is authorized to sell and/or lease respiratory equipment, including sleep apnea-related treatment devices, to Nevada consumers.

4. On or about June 13, 2024, Patient J.S. was prescribed a CPAP machine by his physician. Patient J.S.'s physician's office sent the CPAP machine prescription to Respondent to be filled.

5. Approximately one month later, Patient J.S. had not received his CPAP machine. When Patient J.S. contacted Respondent to report that he had not yet received his machine, a representative told him that his device had been "lost in transit," and that it would send a new device.

6. On or about July 2024, Patient J.S. began receiving supplies for the CPAP machine, as well as invoices for the use of the device, which he still had not received.

7. During the next several months, Patient J.S. contacted Respondent several times to resolve the issue. Each time he called, he was transferred to the billing department, was placed on hold for long periods of time, and the matter was not resolved.

8. On or about March 24, 2025, Patient J.S. sent a letter to Respondent stating that he had received several invoices for the lease of the CPAP device that he had never received. He demanded that Respondent produce the device within two weeks of the letter.

9. On or about June 13, 2025, Patient J.S. received an invoice from Respondent addressed to a Patient K.P. in Gardnerville, Nevada. The invoice appeared to have been intended for patient K.P. and not Patient J.S.

10. On or about July 8, 2025, Board Investigator Monica Segedy (Segedy) transmitted to Respondent a demand for records concerning the events described above.

11. On or about July 22 and 24, 2025, Segedy attempted to contact Respondent's branch manager, Viliami Helu (Helu), after she had not received a response to the Board's request for records. She was placed on hold for more than 20 minutes each time she called, and Helu did not respond to any of her voice messages.

12. On or about July 24, 2025, Segedy called Respondent's Manager of Licensing and Credentialing in Indianapolis, Indiana, Pat Mahon (Mahon). Mahon contacted Helu on Segedy's behalf. Helu contacted Segedy later that day and stated that he had been investigating what happened with Patient J.S.'s CPAP machine.

13. Helu confirmed that the device had not been delivered to Patient J.S. The only records that Respondent had about Patient J.S.'s device were a copy of the original prescription and a sales agreement dated August 13, 2024 reflecting that Respondent had delivered Patient J.S.'s device. However, Respondent could not confirm delivery because Respondent had not assigned a tracking number to the delivery. Because Respondent's system reflected that the device had been delivered, Patient J.S.'s file had been cleared from the system.

14. Respondent sent a copy of the original prescription and sales agreement to Segedy.

15. Later that day, on or about July 24, 2025, at Helu's direction, Respondent delivered a CPAP machine to Patient J.S. at his home address in Reno, Nevada.

16. From July 2024 until July 2025, Respondent billed and received payments from Patient J.S.'s insurance for the use of and equipment for the CPAP device that had not yet been delivered.

17. As of August 26, 2025, Respondent has not rectified billing issues with Patient J.S.'s insurance company for prior reimbursements related to the undelivered CPAP device and previously delivered CPAP supplies.

APPLICABLE LAW

18. Any person who engages in business as a medical products provider must obtain a license from the Board. NRS 639.233; NAC 639.6942. "Medical products provider" means a person licensed pursuant to NAC 639.693 to 639.6958, inclusive, to sell, lease or otherwise provide medical products to a consumer in Nevada.

19. "Medical products" includes medical devices, equipment, supplies and gases intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease. NAC 639.6935.

20. "Respiratory equipment" means a medical product intended to assist a consumer in the act of breathing or intended to introduce a product or drug, other than a medical gas, into the lungs of a consumer. NAC 639.6938.

21. A medical products provider may be disciplined for violating, attempting to violate, assisting or abetting in the violation of federal or state statutes and regulations governing the sale, service, or maintenance of medical products. NRS 639.210(12); NRS 639.255.

22. A medical products provider may be disciplined for unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

23. Unprofessional conduct includes performing one's duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

24. Unprofessional conduct includes submitting any claim for payment or reimbursement to any person or entity for products or services that is fraudulent, deceitful, unnecessary, or for any products or services not actually provided to a consumer. NAC 639.6941(1)(f).

25. The owner of a medical products provider is responsible for the acts of his or her business administrator and employees. NAC 639.6941(2).

26. A medical products provider must employ an administrator and other employees sufficient to provide the services for all medical products sold, leased or otherwise provided by the medical products provider, including, without limitation, set up, repair and maintenance. NAC 639.6946(1)(b).

27. A medical products provider shall develop and use a written procedure for addressing consumer complaints, including, without limitation, procedures for maintaining a complaint file that documents all complaints from consumers and the resolution of each complaint. NAC 639.6946(6).

28. A medical products provider must keep records for at least 5 years from the date the records are made or received, and the records must be readily retrievable upon request by a member of the Board, or a person conducting an inspection or investigation on behalf of the Board. NAC 639.695.

29. In addition to or in lieu of revoking or suspending a person's license due to an act or omission described above, the Board may impose an administrative fine upon the person. The fine may not exceed $10,000 for each offense. NRS 639.255(1)(f) and (3).

COUNT ONE
Unprofessional Conduct – Improper Billing Practices

30. As alleged above, from July 2024 until July 2025, Respondent billed Patient J.S.'s insurer, and/or collected reimbursements from Patient J.S.'s insurer for the use of a CPAP device prescribed by his physician.

31. Respondent did not deliver a CPAP device to Patient J.S. until July 2025.

32. Respondent conduct was unprofessional because Respondent submitted claims for payment or reimbursement to an insurer between July 2024 and July 2025 but failed to deliver the medical product to Patient J.S. during that timeframe.

33. As of the date of the instant accusation, Respondent has not reimbursed Patient J.S.'s insurer for costs related to the CPAP device that was not delivered between July 2024 and July 2025.

34. Respondent is subject to professional discipline for any one or more of the billings described above. NRS 639.210(4); NRS 639.255; NAC 639.6941(1)(f).

COUNT TWO
Unprofessional Conduct—Failure to Maintain a System for Resolving Complaints

35. As alleged above, Respondent failed to provide Patient J.S. with a CPAP machine within a reasonable time period.

36. From July 2024 until July 2025, Patient J.S. attempted to contact Respondent to resolve the issue several times without success.

37. Patient J.S. attempted to obtain a refund from Respondent for the payments paid by his insurance without success.

38. Respondent is subject to professional discipline for having failed to maintain a system for receiving, documenting, and resolving complaints from Patient J.S. NRS 639.210(4); NRS 639.255; NAC 639.6946(6).

39. Respondent is subject to professional discipline for any one or more of the acts of misconduct described above. NRS 639.210(4) and (12); NRS 639.255; NAC 639.6941(2); NAC 639.945(1)(i).

COUNT THREE
Unprofessional Conduct—Failure to Employ an Administrator or Staff Sufficient to Provide Services

40. As alleged above, Respondent failed to provide Patient J.S. with a CPAP machine within a reasonable time period.

41. From July 2024 until July 2025, Patient J.S. attempted to contact Respondent to resolve the issue several times without success.

42. From July 2024 until July 2025, Respondent failed to respond to Patient J.S. regarding his prescribed CPAP machine.

43. Respondent delivered Patient J.S.'s CPAP machine in July 2025, one year after the prescription was sent and after the Board contacted Respondent.

44. Respondent is subject to professional discipline for having failed to employ an administrator and other employees sufficient to provide the services from Patient J.S. NRS 639.210(4); NRS 639.255; NAC 639.6946(1); NAC 639.6941.

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COUNT FOUR
Unprofessional Conduct—Failure to Maintain Adequate Inventory

45. As alleged above, Respondent failed to provide Patient J.S. with a CPAP machine within a reasonable time period.

46. Respondent's dealings with Patient J.S. indicate that Respondent did not maintain an inventory of medical products that was adequate to serve the needs of Patient J.S.

47. Respondent is subject to professional discipline for having failed to maintain an inventory that was adequate to meet the needs of one or more patients. NRS 639.210(4); NRS 639.255; NAC 639.6946(1)(d).

COUNT FIVE
Unprofessional Conduct—Failure to Maintain and Produce Records

48. As alleged above, Respondent failed to timely respond to the Board's inquiries regarding Patient J.S.'s CPAP device pursuant to NAC 639.695(5).

49. As alleged above, Respondent cleared records that it was required to maintain for five years pursuant to NAC 639.695(2).

50. Respondent is subject to professional discipline for having failed to maintain and produce records. NRS 639.210(4); NRS 639.255; NAC 639.695.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 11th day of March 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **APRIA HEALTHCARE, LLC,** **License No. MP00030,** **Respondent.**	**Case No. 25-138-MP-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 15, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of MARCH 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **APRIA HEALTHCARE, LLC,** **License No. MP00030,** **Respondent.**	**Case No. 25-138-MP-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR
Apria Healthcare, LLC

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Apria Healthcare LLC
1395 Greg St #113
Sparks, NV 89431

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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FILED
MAR 12 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9586,** **Pharmacy License No. PH01821, and** **MARK PARDINI, RPH,** **Certificate of Registration No. 08849,** **Respondents.**	**CASE NOS. 25-350-PH-N** **25-350-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Mark Pardini, RPh (Pardini), Certificate of Registration No. 08849, was a pharmacist registered with the Board, and Respondent CVS Pharmacy #9586, Pharmacy License No. PH01821, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Pardini is employed as floating pharmacist for CVS Pharmacy, Inc. On the date of the events alleged herein, August 21, 2025, Pardini worked a shift at CVS Pharmacy #9586, located at 55 Damonte Ranch Parkway in Reno.

3. On August 21, 2025, CVS Pharmacy #9586 received a prescription for 120 tablets of 1 mg lorazepam from prescriber P.R. for patient S.L. The CVS Pharmacy computer system designated this prescription no. 1717259.

4. On August 21, 2025, pharmaceutical technician in training Theophilus Akoh (Akoh) filled prescription no. 1717259.

5. When filling prescription no. 1717259, Akoh first scanned the stock bottle to verify the prescription. Akoh then physically poured the medication out evenly on the tray and counted the tablets. CVS Pharmacy #9586's system did not alert Akoh that the wrong medication was scanned.

6. When preparing prescription no. 1717259, Akoh used the CVS accuracy scan technology. Akoh snapped a photographic image of the tablets on the counting tray, then created a digital file that correlated the product image with the product information. He then poured the tablets into an amber vial with the label affixed.

7. On August 21, 2025, using the accuracy scan technology described above, Pardini performed final verification of prescription no. 1717259. Pardini noted that the photo was blurry and that he was unable to recognize that some of the tablets were slightly thicker and had different imprints. Nevertheless, Pardini viewed the digital file, including the product image, and concluded that the prescription had been accurately filled with lorazepam.

8. Pardini did not directly inspect the amber vial or its contents. Had he done so, he would have seen that some of the tablets were actually 5 mg Cytomel. Cytomel is commonly prescribed for hypothyroidism. Patient S.L. has never been prescribed Cytomel.

9. On August 24, 2025, CVS #9586 dispensed prescription no. 1717259.

10. On or about August 26, 2025, patient S.L. went to Renown Urgent Care in Reno complaining of symptoms of sweating, excessive anxiety, shakiness, and loss of appetite. Patient S.L. informed the APRN on duty, Sarah Gentile (Gentile) that she routinely took 1 mg lorazepam and had taken approximately four to six tablets between August 24 and August 26, 2025. Patient S.L. noticed that the consistency and appearance of the tablets appeared different than those she had received in the past.

11. Gentile examined patient S.L.'s medication vial for prescription no. 1717259 by pouring out the contents. Upon examination, Gentile discovered that the vial contained 90 tablets of 1 mg lorazepam and 17 tablets of Cytomel.

12. On or about August 26, 2025, Gentile called and reported the issue to CVS Pharmacy #9586. After an internal investigation, CVS Pharmacy #9586 confirmed that it had dispensed the prescription no. 1717259 with at least seventeen (17) tablets of Cytomel instead of 120 tablets of lorazepam, as prescribed.

13. Patient S.L. ingested between four to six tablets before she noticed the error and experienced sweating, excessive anxiety, shakiness, and loss of appetite.

APPLICABLE LAW

14. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d).

15. Unprofessional conduct also includes a registrant or licensee performing duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

16. If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription. NAC 639.252 and NAC 639.702. Such a pharmacist must verify, among other things, the selection and strength of the drug, the dosage form, and the labeling of the prescription. NAC 639.252(2); *see also* NAC 639.700(6).

17. A pharmaceutical technician may perform one or more of the functions necessary to prepare a prescription only if the supervising pharmacist inspects the final product. NAC 639.245(2) and (4)(c).

18. The Board may suspend or revoke the licenses of any pharmacist who engages in unprofessional conduct or conduct contrary to the public interest, including conduct by non-

pharmacist personnel. NRS 639.210(4); NAC 639.702. Furthermore, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Unprofessional Conduct – Error in Dispensing Prescription

(Respondent Pardini)

19. Pardini violated NAC 639.245(2) and (4)(c), NAC 639.252(2), and NAC 639.700(6) and engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when he performed final verification for prescription no. 1717259 and failed to observe that the amber vial contained at least seventeen (17) tablets of Cytomel instead of 120 tablets of lorazepam, as prescribed.

20. Having performed his duties in incompetent, unskillful, or negligent manner, as described above, Pardini is subject to discipline pursuant to NRS 639.210(4) and NAC 639.702.

COUNT TWO

Pharmacy/Pharmacy Owner Responsibility

(Respondent CVS Pharmacy #9586)

21. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Respondent CVS Pharmacy #9586 is responsible for those violations, including all errors and omissions of Respondent Pardini and any other pharmacy personnel in the course of erroneously filling and dispensing prescription no. 1717259.

22. Due to the unprofessional conduct of Pardini, and/or other of its employees, CVS Pharmacy #9586 is subject to professional discipline pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

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WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificates of registration of these Respondents.

Signed this 12th day of MARCH 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9586,** **Pharmacy License No. PH01821,** **Respondent.**	**Case No. 25-350-PH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 15, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 12th day of MARCH 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9586,** **Pharmacy License No. PH01821,** **Respondent.**	**Case No. 25-350-PH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR
CVS Pharmacy #9586

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

CVS Pharmacy #9586
55 Damonte Ranch Pkwy
Reno, NV 89521

Brian J. Convery, Esq.
1 CVS Drive, Mail Code 2325
Woonsocket, RI 02895

And Via Email to: Brian.Convery@CVSHealth.com

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9586,** **Pharmacy License No. PH01821, and** **MARK PARDINI, RPH,** **Certificate of Registration No. 08849,** **Respondents.**	**Case Nos. 25-350-PH-N** **25-350-RPH-N** **STIPULATION AND ORDER** **[CVS PHARMACY #9586 ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Laura M. Tucker, Esq., and CVS Pharmacy #9586, Pharmacy License No. PH01821, ("Respondent"), by and through counsel, Brian J. Convery, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. The Board and Respondent agreed to delay the date for submitting a Notice of Answer and Defense as the parties pursued settlement negotiations.

4. Respondent acknowledges that it understands the terms of this Stipulation and Proposed Order ("Stipulation"), and that it has executed it knowingly and voluntarily.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative

procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

6. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives its right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

7. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in Count Two of the Accusation, *to wit*:

A. As the pharmacy/pharmacy owner at which unprofessional conduct and violations of law alleged occurred, Respondent CVS Pharmacy #9586 is responsible for those violations, including all errors and omissions of employee Mark Pardini and any other pharmacy personnel in the course of erroneously filling and dispensing prescription no. 1717259, and is subject to professional discipline pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

8. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent shall pay an administrative fine of **One Thousand and 00/100 Dollars ($1,000.00)**, payable by *cashier's check, certified check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation.

B. Respondent shall pay the sum of **Five Hundred and 00/100 Dollars ($500.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Respondent shall remit

payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation.

9. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 25-350-PH-N. However, Respondent understands and acknowledges that its failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

10. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on April 15, 2026, in Reno, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

11. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

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Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ____ day of _____ 2026.
CVS Pharmacy #9586

By:_____
Name:_____
Title:_____

Signed this ____ day of _____ 2026.
Nevada State Board of Pharmacy

By_____
LAURA M. TUCKER, ESQ.
General Counsel

DECISION AND ORDER

As to CVS Pharmacy #9586, in Case No. 25-350-RPH-N, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____day of April 2026.

_____
Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9586,** **Pharmacy License No. PH01821, and** **MARK PARDINI, RPH,** **Certificate of Registration No. 08849,** **Respondents.**	**CASE NOS. 25-350-PH-N** **25-350-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Mark Pardini, RPh (Pardini), Certificate of Registration No. 08849, was a pharmacist registered with the Board, and Respondent CVS Pharmacy #9586, Pharmacy License No. PH01821, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Pardini is employed as floating pharmacist for CVS Pharmacy, Inc. On the date of the events alleged herein, August 21, 2025, Pardini worked a shift at CVS Pharmacy #9586, located at 55 Damonte Ranch Parkway in Reno.

3. On August 21, 2025, CVS Pharmacy #9586 received a prescription for 120 tablets of 1 mg lorazepam from prescriber P.R. for patient S.L. The CVS Pharmacy computer system designated this prescription no. 1717259.

4. On August 21, 2025, pharmaceutical technician in training Theophilus Akoh (Akoh) filled prescription no. 1717259.

5. When filling prescription no. 1717259, Akoh first scanned the stock bottle to verify the prescription. Akoh then physically poured the medication out evenly on the tray and counted the tablets. CVS Pharmacy #9586's system did not alert Akoh that the wrong medication was scanned.

6. When preparing prescription no. 1717259, Akoh used the CVS accuracy scan technology. Akoh snapped a photographic image of the tablets on the counting tray, then created a digital file that correlated the product image with the product information. He then poured the tablets into an amber vial with the label affixed.

7. On August 21, 2025, using the accuracy scan technology described above, Pardini performed final verification of prescription no. 1717259. Pardini noted that the photo was blurry and that he was unable to recognize that some of the tablets were slightly thicker and had different imprints. Nevertheless, Pardini viewed the digital file, including the product image, and concluded that the prescription had been accurately filled with lorazepam.

8. Pardini did not directly inspect the amber vial or its contents. Had he done so, he would have seen that some of the tablets were actually 5 mg Cytomel. Cytomel is commonly prescribed for hypothyroidism. Patient S.L. has never been prescribed Cytomel.

9. On August 24, 2025, CVS #9586 dispensed prescription no. 1717259.

10. On or about August 26, 2025, patient S.L. went to Renown Urgent Care in Reno complaining of symptoms of sweating, excessive anxiety, shakiness, and loss of appetite. Patient S.L. informed the APRN on duty, Sarah Gentile (Gentile) that she routinely took 1 mg lorazepam and had taken approximately four to six tablets between August 24 and August 26, 2025. Patient S.L. noticed that the consistency and appearance of the tablets appeared different than those she had received in the past.

11. Gentile examined patient S.L.'s medication vial for prescription no. 1717259 by pouring out the contents. Upon examination, Gentile discovered that the vial contained 90 tablets of 1 mg lorazepam and 17 tablets of Cytomel.

12. On or about August 26, 2025, Gentile called and reported the issue to CVS Pharmacy #9586. After an internal investigation, CVS Pharmacy #9586 confirmed that it had dispensed the prescription no. 1717259 with at least seventeen (17) tablets of Cytomel instead of 120 tablets of lorazepam, as prescribed.

13. Patient S.L. ingested between four to six tablets before she noticed the error and experienced sweating, excessive anxiety, shakiness, and loss of appetite.

APPLICABLE LAW

14. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d).

15. Unprofessional conduct also includes a registrant or licensee performing duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

16. If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription. NAC 639.252 and NAC 639.702. Such a pharmacist must verify, among other things, the selection and strength of the drug, the dosage form, and the labeling of the prescription. NAC 639.252(2); *see also* NAC 639.700(6).

17. A pharmaceutical technician may perform one or more of the functions necessary to prepare a prescription only if the supervising pharmacist inspects the final product. NAC 639.245(2) and (4)(c).

18. The Board may suspend or revoke the licenses of any pharmacist who engages in unprofessional conduct or conduct contrary to the public interest, including conduct by non-

pharmacist personnel. NRS 639.210(4); NAC 639.702. Furthermore, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Unprofessional Conduct – Error in Dispensing Prescription

(Respondent Pardini)

19. Pardini violated NAC 639.245(2) and (4)(c), NAC 639.252(2), and NAC 639.700(6) and engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when he performed final verification for prescription no. 1717259 and failed to observe that the amber vial contained at least seventeen (17) tablets of Cytomel instead of 120 tablets of lorazepam, as prescribed.

20. Having performed his duties in incompetent, unskillful, or negligent manner, as described above, Pardini is subject to discipline pursuant to NRS 639.210(4) and NAC 639.702.

COUNT TWO

Pharmacy/Pharmacy Owner Responsibility

(Respondent CVS Pharmacy #9586)

21. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Respondent CVS Pharmacy #9586 is responsible for those violations, including all errors and omissions of Respondent Pardini and any other pharmacy personnel in the course of erroneously filling and dispensing prescription no. 1717259.

22. Due to the unprofessional conduct of Pardini, and/or other of its employees, CVS Pharmacy #9586 is subject to professional discipline pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

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WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificates of registration of these Respondents.

Signed this 12th day of MARCH 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARK PARDINI, RPH,** **Certificate of Registration No. 08849,** **Respondent.**	**Case No. 25-350-RPH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 15, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 12th day of MARCH 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARK PARDINI, RPH,** **Certificate of Registration No. 08849,** **Respondent.**	**Case No. 25-350-RPH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

Mark Pardini, RPh

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Mark Pardini, RPh
[redacted]
Reno, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9586,** **Pharmacy License No. PH01821, and** **MARK PARDINI, RPH,** **Certificate of Registration No. 08849,** **Respondents.**	**Case Nos. 25-350-PH-N** **25-350-RPH-N** **STIPULATION AND ORDER** **[MARK PARDINI ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Laura M. Tucker, Esq., and Mark Pardini, RPH, Certificate of Registration No. 08849, ("Respondent"), hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that he understands the terms of this Stipulation and Proposed Order ("Stipulation"), and that he has executed it knowingly and voluntarily.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this

Stipulation, Respondent hereby freely and voluntarily waives his right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in Count One of the Accusation, *to wit*:

A. Respondent violated NAC 639.245(2) and (4)(c), NAC 639.252(2), and NAC 639.700(6) and engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when he performed final verification for prescription no. 1717259 and failed to observe that the amber vial contained at least seventeen (17) tablets of Cytomel instead of 120 tablets of lorazepam, as prescribed.

B. Having performed his duties in an incompetent, unskillful, or negligent manner, as described above, Respondent is subject to discipline pursuant to NRS 639.210(4) and NAC 639.702.

7. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent shall pay an administrative fine of **One Thousand and 00/100 Dollars ($1,000.00)**, payable by *cashier's check, certified check,* or *money order* written to the **"State of Nevada, Office of the Treasurer."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation.

B. Respondent shall pay the sum of **Five Hundred and 00/100 Dollars ($500.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the **"Nevada State Board of Pharmacy."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation.

8. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 25-350-RPH-N. However, Respondent understands and acknowledges that his failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

9. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on April 15, 2026, in Reno, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

10. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

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Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 27 day of March 2026.

By Mark V. Pardini
MARK PARDINI, RPH
Certificate of Registration No. 08849

Signed this ____ day of _____ 2026.
Nevada State Board of Pharmacy

By_____
LAURA M. TUCKER, ESQ.
General Counsel

DECISION AND ORDER

As to Mark Pardini, in Case No. 25-350-RPH-N, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____day of April 2026.

_____
Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LYFE PHARMACY,** **Pharmacy License No. PH04561, and** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601,** **Respondents.**	**Case No. 25-360-PH-S** **25-360-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Lyfe Pharmacy, Inc. (Lyfe), License No. PH04561, held a license issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy, and Respondent Nazakat Nigmatova, RPh (Nigmatova), Certificate of Registration No. 20601, was a pharmacist registered with the Board.

FACTUAL ALLEGATIONS

2. From February 5, 2024, through February 4, 2026, Lyfe, located at 9280 W. Sunset Road #230, in Las Vegas, held Pharmacy License No. PH04561 authorizing the operation of a pharmacy in compliance with the terms of the new pharmacy application personally submitted by Nigmatova on Lyfe's behalf.

3. Respondent Nigmatova, a registered pharmacist, signed the initial application in her capacity as the president and 100% shareholder of Lyfe.

4. On information and belief, dangerous drugs and controlled substances were received, stored, and dispensed at Lyfe Pharmacy between February 5, 2024, and September 26, 2024.

5. On or about September 26, 2024, without giving prior notice to the Board pursuant to NAC 639.227, Nigmatova ostensibly caused the assets of Lyfe to be sold to Ramy Massoud (Massoud) outside the jurisdiction of the Board. Massoud was not and is not currently licensed by the Board to operate a pharmacy at 9280 W. Sunset Road #230, in Las Vegas, Nevada.

6. Massoud took possession of Lyfe's assets on September 26, 2024, and he began to act at that time as the putative pharmacy owner in control of the premises at 9280 W. Sunset Road #230, in Las Vegas.

7. From September 26, 2024 until January 27, 2026, with putative owner Massoud having assumed control of the assets of the pharmacy, Massoud began, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell controlled substances.

8. On or about January 27, 2026, the Board received notice that agents from the federal Drug Enforcement Administration (DEA) had seized the stock of controlled substances at 9280 W. Sunset Road #230, in Las Vegas, Nevada. The DEA seized the controlled substances because no pharmacy owner was registered with the DEA at that location to prescribe or dispense controlled substances as required by federal law.

9. From September 26, 2024 through February 4, 2026, putative owner Massoud continued, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell dangerous drugs. During that time, Nigmatova did not act as pharmacy owner of Lyfe, and Nigmatova never submitted, and the Board had never approved, a change of ownership application for Lyfe with Massoud as the owner.

10. On or about February 4, 2026, following a Board investigation, Nigmatova surrendered the pharmacy license for Lyfe. Nigmatova did not agree to temporarily assume a managerial role pending licensure of a qualified owner. As a result, Lyfe was closed by the Board.

11. On or about February 4, 2026, the Board secured all drugs and medical records on Lyfe's premises. Lyfe's managing pharmacist volunteered to properly secure the drugs and patient records on site and assist patients to transfer their prescription information to other pharmacies pending new ownership approved by the Board.

APPLICABLE LAW

12. Any person operating a pharmacy within this State shall obtain a license from the Board. NRS 639.230(1). Each license must be issued to a specific person and for a specific location and is not transferable. NRS 639.230(2).

13. The holder of a pharmacy license must file an application for a change of ownership at least 15 days prior to any change involving a transfer of 50 percent or more of the beneficial interest in the pharmacy. NAC 639.227(1). If the Board does not receive an application for change of ownership within the required timeframe, the Board may initiate proceedings to suspend the license to operate the pharmacy. NAC 639.227(3).

14. Pursuant to NRS 639.100(1), it is unlawful for any person to permit to be manufactured, distributed at wholesale, sold or dispensed, any drug, poison, medicine or chemical, or to dispense, or permit to be dispensed, any prescription of a practitioner, unless the person holds the appropriate certificate, license or permit and complies with the regulations adopted by the Board.

15. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada is unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(j).

16. The Board may revoke or suspend the registration of any licensee who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the

provisions of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12).

17. The Board may revoke or suspend the registration of any licensee who has engaged in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

18. Any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in its employ. NAC 639.945(3).

19. In lieu of, or in addition to revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

COUNT ONE
Violation of State Regulation – Failure to Submit Change of Ownership
(Respondent Nigmatova)

20. As alleged above, on or about September 26, 2024, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Lyfe to be sold to Massoud.

21. As the seller, Nigmatova had a legal obligation pursuant to NAC 639.227(1) to file an application for a change of ownership at least 15 days prior to the transfer of the beneficial interest in the pharmacy at 9280 W. Sunset Road #230, in Las Vegas, Nevada.

22. By failing to file an application for change of ownership pursuant to NAC 639.227(1), Nigmatova violated a Nevada regulation relating to the practice of pharmacy.

23. Nigmatova's conduct as alleged above amounts to a violation for which the Board may impose administrative discipline. *See* NRS 639.210(12).

COUNT TWO
Permitting Unlicensed Practice
(Respondent Nigmatova)

24. As alleged above, on or about September 26, 2024, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Lyfe to be sold to Massoud.

25. When Nigmatova failed to file an application for change of ownership pursuant to NAC 639.227(1), Massoud, the putative new owner of Lyfe, did not legally obtain licensure to

operate the pharmacy. As such, during the relevant time period, Massoud did not hold a license with the Board to engage in the practice of pharmacy in Nevada.

26. As alleged above, during the relevant time period, Massoud, on his own account and without knowledge or consent of the Board, continued to operate the pharmacy, including by continuing to receive, possess, store, hold for sale, and/or sell controlled substances and dangerous drugs, without a license as required by NRS 639.230.

27. By failing to file an application for change of ownership for Lyfe and causing putative owner Massoud, on his own account and without knowledge and consent of the Board, to operate the pharmacy location without an owner licensed by the Board pursuant to NRS 639.230(2), Nigmatova permitted Massoud to engage in unlicensed selling and/or dispensing of drugs in violation of NRS 639.100(1).

28. Respondent's conduct as alleged above amounts to a violation of NRS 639.100, as well as unprofessional conduct as defined by NAC 639.945(1)(j); therefore, the Board may impose administrative discipline. *See* NRS 639.210(4); NRS 639.210(12); NAC 639.945(1)(j).

COUNT THREE
Pharmacy/Pharmacy Owner Responsibility
(Respondent Lyfe Pharmacy)

29. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Lyfe is responsible for those violations, including all errors and omissions of Respondent Nigmatova and any other pharmacy personnel in the course of conduct alleged above.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondents Lyfe Pharmacy, Inc. and Nazakat Nigmatova, RPh.

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DATED this 6th day of February 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LYFE PHARMACY,** **Pharmacy License No. PH04561, and** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601,** **Respondent(s).**	**Case Nos. 25-360-PH-S** **25-360-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LYFE PHARMACY,** **Pharmacy License No. PH04561,** **Respondent.**	**Case No. 25-360-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR LYFE PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day of February 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Lyfe Pharmacy
9280 W Sunset Rd. #230
Las Vegas, NV 89148

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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FILED
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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

LYFE PHARMACY,
Pharmacy License No. PH04561, and

NAZAKAT NIGMATOVA, RPH,
Certificate of Registration No. 20601,

Respondents.

Case No. 25-360-PH-S
25-360-RPH-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Lyfe Pharmacy, Inc. (Lyfe), License No. PH04561, held a license issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy, and Respondent Nazakat Nigmatova, RPh (Nigmatova), Certificate of Registration No. 20601, was a pharmacist registered with the Board.

FACTUAL ALLEGATIONS

2. From February 5, 2024, through February 4, 2026, Lyfe, located at 9280 W. Sunset Road #230, in Las Vegas, held Pharmacy License No. PH04561 authorizing the operation of a pharmacy in compliance with the terms of the new pharmacy application personally submitted by Nigmatova on Lyfe's behalf.

3. Respondent Nigmatova, a registered pharmacist, signed the initial application in her capacity as the president and 100% shareholder of Lyfe.

4. On information and belief, dangerous drugs and controlled substances were received, stored, and dispensed at Lyfe Pharmacy between February 5, 2024, and September 26, 2024.

5. On or about September 26, 2024, without giving prior notice to the Board pursuant to NAC 639.227, Nigmatova ostensibly caused the assets of Lyfe to be sold to Ramy Massoud (Massoud) outside the jurisdiction of the Board. Massoud was not and is not currently licensed by the Board to operate a pharmacy at 9280 W. Sunset Road #230, in Las Vegas, Nevada.

6. Massoud took possession of Lyfe's assets on September 26, 2024, and he began to act at that time as the putative pharmacy owner in control of the premises at 9280 W. Sunset Road #230, in Las Vegas.

7. From September 26, 2024 until January 27, 2026, with putative owner Massoud having assumed control of the assets of the pharmacy, Massoud began, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell controlled substances.

8. On or about January 27, 2026, the Board received notice that agents from the federal Drug Enforcement Administration (DEA) had seized the stock of controlled substances at 9280 W. Sunset Road #230, in Las Vegas, Nevada. The DEA seized the controlled substances because no pharmacy owner was registered with the DEA at that location to prescribe or dispense controlled substances as required by federal law.

9. From September 26, 2024 through February 4, 2026, putative owner Massoud continued, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell dangerous drugs. During that time, Nigmatova did not act as pharmacy owner of Lyfe, and Nigmatova never submitted, and the Board had never approved, a change of ownership application for Lyfe with Massoud as the owner.

10. On or about February 4, 2026, following a Board investigation, Nigmatova surrendered the pharmacy license for Lyfe. Nigmatova did not agree to temporarily assume a managerial role pending licensure of a qualified owner. As a result, Lyfe was closed by the Board.

11. On or about February 4, 2026, the Board secured all drugs and medical records on Lyfe's premises. Lyfe's managing pharmacist volunteered to properly secure the drugs and patient records on site and assist patients to transfer their prescription information to other pharmacies pending new ownership approved by the Board.

APPLICABLE LAW

12. Any person operating a pharmacy within this State shall obtain a license from the Board. NRS 639.230(1). Each license must be issued to a specific person and for a specific location and is not transferable. NRS 639.230(2).

13. The holder of a pharmacy license must file an application for a change of ownership at least 15 days prior to any change involving a transfer of 50 percent or more of the beneficial interest in the pharmacy. NAC 639.227(1). If the Board does not receive an application for change of ownership within the required timeframe, the Board may initiate proceedings to suspend the license to operate the pharmacy. NAC 639.227(3).

14. Pursuant to NRS 639.100(1), it is unlawful for any person to permit to be manufactured, distributed at wholesale, sold or dispensed, any drug, poison, medicine or chemical, or to dispense, or permit to be dispensed, any prescription of a practitioner, unless the person holds the appropriate certificate, license or permit and complies with the regulations adopted by the Board.

15. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada is unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(j).

16. The Board may revoke or suspend the registration of any licensee who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the

provisions of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12).

17. The Board may revoke or suspend the registration of any licensee who has engaged in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

18. Any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in its employ. NAC 639.945(3).

19. In lieu of, or in addition to revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

COUNT ONE
Violation of State Regulation – Failure to Submit Change of Ownership
(Respondent Nigmatova)

20. As alleged above, on or about September 26, 2024, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Lyfe to be sold to Massoud.

21. As the seller, Nigmatova had a legal obligation pursuant to NAC 639.227(1) to file an application for a change of ownership at least 15 days prior to the transfer of the beneficial interest in the pharmacy at 9280 W. Sunset Road #230, in Las Vegas, Nevada.

22. By failing to file an application for change of ownership pursuant to NAC 639.227(1), Nigmatova violated a Nevada regulation relating to the practice of pharmacy.

23. Nigmatova's conduct as alleged above amounts to a violation for which the Board may impose administrative discipline. *See* NRS 639.210(12).

COUNT TWO
Permitting Unlicensed Practice
(Respondent Nigmatova)

24. As alleged above, on or about September 26, 2024, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Lyfe to be sold to Massoud.

25. When Nigmatova failed to file an application for change of ownership pursuant to NAC 639.227(1), Massoud, the putative new owner of Lyfe, did not legally obtain licensure to

operate the pharmacy. As such, during the relevant time period, Massoud did not hold a license with the Board to engage in the practice of pharmacy in Nevada.

26. As alleged above, during the relevant time period, Massoud, on his own account and without knowledge or consent of the Board, continued to operate the pharmacy, including by continuing to receive, possess, store, hold for sale, and/or sell controlled substances and dangerous drugs, without a license as required by NRS 639.230.

27. By failing to file an application for change of ownership for Lyfe and causing putative owner Massoud, on his own account and without knowledge and consent of the Board, to operate the pharmacy location without an owner licensed by the Board pursuant to NRS 639.230(2), Nigmatova permitted Massoud to engage in unlicensed selling and/or dispensing of drugs in violation of NRS 639.100(1).

28. Respondent's conduct as alleged above amounts to a violation of NRS 639.100, as well as unprofessional conduct as defined by NAC 639.945(1)(j); therefore, the Board may impose administrative discipline. *See* NRS 639.210(4); NRS 639.210(12); NAC 639.945(1)(j).

COUNT THREE

Pharmacy/Pharmacy Owner Responsibility
(Respondent Lyfe Pharmacy)

29. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Lyfe is responsible for those violations, including all errors and omissions of Respondent Nigmatova and any other pharmacy personnel in the course of conduct alleged above.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondents Lyfe Pharmacy, Inc. and Nazakat Nigmatova, RPh.

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DATED this 6th day of February 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LYFE PHARMACY,** **Pharmacy License No. PH04561, and** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601,** **Respondent(s).**	**Case Nos. 25-360-PH-S** **25-360-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601,** **Respondent.**	**Case No. 25-360-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

NAZAKAT NIGMATOVA, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day of February 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Nazokat Nigmatova, RPH
c/o Evergreen Pharmacy
4110 S Maryland Pkwy., Ste. 17
Las Vegas, NV 89119

Nazokat Nigmatova, RPH
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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FILED
FEB 0 6 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TERA PHARMACY,** **Pharmacy License No. PH04648,** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601, and** **GRACE SINGSON, RPH,** **Certificate of Registration No. 24727,** **Respondents.**	**Case No. 25-370-PH-S** **25-370-RPH-A-S** **25-370-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Tera Pharmacy (Tera), License No. PH04648, held a license issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy, Respondent Nazakat Nigmatova, RPh (Nigmatova), Certificate of Registration No. 20601, was a pharmacist registered with the Board, and Respondent Grace Singson, RPh (Singson), Certificate of Registration No. 24727, was a pharmacist registered with the Board.

FACTUAL ALLEGATIONS

2. From November 21, 2024, through February 4, 2026, Tera, located at 8995 W. Flamingo Road, Suite 120, in Las Vegas, held Pharmacy License No. PH04648 authorizing the

operation of a pharmacy in compliance with the terms of the new pharmacy application personally submitted by Nigmatova on Tera's behalf.

3. Respondent Nigmatova, a registered pharmacist, signed the initial application in her capacity as the president and 100% shareholder of Tera. As stated in the application, Tera initially conducted business under the name Lyfe Pharmacy 2.

4. On or about December 2, 2024, Nigmatova filed an application with the Board to change the pharmacy's name from Lyfe Pharmacy 2 to Tera Pharmacy. The Board's staff approved the application.

5. On or about June 11, 2025, without giving prior notice to the Board pursuant to NAC 639.227, Nigmatova ostensibly caused the assets of Tera to be sold outside the jurisdiction of the Board. The assets of Tera were ostensibly relinquished to a buyer who is not licensed by the Board to operate a pharmacy.

6. On or about September 19, 2025 without giving prior notice to the Board pursuant to NAC 639.227, Nigmatova again ostensibly caused the assets of Tera to be sold outside the jurisdiction of the Board. The assets of Tera were ostensibly relinquished to Mark Mahfouz (Mahfouz), who was not and is not currently licensed by the Board to operate a pharmacy at 8995 W. Flamingo Road, Suite 120.

7. Mahfouz took possession of Tera's assets on September 19, 2025, and he began to act at that time as the putative pharmacy owner in control of the premises at 8995 W. Flamingo Road, Suite 120, in Las Vegas.

8. From September 19, 2025 until January 27, 2026, with putative owner Mahfouz having assumed control of the assets of the pharmacy, Mahfouz began, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell controlled substances.

9. On or about October 16, 2025, Singson notified the Board that she had become managing pharmacist at Tera.

10. On or about November 25, 2025, Board Inspector Leo Basch (Basch) performed an annual inspection of Tera. During the inspection, Basch noted several deficiencies, including:

a. From on or about October 29, 2025 to October 30, 2025, Singson processed at least seven (7) prescriptions for various controlled substances that did not have a quantity indicated on the prescription or a prescriber's signature;

b. On or about October 29, 2025, Singson processed at least one (1) prescription for a controlled substance that did not have the prescriber's signature;

c. On or about November 4, 2025, Singson accepted a transferred prescription for testosterone, a controlled substance, that was missing the days' supply, the address of the pharmacy the prescription was received from, the total number of refills, and the number of refills remaining; and

d. On or about October 22, 2025, a phoned-in prescription was written for multiple medications for one patient and was missing the initials of the pharmacist who took the call. When questioned, Singson stated that she took the prescription over the phone.

11. On or about January 27, 2026, the Board received notice that agents from the federal Drug Enforcement Administration (DEA) had seized the stock of controlled substances at 8995 W. Flamingo Road, Suite 120, in Las Vegas, Nevada. The DEA seized the controlled substances because no pharmacy owner was registered with the DEA at that location to prescribe or dispense controlled substances as required by federal law.

12. From September 19, 2025 through February 4, 2026, putative owner Mahfouz continued, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell dangerous drugs. During that time, Nigmatova did not act as pharmacy owner of Tera, and Nigmatova never submitted, and the Board had never approved, a change of ownership application for Tera with Mahfouz as the owner.

13. On or about February 4, 2026, following a Board investigation, Nigmatova surrendered the pharmacy license for Tera. Nigmatova did not agree to temporarily assume a managerial role pending licensure of a qualified owner. As a result, Tera was closed by the Board.

14. On or about February 4, 2026, the Board secured all drugs and medical records on Tera's premises. On February 5, 2026, Singson volunteered to properly secure the drugs and patient records on site and assist patients to transfer their prescription information to other pharmacies pending new ownership approved by the Board.

APPLICABLE LAW

15. Any person operating a pharmacy within this State shall obtain a license from the Board. NRS 639.230(1). Each license must be issued to a specific person and for a specific location and is not transferable. NRS 639.230(2).

16. The holder of a pharmacy license must file an application for a change of ownership at least 15 days prior to any change involving a transfer of 50 percent or more of the beneficial interest in the pharmacy. NAC 639.227(1). If the Board does not receive an application for change of ownership within the required timeframe, the Board may initiate proceedings to suspend the license to operate the pharmacy. NAC 639.227(3).

17. Pursuant to NRS 639.100(1), it is unlawful for any person to permit to be manufactured, distributed at wholesale, sold or dispensed, any drug, poison, medicine or chemical, or to dispense, or permit to be dispensed, any prescription of a practitioner, unless the person holds the appropriate certificate, license or permit and complies with the regulations adopted by the Board.

18. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada is unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(j).

19. In Nevada, written prescriptions for controlled substances must contain, among other things, the name and signature of the practitioner and the name, strength and quantity of the drug prescribed and the number of days that the drug is to be used, beginning on the day on which the prescription is filled. NRS 639.2353(2). All filled prescriptions must be retained on file for at least two years, and each prescription on file must be personally signed or initialed by the registered pharmacist who filled it. NRS 639.236(2); NAC 639.751.

20. Only a registered pharmacist or a registered pharmaceutical intern acting under the direct supervision of a registered pharmacist may identify, evaluate, and interpret a prescription. NAC 639.700(2). Pharmacists are responsible for verifying prescriptions prepared by pharmaceutical technicians, including, but not limited to the selection and strength of the drug and the dosage form. NAC 639.252(2). Pharmacists also have discretion not to fill a prescription if the prescription does not meet certain standards. NAC 639.752.

21. Performing any duties as the holder of a license, certificate or registration issued by the Board in an incompetent, unskillful, or negligent manner is unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(i).

22. The Board may revoke or suspend the registration of any licensee who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12).

23. The Board may revoke or suspend the registration of any licensee who has engaged in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

24. Any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in its employ. NAC 639.945(3).

25. In lieu of, or in addition to revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

COUNT ONE

Violation of State Regulation – Failure to Submit Change of Ownership
(Respondent Nigmatova)

26. As alleged above, on or about September 19, 2025, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Tera to be sold to Mahfouz.

27. As the seller, Nigmatova had a legal obligation pursuant to NAC 639.227(1) to file an application for a change of ownership at least 15 days prior to the transfer of the beneficial interest in the pharmacy at 8995 W. Flamingo Road, Suite 120, in Las Vegas, Nevada.

28. By failing to file an application for change of ownership pursuant to NAC 639.227(1), Nigmatova violated a Nevada regulation relating to the practice of pharmacy.

29. Nigmatova's conduct as alleged above amounts to a violation for which the Board may impose administrative discipline. *See* NRS 639.210(12).

COUNT TWO

Permitting Unlicensed Practice
(Respondent Nigmatova)

30. As alleged above, on or about September 19, 2025, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Tera to be sold to Mahfouz.

31. When Nigmatova failed to file an application for change of ownership pursuant to NAC 639.227(1), Mahfouz, the putative new owner of Tera, did not legally obtain licensure to operate the pharmacy. As such, during the relevant time period, Mahfouz did not hold a license with the Board to engage in the practice of pharmacy in Nevada.

32. As alleged above, during the relevant time period, Mahfouz, on his own account and without knowledge or consent of the Board, continued to operate the pharmacy, including by continuing to receive, possess, store, hold for sale, and/or sell controlled substances and dangerous drugs, without a license as required by NRS 639.230.

33. By failing to file an application for change of ownership for Tera and causing putative owner Mahfouz, on his own account and without knowledge and consent of the Board, to operate the pharmacy location without an owner licensed by the Board pursuant to NRS

639.230(2), Nigmatova permitted Mahfouz to engage in unlicensed selling and/or dispensing of drugs in violation of NRS 639.100(1).

34. Respondent's conduct as alleged above amounts to a violation of NRS 639.100, as well as unprofessional conduct as defined by NAC 639.945(1)(j); therefore, the Board may impose administrative discipline. *See* NRS 639.210(4); NRS 639.210(12); NAC 639.945(1)(j).

COUNT THREE
Unprofessional Conduct – Performing Duties in a Negligent Manner
(Respondent Singson)

35. As alleged above, between October 22, 2025 to November 4, 2025, Singson, as managing pharmacist at Tera, processed at least ten (10) prescriptions with missing information that is required by Nevada law or regulation. NRS 639.2353(2); NRS 639.236(2); NAC 639.751.

36. As the registered pharmacist on duty, Singson had a duty to verify, evaluate and interpret the prescriptions received at Tera. NAC 639.700(2); NAC 639.252(2); NAC 639.752.

37. By filling prescriptions that were not valid under Nevada law, Signson performed her duties as a licensee in a negligent manner. NAC 639.945(1)(i).

38. Singson's conduct as alleged above amounts to unprofessional conduct as defined by NAC 639.945(1)(i); therefore, the Board may impose administrative discipline. *See* NRS 639.210(4).

COUNT FOUR
Pharmacy/Pharmacy Owner Responsibility
(Respondent Tera Pharmacy)

39. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Tera is responsible for those violations, including all errors and omissions of Respondent Nigmatova and Respondent Singson and any other pharmacy personnel in the course of conduct alleged above.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondents Tera Pharmacy, Nazakat Nigmatova, RPh, and Grace Singson, RPh.

DATED this 6th day of February 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TERA PHARMACY,** **Pharmacy License No. PH04648,** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601, and** **GRACE SINGSON, RPH,** **Certificate of Registration No. 24727,** **Respondents.**	**Case No(s). 25-370-PH-S** **25-370-RPH-A-S** **25-370-RPH-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2)

copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TERA PHARMACY,** **Pharmacy License No. PH04648,** **Respondent.**	**Case No. 25-370-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR TERA PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day of February 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Tera Pharmacy
8995 W Flamingo Rd., Ste. 120
Las Vegas, NV 89147

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

5Z

FILED
FEB 0 6 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TERA PHARMACY,** **Pharmacy License No. PH04648,** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601, and** **GRACE SINGSON, RPH,** **Certificate of Registration No. 24727,** **Respondents.**	**Case No. 25-370-PH-S** **25-370-RPH-A-S** **25-370-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Tera Pharmacy (Tera), License No. PH04648, held a license issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy, Respondent Nazakat Nigmatova, RPh (Nigmatova), Certificate of Registration No. 20601, was a pharmacist registered with the Board, and Respondent Grace Singson, RPh (Singson), Certificate of Registration No. 24727, was a pharmacist registered with the Board.

FACTUAL ALLEGATIONS

2. From November 21, 2024, through February 4, 2026, Tera, located at 8995 W. Flamingo Road, Suite 120, in Las Vegas, held Pharmacy License No. PH04648 authorizing the

operation of a pharmacy in compliance with the terms of the new pharmacy application personally submitted by Nigmatova on Tera's behalf.

3. Respondent Nigmatova, a registered pharmacist, signed the initial application in her capacity as the president and 100% shareholder of Tera. As stated in the application, Tera initially conducted business under the name Lyfe Pharmacy 2.

4. On or about December 2, 2024, Nigmatova filed an application with the Board to change the pharmacy's name from Lyfe Pharmacy 2 to Tera Pharmacy. The Board's staff approved the application.

5. On or about June 11, 2025, without giving prior notice to the Board pursuant to NAC 639.227, Nigmatova ostensibly caused the assets of Tera to be sold outside the jurisdiction of the Board. The assets of Tera were ostensibly relinquished to a buyer who is not licensed by the Board to operate a pharmacy.

6. On or about September 19, 2025 without giving prior notice to the Board pursuant to NAC 639.227, Nigmatova again ostensibly caused the assets of Tera to be sold outside the jurisdiction of the Board. The assets of Tera were ostensibly relinquished to Mark Mahfouz (Mahfouz), who was not and is not currently licensed by the Board to operate a pharmacy at 8995 W. Flamingo Road, Suite 120.

7. Mahfouz took possession of Tera's assets on September 19, 2025, and he began to act at that time as the putative pharmacy owner in control of the premises at 8995 W. Flamingo Road, Suite 120, in Las Vegas.

8. From September 19, 2025 until January 27, 2026, with putative owner Mahfouz having assumed control of the assets of the pharmacy, Mahfouz began, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell controlled substances.

9. On or about October 16, 2025, Singson notified the Board that she had become managing pharmacist at Tera.

10. On or about November 25, 2025, Board Inspector Leo Basch (Basch) performed an annual inspection of Tera. During the inspection, Basch noted several deficiencies, including:

a. From on or about October 29, 2025 to October 30, 2025, Singson processed at least seven (7) prescriptions for various controlled substances that did not have a quantity indicated on the prescription or a prescriber's signature;

b. On or about October 29, 2025, Singson processed at least one (1) prescription for a controlled substance that did not have the prescriber's signature;

c. On or about November 4, 2025, Singson accepted a transferred prescription for testosterone, a controlled substance, that was missing the days' supply, the address of the pharmacy the prescription was received from, the total number of refills, and the number of refills remaining; and

d. On or about October 22, 2025, a phoned-in prescription was written for multiple medications for one patient and was missing the initials of the pharmacist who took the call. When questioned, Singson stated that she took the prescription over the phone.

11. On or about January 27, 2026, the Board received notice that agents from the federal Drug Enforcement Administration (DEA) had seized the stock of controlled substances at 8995 W. Flamingo Road, Suite 120, in Las Vegas, Nevada. The DEA seized the controlled substances because no pharmacy owner was registered with the DEA at that location to prescribe or dispense controlled substances as required by federal law.

12. From September 19, 2025 through February 4, 2026, putative owner Mahfouz continued, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell dangerous drugs. During that time, Nigmatova did not act as pharmacy owner of Tera, and Nigmatova never submitted, and the Board had never approved, a change of ownership application for Tera with Mahfouz as the owner.

13. On or about February 4, 2026, following a Board investigation, Nigmatova surrendered the pharmacy license for Tera. Nigmatova did not agree to temporarily assume a managerial role pending licensure of a qualified owner. As a result, Tera was closed by the Board.

14. On or about February 4, 2026, the Board secured all drugs and medical records on Tera's premises. On February 5, 2026, Singson volunteered to properly secure the drugs and patient records on site and assist patients to transfer their prescription information to other pharmacies pending new ownership approved by the Board.

APPLICABLE LAW

15. Any person operating a pharmacy within this State shall obtain a license from the Board. NRS 639.230(1). Each license must be issued to a specific person and for a specific location and is not transferable. NRS 639.230(2).

16. The holder of a pharmacy license must file an application for a change of ownership at least 15 days prior to any change involving a transfer of 50 percent or more of the beneficial interest in the pharmacy. NAC 639.227(1). If the Board does not receive an application for change of ownership within the required timeframe, the Board may initiate proceedings to suspend the license to operate the pharmacy. NAC 639.227(3).

17. Pursuant to NRS 639.100(1), it is unlawful for any person to permit to be manufactured, distributed at wholesale, sold or dispensed, any drug, poison, medicine or chemical, or to dispense, or permit to be dispensed, any prescription of a practitioner, unless the person holds the appropriate certificate, license or permit and complies with the regulations adopted by the Board.

18. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada is unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(j).

19. In Nevada, written prescriptions for controlled substances must contain, among other things, the name and signature of the practitioner and the name, strength and quantity of the drug prescribed and the number of days that the drug is to be used, beginning on the day on which the prescription is filled. NRS 639.2353(2). All filled prescriptions must be retained on file for at least two years, and each prescription on file must be personally signed or initialed by the registered pharmacist who filled it. NRS 639.236(2); NAC 639.751.

20. Only a registered pharmacist or a registered pharmaceutical intern acting under the direct supervision of a registered pharmacist may identify, evaluate, and interpret a prescription. NAC 639.700(2). Pharmacists are responsible for verifying prescriptions prepared by pharmaceutical technicians, including, but not limited to the selection and strength of the drug and the dosage form. NAC 639.252(2). Pharmacists also have discretion not to fill a prescription if the prescription does not meet certain standards. NAC 639.752.

21. Performing any duties as the holder of a license, certificate or registration issued by the Board in an incompetent, unskillful, or negligent manner is unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(i).

22. The Board may revoke or suspend the registration of any licensee who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12).

23. The Board may revoke or suspend the registration of any licensee who has engaged in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

24. Any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in its employ. NAC 639.945(3).

25. In lieu of, or in addition to revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

COUNT ONE
Violation of State Regulation – Failure to Submit Change of Ownership (Respondent Nigmatova)

26. As alleged above, on or about September 19, 2025, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Tera to be sold to Mahfouz.

27. As the seller, Nigmatova had a legal obligation pursuant to NAC 639.227(1) to file an application for a change of ownership at least 15 days prior to the transfer of the beneficial interest in the pharmacy at 8995 W. Flamingo Road, Suite 120, in Las Vegas, Nevada.

28. By failing to file an application for change of ownership pursuant to NAC 639.227(1), Nigmatova violated a Nevada regulation relating to the practice of pharmacy.

29. Nigmatova's conduct as alleged above amounts to a violation for which the Board may impose administrative discipline. *See* NRS 639.210(12).

COUNT TWO
Permitting Unlicensed Practice (Respondent Nigmatova)

30. As alleged above, on or about September 19, 2025, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Tera to be sold to Mahfouz.

31. When Nigmatova failed to file an application for change of ownership pursuant to NAC 639.227(1), Mahfouz, the putative new owner of Tera, did not legally obtain licensure to operate the pharmacy. As such, during the relevant time period, Mahfouz did not hold a license with the Board to engage in the practice of pharmacy in Nevada.

32. As alleged above, during the relevant time period, Mahfouz, on his own account and without knowledge or consent of the Board, continued to operate the pharmacy, including by continuing to receive, possess, store, hold for sale, and/or sell controlled substances and dangerous drugs, without a license as required by NRS 639.230.

33. By failing to file an application for change of ownership for Tera and causing putative owner Mahfouz, on his own account and without knowledge and consent of the Board, to operate the pharmacy location without an owner licensed by the Board pursuant to NRS

639.230(2), Nigmatova permitted Mahfouz to engage in unlicensed selling and/or dispensing of drugs in violation of NRS 639.100(1).

34. Respondent's conduct as alleged above amounts to a violation of NRS 639.100, as well as unprofessional conduct as defined by NAC 639.945(1)(j); therefore, the Board may impose administrative discipline. *See* NRS 639.210(4); NRS 639.210(12); NAC 639.945(1)(j).

COUNT THREE
Unprofessional Conduct – Performing Duties in a Negligent Manner
(Respondent Singson)

35. As alleged above, between October 22, 2025 to November 4, 2025, Singson, as managing pharmacist at Tera, processed at least ten (10) prescriptions with missing information that is required by Nevada law or regulation. NRS 639.2353(2); NRS 639.236(2); NAC 639.751.

36. As the registered pharmacist on duty, Singson had a duty to verify, evaluate and interpret the prescriptions received at Tera. NAC 639.700(2); NAC 639.252(2); NAC 639.752.

37. By filling prescriptions that were not valid under Nevada law, Signson performed her duties as a licensee in a negligent manner. NAC 639.945(1)(i).

38. Singson's conduct as alleged above amounts to unprofessional conduct as defined by NAC 639.945(1)(i); therefore, the Board may impose administrative discipline. *See* NRS 639.210(4).

COUNT FOUR
Pharmacy/Pharmacy Owner Responsibility
(Respondent Tera Pharmacy)

39. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Tera is responsible for those violations, including all errors and omissions of Respondent Nigmatova and Respondent Singson and any other pharmacy personnel in the course of conduct alleged above.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondents Tera Pharmacy, Nazakat Nigmatova, RPh, and Grace Singson, RPh.

DATED this 6th day of February 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TERA PHARMACY,** **Pharmacy License No. PH04648,** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601, and** **GRACE SINGSON, RPH,** **Certificate of Registration No. 24727,** **Respondents.**	**Case No(s). 25-370-PH-S** **25-370-RPH-A-S** **25-370-RPH-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2)

copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601,** **Respondent.**	**Case No. 25-370-RPH-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

NAZAKAT NIGMATOVA, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day of February 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Nazokat Nigmatova, RPH
c/o Evergreen Pharmacy
4110 S Maryland Pkwy., Ste. 17
Las Vegas, NV 89119

Nazokat Nigmatova, RPH
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

5AA

FILED
MAR 26 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **GEZEL ASHLEY GONZALEZ. PTT,** **Certificate of Registration No. PT28532,** **Respondent.**	**CASE NO. 26-092-PTT-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this Respondent because, at the time of the events alleged herein, Respondent Gezel Ashley Gonzalez, PTT, held a Nevada pharmaceutical technician in training registration, Certificate of Registration No. PT28532, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent falsely represented to the Board on her 2023 application for registration as a pharmaceutical technician in training that she was a high school graduate or the equivalent, and was issued Certificate of Registration No. PT28532.

3. On or about March 26, 2026, the Board issued a cease-and-desist order pursuant to NRS 639.2895(1) directing Respondent to immediately CEASE and DESIST performing any duties as a pharmaceutical technician in training.

APPLICABLE LAW

4. An applicant for registration as a pharmaceutical technician in training must be a high school graduate or the equivalent. NAC 639.242(1)(B).

5. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 639. NRS 639.281(1).

6. Willfully making to the Board any false statement which is material to the administration or enforcement of Nevada law is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

7. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

8. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

COUNT ONE
Furnishing False Material Information to Board

9. By falsely representing to the Board on her 2023 application for registration as a pharmaceutical technician in training that she was a high school graduate or the equivalent, Respondent violated NRS 639.281 and is subject to discipline pursuant to NRS 639.210(9) and/or NRS 639.210(12).

COUNT TWO
Obtaining Registration by False or Fraudulent Application

10. By falsely representing to the Board on her 2023 application for registration as a pharmaceutical technician in training that she was a high school graduate or the equivalent, Respondent is subject to discipline pursuant to NRS 639.210(10).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

DATED this 26th day of March 2026.

Yenh Long, Pharm.D., Deputy Executive Secretary
of the Nevada State Board of Pharmacy,
for and on behalf of J. David Wuest, R.Ph.,
Executive Secretary of the Nevada State Board of
Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **GEZEL ASHLEY GONZALEZ. PTT,** **Certificate of Registration No. PT28532,** **Respondent.**	**Case No. 26-092-PTT-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 15, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26th day of March 2026.

Yenh Long, Pharm.D., Deputy Executive Secretary
of the Nevada State Board of Pharmacy,
for and on behalf of J. David Wuest, R.Ph.,
Executive Secretary of the Nevada State Board of
Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **GEZEL ASHLEY GONZALEZ. PTT, Certificate of Registration No. PT28532,** **Respondent.**	**Case No. 26-097-PTT-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

GEZEL ASHLEY GONZALEZ. PTT

JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

March 26, 2026

VIA PERSONAL SERVICE

Gezel Ashley Gonzalez
1155 Mill Street
Reno, NV 89502

Re: CEASE-AND-DESIST ORDER (Case No. 26-092-PTT-N)

Dear Gonzalez:

The Nevada State Board of Pharmacy (Board) has determined that you falsely represented to the Board on your 2023 application for registration as a pharmaceutical technician in training that you are a high school graduate or the equivalent as required by NAC 639.242(1)(B), and you do not qualify to hold Certificate of Registration No. PT28532.

You are hereby ordered pursuant to NRS 639.2895(1) to immediately CEASE and DESIST performing any duties as a pharmaceutical technician in training. This notice shall serve as a CITATION pursuant to NRS 639.2895(2) for this violation. You have the right to appeal this citation by submitting a written request for a hearing to the Board at the Board's Reno office no later than 30 days after receipt of this notice. *See* NRS 639.2895(2).

Regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

AFFIDAVIT OF SERVICE

I HEREBY certify on the 26th day of March, 2026, I personally served a copy of the Cease and Desist Order, Notice of Intended Action and Accusation, Statement to the Respondent and Notice of Hearing, and Answer and Notice of Defense in Case # 26-092-PTT-N upon Gezel Gonzalez

at Renown Regional Medical Center, Reno, NV in the presence of James Milner, Director of Pharmacy, and Jessica Wise, HRBP.
(address)

I declare under penalty of perjury under the law of the State of Nevada that the foregoing is true and correct.

Monica Sue Segedy
Signature

Monica Segedy, Investigator
Name and Title (print)
Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician IN TRAINING (PTT) Application

Non-Refundable $50 fee

Rev (01/18/2023)

Section 1: General Information

First: Gezel Middle: Ashley Last: Gonzalez

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Carson City State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you are enrolled in a PT school or training program.) NAC 639.258

Program/School Name: ~~Renown~~ N

Address: ~~1155 mill st~~ N

City: ~~Reno~~ N State: ~~NV~~ N Zip: ~~89502~~ N

Name of Program Director:

Signature of Program Director:

Section 3: Employment Information

Pharmacy Name: Renown Regional Med Center License #: IA00610

Address: 1155 Mill St

City: Reno State: NV Zip: 89502

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	Yes	No
1. Are you 18 years of age or older?	X	
2. Are you a high school graduate or the equivalent?	X	

High School Name: I can do Anything Charter H.S. Graduation Date OR Date GED obtained (mm/yy): 06/02

Address: 1195 Corporate Blvd

City: Reno State: NV Zip: 89502

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 7: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		X
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state even if the case or charge has been dismissed, sealed, acquitted, or expunged?		X
3. Have you been the subject of a board citation or administrative action whether completed or pending in <u>any</u> state?		X
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician in training who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Gezel Gonzalez

Print Name

Original Signature (electronic, copies or stamps not accepted)

4/7/23

Date

Board Use Only	Date Received: 4-10-23	Amount: 50.00cc

FILED
APR 01 2026
NEVADA STATE BOARD
OF PHARMACY

I, Gezel Gonzalez, do attest and affirm that the following information is true:

I have been an employee of Renown Regional Medical Center since 2015. I was initially hired as a clerical employee. In 2023, I was transferred to the Pharmacy where I currently work as a Pharmacy Technician in Training. (PTT) .

I do not have a high school diploma from I Can Do Anything Charter School as noted on my PTT application, or any other high school. Nor do I have a GED equivalent.

I have been working on getting my GED Certificate since about 2023. Initially, I was enrolled in classes at Truckee Meadows Community College (TMCC). I am currently enrolled at Northern Nevada Literary Council (NNLC) in Reno, NV. and I have attended this school since about 2023. I am currently on track to receive my GED Certificate 30 days.

Signed: _____
Gezel Gonzalez

Date: April 1, 2026

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6A

December 18, 2025

State of Nevada Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521
Email: Skylaryoung@pharmacy.nv.gov

Subject: Case No. 25-470-O, Unlicensed Wholesaling of Medical Devices

Oxus America, Inc. acknowledges receipt of your letter **RE: CEASE & DESIST/CITATION & FINE: Case No. 25-470-O, Unlicensed Wholesaling of Medical Devices**, dated December 10, 2025. Oxus is submitting this written response to appeal this Cease & Desist, Citation, and Fine by request of a hearing with the Board's Reno Office.

Specifically, the State of Nevada Board of Pharmacy claim that *"Oxus sold and/or shipped Stationary Sieve Replacements in Reno, Nevada from its Michigan Facility. This device qualifies as a prescription only medical device under NRS 639.007 and 639.016 because it is restricted by federal law to sale by or on the order of a licensed healthcare provider."*

The US FDA has released the guidance document, *Remanufacturing of Medical Devices: Guidance for Industry, Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff*, dated May 10, 2024. Many medical devices are reusable and need preventive maintenance and repair during their useful life. For these devices, proper servicing is critical to their continued safe and effective use. Servicing is the repair and/or preventive or routine maintenance of one or more parts in a finished device, after distribution, for purposes of returning it to the safety and performance specifications established by the OEM and to meet its original intended use. Specific to oxygen concentrators, the Stationary Sieve Replacements are a standard service repair part and are not remanufacturing; therefore, they are not a prescription only medical device.

Oxus America, Inc. disagrees with the State of Nevada Board of Pharmacy claim that this product qualifies as a prescription only medical device under NRS 639.007. The subject product, supplied by Oxus America, Inc, is a repair part and not a finished medical device. The subject repair part is not intended for use in the diagnosis, cure, mitigation, treatment of prevention of a disease. The subject repair part does not require a prescription to be sold and is not shipped or sold to end user patients.

The subject repair part is shipped and sold to medical products providers that employ trained technicians to repair medical products. The subject repair part is equivalent to the replacement of any other defective or worn item to service the medical product (e.g. a

caster wheel replacement for one that is broken, replacement of a housing that has been cracked, etc.). The subject repair part is specifically intended to replace an identical component of the EverFlo oxygen concentrator that is defective or worn. Replacement of these parts restores the function of the device without changing its performance, safety characteristics, or intended use.

Oxus America, Inc. disagrees with the State of Nevada Board of Pharmacy claim that Oxus America, Inc. is a “wholesaler” as defined by NRS 639.016 or “Medical products wholesaler” as defined by NAC 639.6937. Oxus America, Inc. does not sell, lease or otherwise provide medical products to a health care facility, agency, practitioner or provider in the State of Nevada. The subject product does not meet the definition of the term “drug” under NRS 639.007; therefore, Oxus America Inc. does not distribute prescription drugs or devices into the State of Nevada. The subject product, supplied by Oxus America, Inc, is a repair part and not a finished medical device.

Oxus America, Inc. respectfully requests Case No. 25-470-O rescinded without undue delay. If an expedited withdrawal is not possible, please extend the 30-day payment of the fine until resolution can be reached. If further questions or clarifications are requested by the State of Nevada Board of Pharmacy, please contact me directly at rlenarcic@oxusamerica.com or 248-709-0490.

Thank you for your prompt response to this matter.



Ryan Lenarcic
Quality & Regulatory Affairs Manager

FILED
JAN 7 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **OXUS AMERICA, INC,** **Respondent.**	**Case Nos. 25-470-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED, PLEASE TAKE NOTICE THAT:

On or about December 15, 2025, pursuant to NRS 639.2895, the Nevada State Board of Pharmacy (Board) issued a Cease-and-Desist/Citation-and-Fine (Citation) to Oxus America, Inc. (Oxus). On December 18, 2025, Oxus requested a hearing before the Board pursuant to NRS 639.2895(2). For purposes of the hearing, it is alleged that:

FACTUAL ALLEGATIONS

1. Oxus is a company that specializes in medical devices and gas separation technology. Oxus is located at 175 Kay Industrial Drive, Orion Township, Michigan.

2. Oxus is ISO 13485 certified. ISO 13485 is the internationally recognized standard for quality management systems in the design and manufacture of medical devices.

3. Oxus is also a U.S. Food and Drug Administration (FDA) registered manufacturer.

4. Oxus sold and/or shipped Stationary Sieve Replacements in Reno, Nevada from its Michigan facility.

5. Stationary Sieve Replacements incorporate molecular sieve technology and are intended to replace an identical component of an oxygen concentrator. Molecular sieve technology separates oxygen from carbon dioxide and nitrogen.

6. Stationary Sieve Replacements are shipped and sold only to medical products providers. A trained technician must install the Stationary Sieve Replacement.

7. Mui Lee, the Board's investigator, conducted a routine inspection of Bennett Medical Services, also known as Adapt Health. During her inspection, Inspector Lee discovered an invoice from Oxus for Stationary Sieve Replacements.

8. Inspector Lee attempted to contact Oxus to inquire about the invoice; however, no representatives responded to phone calls or emails.

9. Oxus received the Board's citation on or about December 15, 2025. The Board cited Oxus for engaging in the unlawful wholesale distribution of prescription only drugs without the required Nevada wholesale license.

10. On December 18, 2025, Oxus submitted an appeal arguing that the Stationary Sieve Replacements are not prescription devices as they are just a repair component of an oxygen concentrator. Oxus also disagreed that it is a wholesaler as defined by Nevada regulations.

APPLICABLE LAW

11. Any person, including a wholesaler or manufacturer, who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license. NRS 639.233, NAC 639.6942.

12. Pursuant to NRS 639.016, a "wholesaler" includes any person or business that distributes drugs or devices that are restricted by federal law to sale by or on the order of a physician to a person other than the consumer or patient.

13. "Medical products wholesaler" means a person who sells, leases, or otherwise provides medical products to a health care facility, agency, practitioner or provider in Nevada. NAC 639.6937

14. The term "drug" includes "articles and *devices* intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease" including "articles intended for use as a *component* of any article specified." (*italics* added). NRS 639.007. Similarly, 21 U.S.C. § 321(h)(1) defines a "device" to include any instrument, apparatus, or other similar or related

article, including any *component, part, or accessory,* that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or that is intended to affect the structure or any function of the body (emphasis added).

15. "Medical products" includes medical devices, equipment, supplies and gases intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease. NAC 639.6935. It also includes "medical devices, equipment, supplies or gases" which are governed by any other board or agency other than the Board of Pharmacy.

16. The FDA is a U.S. government agency under the Department of Health and Human Services.

17. An oxygen concentrator is a "device" as that term is defined at 21 U.S.C. § 321(h). The product's purpose is for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.

18. Oxygen concentrators are "prescription devices" within the meaning of 21 CFR § 801.109. Oxygen concentrators incorporate molecular sieve technology to separate oxygen from carbon dioxide and nitrogen.

19. Devices that use molecular sieve technology are categorized by the FDA as class II medical devices. *See* 21 CFR § 868.5440. This means that they may not be sold at retail except pursuant to a prescription. *See* 21 CFR § 860.3; 21 CFR § 801.109.

20. Under both state and federal law, the term "device" means and includes the component parts of the device. *See* NRS 639.007; 21 U.S.C. § 321(h)(1). By definition, if an oxygen concentrator may not be sold at retail without a prescription, its component parts may not be sold at retail without a prescription.

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COUNT ONE

Violation of State Law: Wholesale Distribution in Nevada without a License

21. The Stationary Sieve Replacement is an FDA regulated component that is critical to the prescription-only oxygen concentrator. Because the component materially impacts physician-prescribed oxygen therapy and is not safe for use without professional installation, it is restricted to prescription use.

22. Respondent engaged in wholesale distribution into Nevada of an FDA regulated component device without first obtaining a license required by NRS 639.233 and NAC 639.593.

23. Because of these actions, Respondent unlawfully engaged in wholesale distribution within the state. NRS 639.100(1), 21 U.S.C. § 353(e)(l)(A) and/or 21 CFR Part 205.

24. Having engaged in unlawful conduct as alleged above, Respondent is subject to an administrative fine of $5,000. NRS 639.100(1); NRS 639.2895.

25. In addition to collecting the $5,000 fine as authorized by NRS 639.2895, the Board may recover its costs of investigation and prosecution pursuant to NRS 622.400.

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 639.2895(2); NRS 233B.127(3). You have the right to a hearing before the Board to answer the allegations and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.127(3); NRS 622A.300(1) and (3). If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

The Board has scheduled your hearing on this matter for March 4, 2026, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 South Las Vegas Boulevard, Las Vegas, Nevada 89123.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. You may request and the Board may at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session. NRS 241.030 and NRS 241.033.

DATED this 7th day of January 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of January, 2026, I personally served a true and correct copy of the foregoing **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** by placing a copy by Certified U.S. Mail and Standard U.S. mail to the following:

Oxus America, Inc
175 Kay Industrial Drive
Orion Township, MI 48359

And by sending a copy via email to:

Jessica Shopp (jshopp@oxusamerica.com)
Gary Abusamra (gabusamra@oxusamerica.com)
Ryan Lenarcic (rlenarcic@oxusamerica.com)

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

301 East Fourth Street, Suite 2800
Cincinnati, OH 45202-3957
Tel: 513.381.2838 | Fax: 513.381.0205
taftlaw.com

Mark A. McAndrew
513.357.9352
mcandrew@taftlaw.com

February 24, 2026

Gregory L. Zunino
Senior General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

Re: Case No. 25-470-O (Oxus America, Inc.)

Dear Greg:

Thank you again for your time last week to discuss the above citation issued by the Board of Pharmacy to Oxus America, Inc. ("Oxus"), as well as your follow-up email dated February 18, 2026, indicating that the hearing in the above matter was continued to April 15, 2026. On behalf of Oxus, I am confirming the new date.

I also appreciate your willingness to discuss Oxus' position with the Executive Director. As an initial matter, Oxus is committed to operating in a compliant manner and takes its regulatory obligations very seriously. Oxus has been in operation for more than 16 years and is proud of its long-standing commitment to supply high-quality aftermarket components to customers that principally include service and repair technicians, medical part distributors and health systems that supply certain brands of oxygen concentrators to end users. As we discussed, Oxus does not manufacture, sell or distribute finished medical devices to customers or end users; instead, it supplies replacement service components (such as the sieve at issue here) that its customers then use to service finished products manufactured and distributed by third parties such as Invacare, Respironics and DeVilbiss.

Nor does Oxus currently manufacture or distribute any medical devices regulated by the FDA. All products in Oxus' current product portfolio are aftermarket replacement products that do not require a prescription. Further, the activities undertaken by Oxus to produce the replacement sieve at issue do not constitute "manufacturing" or "remanufacturing" of a finished device as would require a new 510(k) submission, clearance by FDA, and distribution to end users only with a prescription. In its final guidance document, Remanufacturing of Medical Devices: Guidance for Industry,

Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff, dated May 10, 2024, FDA provided examples of regulated remanufacturing of medical devices vs. servicing or reconditioning of components of medical devices.[1] One example provided by FDA is instructive and informs Oxus' view that (1) its activities do not constitute regulated remanufacturing; and (2) the replacement sieve product at issue does not require a prescription because the component is only for use within a regulated finished product and does not introduce new risks or functions that would require practitioner supervision:

> ***Activity****: The gradient coil of an MR system was damaged during an imaging session and needs to be replaced. It is replaced with a non-OEM gradient coil that has different dimensional specifications and coil design.*
>
> ***Relevant questions****:*
>
> *A2.1 Is there a significant change to device performance or safety specifications?*
>
> *No. The new gradient coil only differs by small changes in design and dimensional specifications. There are no significant changes to the performance and safety specifications (e.g., slew rate, peak gradient strength, power).*
>
> *A3. Is there a new or modified risk or is there a change in the performance or safety specifications?*
>
> *No. A risk-based assessment identified no new or modified risks or change in the performance or safety specifications due to this change because the non-OEM gradient coil has the same hardware performance specifications (e.g., slew rate), equivalent imaging performance, and meets the same safety and performance specifications (e.g., acoustic output) when compared to the OEM gradient coil.*
>
> ***Decision****: Not Remanufacturing*

Remanufacturing of Medical Devices: Guidance for Industry, Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff (May 10, 2024), p. 25.

Oxus' sieve product is very similar (if not identical) to replacement sieves distributed by various other aftermarket component suppliers and by the finished product manufacturers too. To Oxus' knowledge, none of those suppliers' replacement sieve

[1] See https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices.

products are subject to a 510(k) or require a prescription, principally because the sieve products are not intended to be sold and distributed directly to end users. Oxus is sensitive to this distinction, as prior to 2024 Oxus sold a sieve product covered by a 510(k) that was replaceable by end user patients. However, this particular product (510(k) K211056) was discontinued by Oxus in 2024 and is no longer commercially available.

We note that the Board's December 1, 2025 Inspection Violation Form indicates that the Board considered an "invoice showing that the entity shipped 'Rx Only' product into Nevada" and that the inspector was to secure "confirmation that the item sold are 'Rx Only' products by either taking a photo of the product indicating "Rx Only" or by confirming through the AccessGUDID database. However, Oxus' sieve product does not bear an "Rx Only" legend on its packaging (because it is a non-prescription product) and the GUDID database entry for the Oxus sieve product relates to the sieve product that was discontinued in 2024. Is it possible that the Board inspector believed that the product referred to in the GUDID entry was the same as the product described in the invoice? Those are two different products.

Because the Oxus replacement sieve product is not a prescription only product and is not sold directly to patient end users, Oxus respectfully submits:

1. That the replacement sieve product at issue is not a prescription only medical device under NRS 639.007 or 639.106;

2. It is not engaging in wholesaling activities as would require it to obtain licensure as a wholesaler under NRS 639.233.

******

On behalf of Oxus, we appreciate your attention to these matters and your consideration of the above information. If you have additional questions, please do not hesitate to contact me directly.

Respectfully submitted,

Mark A. McAndrew

MAM:pjh

7

7A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	■ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	● Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Dignified Medical Equipment Llc

MDEG Physical Address: 3175 E Warm Springs Rd Ste 128

City: Las Vegas State: NV Zip: 89120

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (702) 763-1382 Website: _____

Email: dignifieddme@gmail.com

Name of MDEG Administrator (NAC 639.694): Maan Basim Simon

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	■ Assistive Equipment
☐ Wholesalers[a]	■ Diabetic Supplies
☐ Other business entities (specify)[a]:	■ Orthotics and Prosthetics
	■ Others: Incontinence Supplies
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an (a) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Maan Simon
	Telephone: 702-970-1254

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9AM-6PM	■ Tue: 9AM-6PM	■ Wed: 9AM-6PM	■ Thurs: 9AM-6PM	■ Fri: 9AM-6PM
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company:	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(l))
N/A

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse-Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership (NAC 639.6943, NAC 693.6933).

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: Maan B. Simon

Business Name: Dignified Medical Equipment Llc

Business Address: 3175 E Warm Springs Rd Ste 128

City: Las Vegas State: Nv Zip: 89120

Telephone: 702-763-1382 Email: dignifieddme@gmail.com

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Maan B. Simon

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

2-11-26

Date

Board Use Only	Date Received: 2/23/26	Amount: $500 cc

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 2/10/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Yordanys Diaz	
Insurance Now LLC 3175 E Warm Springs Rd Ste 128 Las Vegas NV 89120	PHONE (A/C, No, Ext): (702) 622-1157	FAX (A/C, No):
	E-MAIL ADDRESS: yordanys@insurancenow-nv.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : UNITED FNCL CAS CO	11770
INSURED Dignified Medical Equipment Llc 3175 E Warm Springs Rd Ste 128 Las Vegas NV 89120-3138	INSURER B :	
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			PGR973396054	02/02/2026	02/02/2027	EACH OCCURRENCE	$ 1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 50,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$
							GENERAL AGGREGATE	$ 2,000,000
							PRODUCTS - COMP/OP AGG	$
								$
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident)	$
							BODILY INJURY (Per person)	$
							BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
								$
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $						EACH OCCURRENCE	$
							AGGREGATE	$
								$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N/A (Mandatory In NH) If yes, describe under DESCRIPTION OF OPERATIONS below						[ ] PER STATUTE [ ] OTH-ER	
							E.L. EACH ACCIDENT	$
							E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Proof of liability insurance

CERTIFICATE HOLDER

Dignified Medical Equipment Llc
3175 E Warm Springs Rd
Suite 128
Las Vegas NV 89120

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Yordanys Diaz

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SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Dignified Medical Equipment Llc** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 01/09/2026, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/09/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202602096477340
You may verify this certificate online at https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners or Trustees:

CORPORATION, INDICATE THE Managing Member:

Name	Country
Maan Basim Simon	USA

Address	City	State	Zip/Postal Code
3175 E Warm Springs Rd #128	Las Vegas	NV	89120

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the office of the Secretary of State.

X Maan Basim Simon
Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

Managing Member
Title

01/09/2026
Date

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application

Initial List Of Officers, Managers, Members, General Partners, Managing Partners, or Trustees:

Dignified Medical Equipment Llc

NAME OF ENTITY

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: *Read instructions before completing and returning this form.*

Please indicate the entity type (check only one):

- ☐ Corporation
  - ☐ This corporation is publicly traded, the Central Index Key number is:
- ☐ Nonprofit Corporation (see nonprofit sections below)
- ☑ Limited-Liability Company
- ☐ Limited Partnership
- ☐ Limited-Liability Partnership
- ☐ Limited-Liability Limited Partnership (if formed at the same time as the Limited Partnership)
- ☐ Business Trust

Filed in the Office of	Business Number
FVAguilar	**E54360482026-0**
Secretary of State	Filing Number
State Of Nevada	**20265436049**
	Filed On
	01/09/2026 15:25:09 PM
	Number of Pages
	2

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.

- ☐ 001 - Governmental Entity
- ☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is $200.00. Those claiming and exemption under 501(c) designation must indicate by checking box below.

- ☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee. Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C $ 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit $200.00 for the state business license.

- ☐ Unit-owners' Association
- ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. $501(c)

For nonprofit entities formed under NRS Chapter 82 and 80: **Charitable Solicitation Information - check applicable box**

Does the Organization intend to solicit charitable or tax deductible contributions?

- ☐ No - no additional form is required
- ☐ Yes - the *Charitable Solicitation Registration Statement* is required.
- ☐ The Organization claims exemption pursuant to NRS 82A 210 - the *Exemption From Charitable Solicitation Registration Statement* is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Dignified Medical Equipment Llc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 3175 E Warm Springs Rd Ste 128

City: Las Vegas State: Nv Zip: 89120

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 7027631382 Website: _____

Licensing Company Email: dignifieddme@gmail.com

Section 2: Personal Information

First: Maan Middle: Basim Last: Simon

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: Nv Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Al- Mutanabbi Preparatory School			09/04-06/10
Address	**City**	**State**	**Zip**
Basra Governorate, 61001, Iraq			
Diploma/Degree obtained, if any			
High School Diploma			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/21- present	[redacted]	LAS VEGAS	NV	[redacted]
10/16-08/21		LAS VEGAS	NV	
10/15-10/16		LAS VEGAS	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Brothers Road Service			10/22-present
Business Address	**City**	**State**	**Zip**
4144 Hazelridge Dr	Las Vegas	NV	89129
Phone	**Title**		
702-970-1254	Owner		

Description of Duties

Receive dispatches for breakdowns, flat tires, dead batteries, lockouts, fuel delivery, or towing needs.

Business Name			From - To (MM/YY – MM/YY)
Above the Rest Home Care			03/24 - present
Business Address	**City**	**State**	**Zip**
2001 S Jones Blvd Suite E3	Las Vegas	Nv	89146
Phone	**Title**		
702-425-3377	PCA Caregiver		

Description of Duties

Provide support with daily living tasks while monitoring the client's well being. Helping individual remain safe and comfortable by following the authorized care plan.

Business Name			From - To (MM/YY – MM/YY)
HeartFelt Personal Care			09/23-08/24
Business Address	**City**	**State**	**Zip**
2001 S Jones Blvd Suite H	Las Vegas	Nv	89146
Phone	**Title**		
702-367-0111	PCA Caregiver		

Description of Duties

Provide support with daily living tasks while monitoring the client's well being. Helping individual remain safe and comfortable by following the authorized care plan.

Business Name			From - To (MM/YY – MM/YY)
All Valley Home Care			04/20-03/24
Business Address	**City**	**State**	**Zip**
2001 S Jones Blvd Suite J	Las Vegas	Nv	89146
Phone	**Title**		
702-562-2273	PCA Caregiver		

Description of Duties

Provide support with daily living tasks while monitoring the client's well being. Helping individual remain safe and comfortable by following the authorized care plan.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2-11-26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Maan Simon

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-9-26

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Maan B. Simon, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2-11-26

Date

State of Nevada
County of Clark
Subscribed and Sworn to before me this 11 day of February 2026 by Maan Basim Simon.

Seth Cose

Notary Public Signature

SETH COSE
Notary Public, State of Nevada
No. 16-2967-1
My Appt. Exp. July 5, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Dignified Medical Equipment Llc MDEG License # (if applicable): _____

Physical Address: 3175 E Warm Springs Rd Ste 128

City: Las Vegas State: Nv Zip: 89120

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-763-1382 Website: _____

Licensing Company Email: dignifieddme@gmail.com

Section 2: Personal Information

First: Maan Middle: Basim Last: Simon

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 3175 E Warm Springs Ste 128

City: Las Vegas State: Nv Zip: 89120

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Al- Mutanabbi Preparatory School		09/04-06/10	
Address	**City**	**State**	**Zip**
Basra Governorate, 61001, Iraq			
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/21-present	[redacted]	Las Vegas	Nv	[redacted]
10/16- 08/21		Las Vegas	Nv	
10/15-10/16		Las Vegas	Nv	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Above The Rest Home Care			03/24-present
Business Address	**City**	**State**	**Zip**
2001 S Jones Blvd Suite E3	Las Vegas	Nv	89146
Phone	**Title**	**Number of Employed Hours**	
702-425-3377	PCA Caregiver	2924	

Description of Duties

Provide support with daily living tasks while monitoring the client's well being. Helping individual remain safe and comfortable by following the authorized care plan.

Business Name			From - To (MM/YY – MM/YY)
HeartFelt Personal Care			09/23-08/24
Business Address	**City**	**State**	**Zip**
2001 S Jones Blvd Suite H	Las Vegas	Nv	89146
Phone	**Title**	**Number of Employed Hours**	
702-367-0111	PCA Caregiver	624	

Description of Duties

Provide support with daily living tasks while monitoring the client's well being. Helping individual remain safe and comfortable by following the authorized care plan.

Business Name			From - To (MM/YY – MM/YY)
All Valley Home Care			04/20-03/24
Business Address	**City**	**State**	**Zip**
2001 S Jones Blvd Suite J	Las Vegas	Nv	89146
Phone	**Title**	**Number of Employed Hours**	
702-562-2273	PCA Caregiver	2304	

Description of Duties

Provide support with daily living tasks while monitoring the client's well being. Helping individual remain safe and comfortable by following the authorized care plan.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2-11-24
Date

I, Maan B. Simon, **certify that as the MDEG Administrator for** Dignified Medical Equipment LLC., **that I (initial that you have read and meet the following requirements):**

1. MS Have a high school diploma or its equivalent;
2. MS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Maan B. Simon
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-11-26
Date

Board Use Only	Date Received: 2/12/26

7B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☑ Nevada	☐ Out-of-State
*Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☒ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
☒ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Interlang LLC dba Montgomery DME

MDEG Physical Address: 2915 Losee Rd #108

City: North Las Vegas State: NV Zip: 89030

Mailing Address (if different from physical address): 14109 Pontlavoy Ave

City: Santa Fe Springs State: CA Zip: 90670

Telephone: 562-777-7088 Website: www.montgomerydme.com

Email: admin@montdme.com

Name of MDEG Administrator (NAC 639.694): Cesar Maceira

Entities the MDEG will Serve	Type of MDEG products that will be sold (check all applicable)
☑ Patients by prescriptions	☒ Medical Gases**
☐ Pharmacies[a]	☒ Respiratory Equipment**
☐ Practitioners[a]	☒ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☒ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☒ Other business entities (specify)[a]: Hospice	☐ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Montgomery DME 24/7 On-Call Line
	Telephone: 562-777-7088

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9am-4pm	■ Tue: 9am-4pm	■ Wed: 9am-4pm	■ Thurs: 9am-4pm	■ Fri: 9am-4pm
■ Sat: 9am-3pm	■ Sun: 9am-3pm	■ Holidays: 9am-3pm		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
NA

Section 4: Are any of the owners a health professional (i.e. practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6949, NAC 639.6955)

Name: NA Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): MDME Holding Corp

Corporation/Organization Name: Interiang LLC dba Montgomery DME

Mailing Address: 14109 Pontaloy Ave

City: Santa Fe Springs State: CA Zip: 90670

Telephone: 562-777-7088 Email: admin@montdme.com

Contact Person Name: Tom Fisher

Section 7: Partnership

Partnership Name: NA

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 8: Sole Owner

Owner's Name: NA

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of <u>all</u> Officers and Directors.**	✓	✓		
• **List of <u>all</u> general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Thomas Fisher

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

2-11-26

Date

Board Use Only	Date Received: 2/13/26	Amount: CC $500

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 12/3/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, this policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Kate Findlay
Edgewood Partners Insurance Center, Inc. 301 Grant Street, Suite 470 Pittsburgh, PA 15219	PHONE (A/C, No, Ext): 412-274-1709 FAX (A/C, No): 412-927-1272 E-MAIL ADDRESS: Kate.Findlay@epicbrokers.com
	INSURER(S) AFFORDING COVERAGE — NAIC #
	INSURER A: Federal Insurance Company — 20281
INSURED Interlang, LLC; Montgomery DME; 2915 Losee Rd #108 North Las Vegas, NV 89030	INSURER B:
	INSURER C:
	INSURER D:
	INSURER E:
	INSURER F:

COVERAGES CERTIFICATE NUMBER: 88130859 REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	✓ COMMERCIAL GENERAL LIABILITY			3608-9747	12/15/2025	12/15/2026	EACH OCCURRENCE	$1,000,000
	☐ CLAIMS-MADE ✓ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
							MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$2,000,000
	☐ POLICY ☐ PRO-JECT ✓ LOC						PRODUCTS - COMP/OP AGG	$
	OTHER:							$
A	AUTOMOBILE LIABILITY			7364-7075	12/15/2025	12/15/2026	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	✓ ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	✓ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY			PP/Light Trucks:			PROPERTY DAMAGE (Per accident)	$
	✓ Hired Auto $2,000 Deds.			Coll. Deductible - $2,000 Comp. Deductible - $2,000				$
A	☐ UMBRELLA LIAB ✓ OCCUR			5672-5767	12/15/2025	12/15/2026	EACH OCCURRENCE	$10,000,000
	✓ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$10,000,000
	☐ DED ✓ RETENTION $0							$
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			7184-2518	12/15/2025	12/15/2026	✓ PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N	N/A					E.L. EACH ACCIDENT	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$1,000,000
							E.L. DISEASE - POLICY LIMIT	$1,000,000

Evidence of coverage

CERTIFICATE HOLDER

For Information Only

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Sean Andreas

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Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	INTERLANG, LLC
Entity No.:	201834510111
Registration Date:	11/07/2016
Entity Type:	Limited Liability Company - CA
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of February 10, 2026.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 420649529

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

Interlang LLC dba Montgomery DME
2915 Losee Road, Suite 108
North Las Vegas, NV 89030

Date: February 12, 2026

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

To Whom It May Concern:

As of the date identified above, the following individuals serve as officers of Interlang, LLC:

- Tom Fisher : CEO/President
- Michael Li : CFO

Thank you for your time and consideration.

x

Tom Fisher
CEO/President
[redacted]
tfisher@montdme.com

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

HOME MEDICAL DEVICE RETAIL LICENSE

Interlang LLC
DBA: Montgomery DME
14109 Pontlavoy Avenue
Santa Fe Springs, CA 90670

LICENSE NUMBER: 95969
EXPIRATION DATE: 3/22/2026

The person named herein is licensed to operate a Home Medical Device Retail Facility through the expiration date of this license. This annual license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee shall be responsible for assuring compliance with all requirements of this article pertaining to Home Medical Device Retail Facilities.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 3/27/2025

OSP 07 102308

Interlang LLC dba Montgomery DME
2915 Losee Road, Suite 108
North Las Vegas, NV 89030

Date: February 12, 2026

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

To Whom It May Concern:

This letter is to formally clarify the ownership structure of Interlang LLC dba Montgomery DME.

MDME Holding Corp holds 100% of the membership interest in Interlang, LLC. Accordingly, no individual holds ten percent (10%) or more ownership interest in Interlang, LLC.

Thank you for your time.

x _____
Tom Fisher
CEO/President
[redacted]
tfisher@montdme.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Interlang LLC dba Montgomery DME MDEG License # (if applicable) _____

Physical Address 2915 Losee Rd #108

City North Las Vegas State NV Zip 89030

Mailing Address (if different from physical address) 14109 Pontlavoy Ave

City Santa Fe Springs State CA Zip 90670

Telephone 562-777-7088 Website www.montgomerydme.com

Licensing Company Email admin@montdme.com

Section 2: Personal Information

First Cesar Middle Julio Last Maceira

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State NV Zip [redacted]

Telephone [redacted] Email cmaceira@montdme.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
John Jay College		01/90 - 05/92	
Address	**City**	**State**	**Zip**
524 W 59th St	New York	NY	10019
Diploma/Degree obtained, if any			
Associate Science in Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Herbert H. Lehman High School		09/85 - 05/89	
Address	**City**	**State**	**Zip**
3000 E Tremont Ave	Bronx	NY	10461
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/13- Current	[redacted]	[redacted]	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Interlang LLC dba Montgomery DME			11/22 - Current	
Business Address		**City**	**State**	**Zip**
14109 Pontlavoy Ave		Santa Fe Springs	CA	90670
Phone	**Title**		**Number of Employed Hours**	
562-777-7088	PCT Designated Rep/Administrator		6240	
Description of Duties				
Continue oversight of DME services and patient care. Serves as point of contact for hospice customers and patients.				

Business Name			From - To (MM/YY – MM/YY)	
Advantage Home Medical			01/22 - 11/22	
Business Address		**City**	**State**	**Zip**
2915 Losee Rd		North Las Vegas	NV	89030
Phone	**Title**		**Number of Employed Hours**	
	Delivery Tech		2000	
Description of Duties				
Delivering Medical Equipment to Hospices.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondant			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Cesar Maceira., **certify that as the MDEG Administrator for**

Interlang LLC dba Montgomery DME,

that I (initial that you have read and meet the following requirements):

1. ✓ Have a high school diploma or its equivalent;
2. ✓ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ✓ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ✓ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cesar Maceira

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-12-26

Date

Board Use Only	Date Received:



Interlang LLC dba Montgomery DME
2915 Losee Road, Suite 108
North Las Vegas, NV 89030

Date: February 12, 2026

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

To Whom It May Concern:

Enclosed here please find Interlang LLC dba Montgomery DME's ("Interlang") application for a Nevada Medical Devices, Equipment and Gases (MDEG) permit at 2915 Losee Road #108 North Las Vegas NV 89030.

Should you have any questions or require additional information, please contact:

Tom Fisher
CEO
[redacted]
tfisher@montdme.com

Ramiro Velazquez
Facility Manager
[redacted]
rvelazquez@montdme.com

Thank you for your time and consideration.

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF REGISTRATION
FOREIGN LIMITED-LIABILITY COMPANY

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **Interlang LLC** did on 02/10/2026 file in this office its registration to do business in this state and is now on file and of record in the office of the Nevada Secretary of State, and further, that said entity is at the date of this certificate duly qualified to exercise therein all the powers recited in its Articles and to transact business in the State of Nevada in accordance with the laws of said State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 02/10/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202602106479351
You may verify this certificate online at https://www.nvsilverflume.gov/home

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Interlang LLC

Nevada Business Identification # NV20263525763
Expiration Date: 02/28/2027

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 02/10/2026.

Certificate Number: B202602106479352
You may verify this certificate online at https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State

7C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located? ☒ Nevada ☐ Out-of-State

[a]Is the business also a wholesaler? (NRS 639.016) ☐ Yes ☒ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
☒ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Sora Health LLC

MDEG Physical Address: 6628 Sky Pointe Dr Suite 100 Room 113

City: Las Vegas State: NV Zip: 89131

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 877-869-0608 Website: mysorahealth.com

Email: mimi@mysorahealth.com

Name of MDEG Administrator (NAC 639.694): Mimi Deng

Entities the MDEG will Serve	Type of MDEG products that will be sold (check all applicable)
☒ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☒ Diabetic Supplies (continuous glucose monitors)
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9AM-4:30PM	■ Tue: 9AM-4:30PM	■ Wed: 9AM-4:30PM	■ Thurs: 9AM-4:30PM	☐ Fri:
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))

no medicare provider number has been registered yet.
we are pending accreditation from a CMS-approved organization called Board of Accreditation/certification (BOC).

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: no owner is a health professional Credentials: _____ %: _____
Name: _____ Credentials: _____ %: _____
Name: _____ Credentials: _____ %: _____
Name: _____ Credentials: _____ %: _____
Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: Mimi Deng

Business Name: Sora Health LLC

Business Address: 6628 Sky Pointe Dr Suite 100 Room 113

City: Las Vegas State: NV Zip: 89131

Telephone: 877-869-0608 Email: mimi@mysorahealth.com

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

mimi deng

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

02/11/26

Date

Board Use Only	Date Received: 2/18/26	Amount: $500 ck 4729

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 08/26/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATIONIS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
360 INSURANCE 53601552 6628 SKY POINTE DR SUITE 119 LAS VEGAS NV 89131	PHONE (A/C, No, Ext): (702) 251-4000	FAX (A/C, No): (702) 800-4634
	E-MAIL ADDRESS:	
	INSURER(S) AFFORDING COVERAGE	NAIC#
	INSURER A : Property and Casualty Insurance Company of Hartford	34690
INSURED SORA HEALTH LLC 6628 SKY POINTE DR SUITE 100 ROOM 113 LAS VEGAS NV 89131-4070	INSURER B :	
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSR	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR [X] General Liability GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:	X		53 SBM BV5NK0	09/01/2025	09/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $1,000,000 $10,000 $1,000,000 $2,000,000 Excluded
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] ALL OWNED AUTOS [ ] HIRED AUTOS [ ] SCHEDULED AUTOS [ ] NON-OWNED AUTOS						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $						EACH OCCURRENCE AGGREGATE	
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) [ ] Y/N N/A If yes, describe under DESCRIPTION OF OPERATIONS below						[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE -EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	
A	Employment Practices Liability Insurance			53 SBM BV5NK0	09/01/2025	09/01/2026	Each Claim Limit Annual Aggregate Limit	$25,000 $25,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Those usual to the Insured's Operations. Notice of Cancellation will be provided in accordance with Form SL9013, attached to this policy. Certificate holder is an additional insured per the Additional Insured - Designated Person Or Organization Form SL3042 attached to this policy. RE: 6628 Sky Pointe Dr Suite 113, Las Vegas, NV 89131.

CERTIFICATE HOLDER	CANCELLATION
2617 Lamb LLC & MDL Group 5960 S JONES BLVD LAS VEGAS NV 89118-2610	SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS. AUTHORIZED REPRESENTATIVE Susan L. Castaneda

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CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Sora Health LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 06/30/2025, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 01/30/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202601306455216
You may verify this certificate online at

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Sora Health LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 6628 Sky Pointe Dr Suite 100 Room 113

City Las Vegas State NV Zip 89131

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (877) 869 - 0608 Website www.mysorahealth.com

Licensing Company Email mimi@mysorahealth.com

Section 2: Personal Information

First Mimi Middle _____ Last Deng

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email mimi@mysorahealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of California, San Diego		08/14 - 06/18	
Address	**City**	**State**	**Zip**
9500 Gilman Dr	La Jolla	CA	92093
Diploma/Degree obtained, if any			
Bachelor of Science, Biochemistry and Cell Biology			

School Name		From - To (MM/YY – MM/YY)	
Walnut High School		08/10 - 06/14	
Address	**City**	**State**	**Zip**
400 Pierre Rd	Walnut	CA	91789
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/24 - Current	[redacted]	Las Vegas	NV	[redacted]
03/23 - 06/24		Monterey Park	CA	
03/22 - 03/23		Los Angeles	CA	
12/20 - 03/22		Los Angeles	CA	
06/19 - 12/20		San Diego	CA	
06/18 - 06/19		San Diego	CA	
06/16 - 06/18		San Diego	CA	
06/15 - 06/16		San Diego	CA	
08/14 - 06/15		La Jolla	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
DME Service Solutions		10/24 - Current	
Business Address	**City**	**State**	**Zip**
402 W Broadway Suite 400	San Diego	CA	92101
Phone	**Title**		
760-518-1330	Senior Account Manager		

Description of Duties

I support the company by being the main point of contact for existing clients with the goal of growing the business.

Business Name		From - To (MM/YY – MM/YY)	
Dexcom		07/18 - 06/24	
Business Address	**City**	**State**	**Zip**
6340 Sequence Dr	San Diego	CA	92121
Phone	**Title**		
888-738-3646	Territory Business Manager; Inside Sales Representative		

Description of Duties

Dexcom is a medical products manufacturer. I spent 3 years selling Dexcom to patients over the phone, and I spent anotehr 3 years selling the product to providers, pharmacies, and hospital systems.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mimi, Deng

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/31/26

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, mimi deng, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01/31/26

Date

Subscribed and Sworn to before me this 31st day of January, 2026

Notary Public Signature

CRAIG THOMAS MORRIS
Notary Public State of Nevada
County of Clark
APPT NO. 22-2647-01
My App. Expires Mar 17 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Sora Health LLC MDEG License # (if applicable) _____

Physical Address 6628 Sky Pointe Dr Suite 100 Room 113

City Las Vegas State NV Zip 89131

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (877) 869-0608 Website www.mysorahealth.com

Licensing Company Email mimi@mysorahealth.com

Section 2: Personal Information

First Mimi Middle _____ Last Deng

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email mimi@mysorahealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of California, San Diego			08/14 - 06/18	
Address		City	State	Zip
9500 Gilman Dr		La Jolla	CA	92092
Diploma/Degree obtained, if any				
Bachelor of Science, Biochemistry and Cell Biology				
School Name			From - To (MM/YY – MM/YY)	
Walnut High School			08/10 - 06/14	
Address		City	State	Zip
400 Pierre Rd		Walnut	CA	91789
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/24 - Current	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)		City	State	
03/23 - 06/24		Monterey Park	CA	
From - To (MM/YY – MM/YY)		City	State	
03/22 - 03/23		Los Angeles	CA	
From - To (MM/YY – MM/YY)		City	State	
12/20 - 03/22		Los Angeles	CA	
From - To (MM/YY – MM/YY)		City	State	
06/19 - 12/20		San Diego	CA	
From - To (MM/YY – MM/YY)		City	State	
06/18 - 06/19		San Diego	CA	
From - To (MM/YY – MM/YY)		City	State	
06/16 - 06/18		San Diego	CA	
From - To (MM/YY – MM/YY)		City	State	
06/15 - 06/16		San Diego	CA	
From - To (MM/YY – MM/YY)		City	State	
08/14 - 06/15		La Jolla	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Dexcom			07/18 - 06/24
Business Address	**City**	**State**	**Zip**
6340 Sequence Dr	San Diego	CA	92121
Phone	**Title**		**Number of Employed Hours**
888-738-3646	Territory Business Manager; Inside Sales Representative		12,520

Description of Duties

Dexcom is a medical device manufacturer. I sold Dexcom to patients for 3 years, and I spent another 3 years selling the product to providers, pharmacies, and hospital systems. We will be selling Dexcom's CGM device at Sora Health.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) _____ Date _____

I, Mimi Deng, **certify that as the MDEG Administrator for**

Sora Health LLC,

that I (initial that you have read and meet the following requirements):

1. MD Have a high school diploma or its equivalent;
2. MD Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MD Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MD Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

mimi deng

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/11/26

Date

Board Use Only	Date Received: 2/18/26

7D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☑ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☑ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☑ Ownership Change*		☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*	M P01363	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*		☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: SuperCare Health

MDEG Physical Address: 6380 South Valley View Blvd Suite 120

City: Las Vegas State: NV Zip: 89118

Mailing Address (if different from physical address): 16017 Valley Blvd

City: City of Industry State: CA Zip: 91744

Telephone: 800-206-4880 Website: https://supercarehealth.com

Email: compliance@excellere.com

Name of MDEG Administrator (NAC 639.694): Tracy Lee Thorpe

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
☑ Patients by prescriptions	☑ Medical Gases**
☐ Pharmacies[a]	☑ Respiratory Equipment**
☐ Practitioners[a]	☑ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Rosette Sandoval, RT
	Telephone: 725-272-0524

Document Ref: WAAOJ-52UCY-VBNME-FMRIK

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9:30am - 5pm	■ Tue: 9:30am - 5pm	■ Wed: 9:30am - 5pm	■ Thurs: 9:30am - 5pm	■ Fri: 9:30am - 5pm
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare: 0261110001, 0261110002, 0282800001, 0282800004, 0282800005, 0282800006, 0282800007, 0282800008,
0282800009, 0282800010, 0282800011, 0282800013, 0282800014, 0282800015, 0282800016, 7071350001
Medicaid: Arizona: 085080, Washington: 2175527, California: 3736735, New Mexico: 47333251, Nevada: 100545354,
Oregon: 500787027

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Document Ref: WAAOJ-52UCY-VBNME-FMRIK

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): Aether Acquistion, LLC

Corporation/Organization Name: Super Care, LLC

Mailing Address: 3033 E. 1st Ave. Suite 700

City: Denver State: CO Zip: 80206

Telephone: 303-765-2400 Email: compliance@excellere.com

Contact Person Name: Alison Vratil

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Document Ref: WAAOJ-52UCY-VBNME-FMRIK

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Cassar

Print Name of Authorized Person Submitting Application

John Cassar

Original signature of Authorized Person (copies or stamps not accepted)

01 / 09 / 2026

Date

Board Use Only	Date Received: 1/12/26	Amount: $500 CK 1000007525

CERTIFICATE *of* SIGNATURE

REF. NUMBER
WAAOJ-52UCY-VBNME-FMRIK

DOCUMENT COMPLETED BY ALL PARTIES ON
09 JAN 2026 23:55:31
UTC

SIGNER	TIMESTAMP	SIGNATURE
JOHN CASSAR EMAIL JOHNC@SUPERCARE.COM	SENT 09 JAN 2026 22:32:22 VIEWED 09 JAN 2026 23:54:49 SIGNED 09 JAN 2026 23:55:31	 IP ADDRESS [redacted] LOCATION RIVERSIDE, UNITED STATES

RECIPIENT VERIFICATION

EMAIL VERIFIED
09 JAN 2026 23:54:49

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	SUPER CARE, LLC
Entity No.:	1294600
Registration Date:	12/20/1985
Entity Type:	Limited Liability Company - CA
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of February 27, 2026.

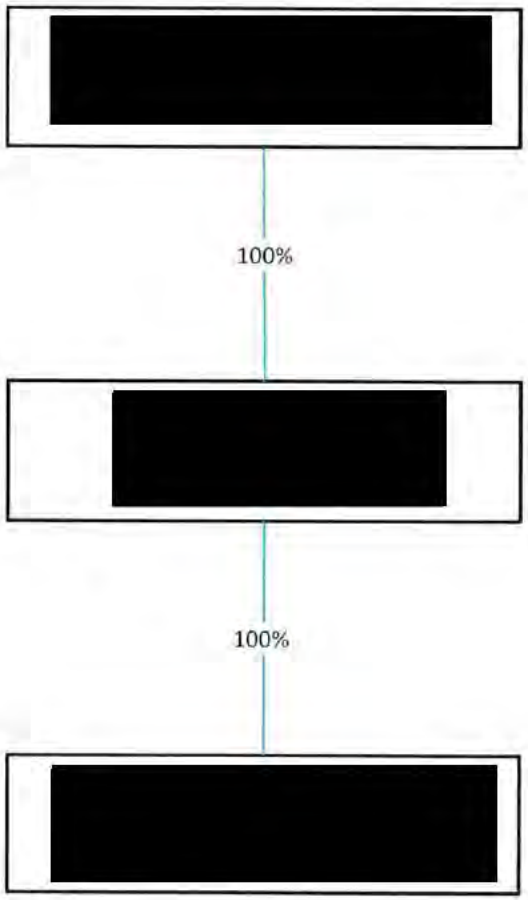
SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 427657836

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

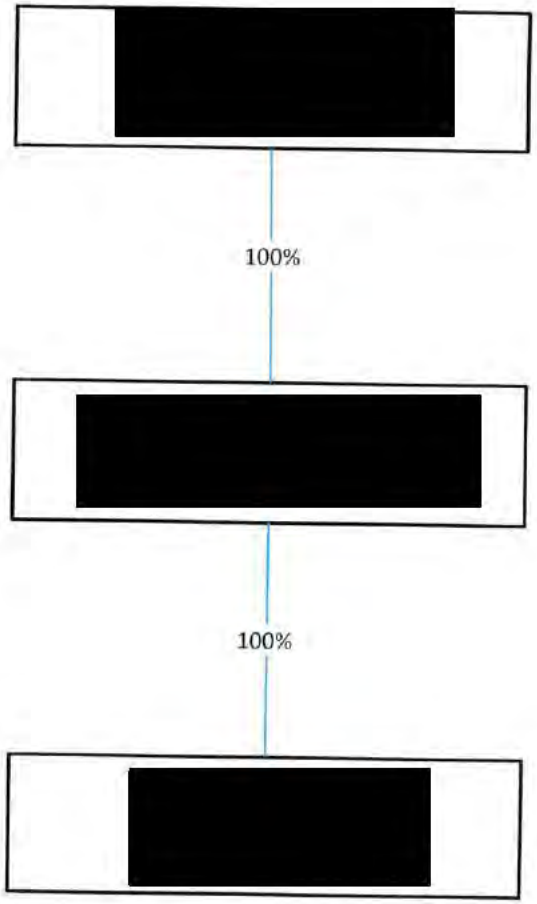
Super Care, Inc. DBA SuperCare Health
Entity Structure (Pre-transaction)

Proprietary and Confidential
Not a public record pursuant to
45 CFR Section 5.31.



SuperCare Health Entity Structure
(Post-transaction)

Proprietary and Confidential
Not a public record pursuant to
45 CFR Section 5.31



CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 1/6/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER ISU Vansa Insurance Services 818-763-9365 710 S Myrtle Ave 511 Monrovia CA 91016-3423 License#: 0B23558	**CONTACT NAME:** Melisa Nusbaum **PHONE (A/C, No, Ext):** 818-763-9365 **FAX (A/C, No):** 818-762-2242 **E-MAIL ADDRESS:** melisan@isuvansa.com
INSURED SuperCare, Inc. 16017 Valley Blvd. City Of Industry CA 91744 SUPEINC-01	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Pharmacists Mutual Insurance — 13714 **INSURER B :** **INSURER C :** **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** 450646173 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC OTHER:	Y	Y	VST0010391 00	1/1/2026	1/1/2027	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 250,000 $ 5,000 $ 1,000,000 $ 3,000,000 $ 2,000,000 $
A	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY [X] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			CAM0006254 01	1/1/2026	1/1/2027	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ 1,000,000 $ $ $ $
A	X UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED [X] RETENTION $ 10,000			UCL0162011 07	1/1/2026	1/1/2027	EACH OCCURRENCE AGGREGATE $	$ 5,000,000 $ 5,000,000 $
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		WCC0161914 01	1/1/2026	1/1/2027	X PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
A	PHARMACY PROFESSIONAL LIABILITY SUPPLMENTAL HEALTHCARE SERVICES			PSP0167224 00	1/1/2026	1/1/2027	EACH OCCURRANCE AGGREGATE RX PRODUCTS	1,000,000 3,000,000 INCLUDED

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

SUPERCARE, INC. LIST OF LOCATIONS: 16017 Valley Blvd, City of Industry, CA 91744 1960 Chicago Ave. Ste E5, Riverside, CA 92507 12176 Industrial Blvd., Ste 4, Victorville, CA 92395-5879 505 Watt Dr., Ste 3, Fairfield, CA 94534 1107 Kansas Ave., Modesto, CA 95351 399 Business Park Ct, Ste 403, Windsor, CA 95492 1637 E. Del Amo Blvd., Carson, CA 90746 14371 Franklin Ave., Tustin, CA 92780 1001 Pecten Ct., Milpitas, CA 95035 1121 Kansas Ave., Modesto, CA 95351 3333 Sunrise Blvd., Ste. J, Rancho Cordova, CA 95742 7243 Engineer Rd. Ste. E, San Diego, CA 92111-1437 2320 Del Monte Ave. Bldg B1, Monterey, CA 93940 870 E. Research Dr. Unit 12, Palm Springs, CA 92262 3335 Pegasus Dr., Ste 308, Bakersfield, CA 93308 710 Ruberta Ave., Glendale, CA 91201 9420 San Mateo NE Ste C, Albuquerque, NM 87113 380 Freeport Blvd, Ste 23, Sparks, NV 89431 3702 E. Roeser Rd., Ste. #7, Phoenix, AZ 85040-9047 6200 Stainless Way, Unit H, Anderson, CA 96007 4175 W. Sierra Madre Ave., Ste. #104, Fresno, CA 93722 5757 Olivas Dr., St. D, Ventura, CA 93003 6380 S. Valley View Blvd., Suites 120 & 122, Las Vegas, NV 89118

CERTIFICATE HOLDER

NPWest
PO Box 100142
Columbia SC 29202

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Melisa Nusbaum

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Super Care, LLC		
Officer List		
Name	**Title**	**Address**
John Cassar	Chief Executive Officer	[redacted]
Michael Geldart	Vice President	

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: SuperCare Health — MDEG License # (if applicable): MP01363

Physical Address: 6380 S Valley View Blvd, Suite 120

City: Las Vegas — State: NV — Zip: 89118

Mailing Address (if different from physical address): 16017 Valley Blvd

City: City of Industry — State: CA — Zip: 91744

Telephone: 800-206-4880 — Website: https://supercarehealth.com

Licensing Company Email: compliance@excellere.com

Section 2: Personal Information

First: Tracy — Middle: Lee — Last: Thorpe

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Henderson — State: NV — Zip: [redacted]

Telephone: [redacted] — Email: tthorpe@supercare.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
King River Community College		08/91 - 05/94	
Address	**City**	**State**	**Zip**
Unknown	Madera	CA	Unknown
Diploma/Degree obtained, if any			
No Degree			

School Name		From - To (MM/YY – MM/YY)	
Madera High School		09/86 - 06/89	
Address	**City**	**State**	**Zip**
200 L Street	Madera	CA	93637
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
More than 10 years	[redacted]	Henderson	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Document Ref: D72E8-PZ77V-PRZLV-RBWHX

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: SuperCare Health			From - To (MM/YY – MM/YY): 02/16 to present
Business Address: 6380 S Valley View Blvd., Suite 120	City: Las Vegas	State: NV	Zip: 89118
Phone: 800-206-4880	Title: Respiratory Account Executive		Number of Employed Hours: 18,720 hours
Description of Duties: Daily Operations, physician education and sales.			

Business Name: Synergy Sleep & Respiratory			From - To (MM/YY – MM/YY): 7/14 to 1/16
Business Address: 6340 McLeod Dr.	City: Las Vegas	State: NV	Zip: 89120
Phone: 661-589-6800	Title: Account Manager		Number of Employed Hours: 40 hours per week
Description of Duties: Daily Operations, physician education and sales.			

Business Name: N/A			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name: N/A			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name: N/A			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Continue on next page if additional space is needed.

Document Ref: D72E8-PZ77V-PRZLV-RBWHX

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Document Ref: D72E8-PZ77V-PRZLV-RBWHX

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Tracy Thorpe

Original Signature (electronic, copies or stamps not accepted)

01 / 09 / 2026

Date

Document Ref: D72E8-PZ77V-PRZLV-RBWHX

I, Tracy Lee Thorpe, **certify that as the MDEG Administrator for**

SuperCare Health,

that I (initial that you have read and meet the following requirements):

1. T.T. Have a high school diploma or its equivalent;
2. T.T. Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. T.T. Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. T.T. Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tracy Lee Thorpe
Print Name (First, Last)

Tracy Thorpe
Original Signature (electronic, copies or stamps not accepted)

01 / 09 / 2026
Date

Board Use Only	Date Received: 1/12/26

Document Ref: D72E8-PZ77V-PRZLV-RBWHX

CERTIFICATE *of* SIGNATURE

REF. NUMBER
D72E8-PZ77V-PRZLV-RBWHX

DOCUMENT COMPLETED BY ALL PARTIES ON
09 JAN 2026 21:55:08
UTC

SIGNER	TIMESTAMP	SIGNATURE
TRACY THORPE EMAIL TTHORPE@SUPERCARE.COM	SENT 09 JAN 2026 21:48:36 VIEWED 09 JAN 2026 21:52:17 SIGNED 09 JAN 2026 21:55:08	Tracy Thorpe IP ADDRESS [redacted]

RECIPIENT VERIFICATION

EMAIL VERIFIED
09 JAN 2026 21:52:17

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Super Care, LLC dba SuperCare Health

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MP01363

Physical Address: 6380 So. Valley View Blvd, Ste 120

City: Las Vegas State: NV Zip: 89118

Mailing Address (if different from physical address): 16017 Valley Blvd

City: City of Industry State: CA Zip: 91744

Telephone: (800) 206-4880 Website: https://supercarehealth.com/

Licensing Company Email: compliance@excellere.com

Section 2: Personal Information

First: John Middle: Louis Last: Cassar

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Long Beach State: CA Zip: [redacted]

Telephone: [redacted] Email: johnc@supercare.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	NA	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Loyola Marymount University		08/84 to 06/88	
Address	**City**	**State**	**Zip**
1 Loyola Marymount University Dr	Los Angeles	CA	90045
Diploma/Degree obtained, if any			
Bachelor Associates of Business			

School Name		From - To (MM/YY – MM/YY)	
Los Altos High School		09/80 to 06/84	
Address	**City**	**State**	**Zip**
15325 Los Robles Ave	Hacienda Heights	CA	91745
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/22 to Present	[redacted]	Long Beach	CA	[redacted]
09/02 to 02/22		Long Beach	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Super Care Health			2008- Present	
Business Address	**City**		**State**	**Zip**
16017 Valley Blvd	City of Industry		CA	91744
Phone	**Title**			
800-206-4880	Chief Executive Officer			
Description of Duties				
Oversee the growth and direction of the company.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	NA	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4-6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	2/4/2015	CA	Sacramento	Sacramento

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
AC201200456600	California Board of Pharmacy

Reason/Charge
See below.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
Super Care, Inc. dba SuperCare

Provide explanation below:

On February 4, 2015, SuperCare's pharmacy license number PHY 45943 was placed on probation by the California Board of Pharmacy for a period of five years as a result of the Stipulated Settlement and Disciplinary Order dated January 28, 2015, for:

1. Failure to Maintain Compounding Training Documentation;
2. Misbranded Drugs;
3. Failure to Complete Self-Assessment;
4. Failure to Maintain Records for Compounded Products;
5. Failure to Maintain Compounding Policies and Procedures;
6. Failure to Maintain Licensed Employee Policies and Procedures;
7. Failure to Maintain Facilities and Equipment Records;
8. Failure to Maintain Compounding Quality Assurance Plan;
9. Unprofessional Conduct: Act of Moral Turpitude, Dishonesty, Fraud, Deceit, Corruption;
10. Unprofessional Conduct: False Document/Misrepresentation;
11. Failure to Maintain Security of Dangerous Drugs;
12. Failure to Maintain Operational Standards and Security;
13. Failure to Maintain Operations Policy During Pharmacist Absence;
14. Failure to Maintain Proper Records of Compounded Drug Products/Supervision;
15. Failure to Ensure Compounding Limitations and Requirements;
16. Dispensing/Sale of Expired Drug;
17. Failure to Include Expiration Date on Labels;
18. Purchase of Dangerous Drugs from Unlicensed Entity;
19. Embargoed Misbranded Dangerous Drugs;
20. Failure to Maintain Facility and Equipment Standards; and
21. Drugs Lacking Quality and Strength.

The probation was successfully completed, effective February 7, 2020, and SuperCare's pharmacy license was fully restored.

Original Signature (electronic, copies or stamps not accepted)

01/06/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Cassar

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/06/2026

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

See Attached Certificate

Notary Public Signature

(Seal)

JURAT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of LOS ANGELES

Subscribed and sworn to (or affirmed) before me on this 6 day of JANUARY,

20 26 by JOHN LOUIS CASSAR,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature (Seal)

ANN MARIE PROVENCIO
COMM. #2431299
Notary Public - California
Orange County
My Comm. Expires Dec. 17, 2026

OPTIONAL INFORMATION

DESCRIPTION OF THE ATTACHED DOCUMENT

PERSONAL HISTORY
(Title or description of attached document)

APPLICATION
(Title or description of attached document continued)

Number of Pages 7 Document Date 1/6/2026

Additional information

INSTRUCTIONS

The wording of all Jurats completed in California after January 1, 2015 must be in the form as set forth within this Jurat. There are no exceptions. If a Jurat to be completed does not follow this form, the notary must correct the verbiage by using a jurat stamp containing the correct wording or attaching a separate jurat form such as this one with does contain the proper wording. In addition, the notary must require an oath or affirmation from the document signer regarding the truthfulness of the contents of the document. The document must be signed AFTER the oath or affirmation. If the document was previously signed, it must be re-signed in front of the notary public during the jurat process.

- State and county information must be the state and county where the document signer(s) personally appeared before the notary public.
- Date of notarization must be the date the signer(s) personally appeared which must also be the same date the jurat process is completed.
- Print the name(s) of the document signer(s) who personally appear at the time of notarization.
- Signature of the notary public must match the signature on file with the office of the county clerk.
- The notary seal impression must be clear and photographically reproducible. Impression must not cover text or lines. If seal impression smudges, re-seal if a sufficient area permits, otherwise complete a different jurat form.
  - Additional information Is not required but could help to ensure this jurat is not misused or attached to a different document.
  - Indicate title or type of attached document, number of pages and date.
- Securely attach this document to the signed document with a staple.

www.NotaryClasses.com 800-873-9865

Disciplinary Questions, Statement of Explanation

Any lawsuit or arbitration, as either a claimant or respondent, that I have been party to as an individual, owner, director, or officer of a corporation, has not been in relation to the practice of pharmacy.

The following California Board of Pharmacy disciplinary action occurred while I was an officer of Super Care, Inc.

Super Care, Inc. dba SuperCare
16017 Valley Blvd
City of Industry, CA 91745

On February 4, 2015, SuperCare's pharmacy license number PHY 45943 was placed on probation by the California Board of Pharmacy for a period of five years as a result of the Stipulated Settlement and Disciplinary Order dated January 28, 2015, for:

1. Failure to Maintain Compounding Training Documentation;
2. Misbranded Drugs;
3. Failure to Complete Self-Assessment;
4. Failure to Maintain Records for Compounded Products;
5. Failure to Maintain Compounding Policies and Procedures;
6. Failure to Maintain Licensed Employee Policies and Procedures;
7. Failure to Maintain Facilities and Equipment Records;
8. Failure to Maintain Compounding Quality Assurance Plan;
9. Unprofessional Conduct: Act of Moral Turpitude, Dishonesty, Fraud, Deceit, Corruption;
10. Unprofessional Conduct: False Document/Misrepresentation;
11. Failure to Maintain Security of Dangerous Drugs;
12. Failure to Maintain Operational Standards and Security;
13. Failure to Maintain Operations Policy During Pharmacist Absence;
14. Failure to Maintain Proper Records of Compounded Drug Products/Supervision;
15. Failure to Ensure Compounding Limitations and Requirements;
16. Dispensing/Sale of Expired Drug;
17. Failure to Include Expiration Date on Labels;
18. Purchase of Dangerous Drugs from Unlicensed Entity;
19. Embargoed Misbranded Dangerous Drugs;
20. Failure to Maintain Facility and Equipment Standards; and
21. Drugs Lacking Quality and Strength.

The probation was successfully completed, effective February 7, 2020, and SuperCare's pharmacy license was fully restored.

I hereby affirm that the above information is true and correct to the best of my knowledge.

John Cassar

Signature

01 / 09 / 2026

Date

John Cassar
Chief Executive Officer, Super Care, LLC

CERTIFICATE *of* SIGNATURE

REF. NUMBER
RPX8J-JQESZ-NPA4Y-NAOTP

DOCUMENT COMPLETED BY ALL PARTIES ON
09 JAN 2026 21:32:05
UTC

SIGNER	TIMESTAMP	SIGNATURE
JOHN CASSAR EMAIL JOHNC@SUPERCARE.COM	SENT 09 JAN 2026 18:18:50 VIEWED 09 JAN 2026 21:31:50 SIGNED 09 JAN 2026 21:32:05	 IP ADDRESS [redacted] LOCATION RIVERSIDE, UNITED STATES

RECIPIENT VERIFICATION

EMAIL VERIFIED
09 JAN 2026 21:31:50

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 10, 2020

RECEIVED
FEB 13 2020
By

Supercare
Attention PIC
16017 Valley Blvd
City of Industry, CA 91745
RE: AC 4566

Dear PIC:

This letter is in regard to the above referenced administrative case and the status of the pharmacy license for Supercare, PHY 45943. Effective February 4, 2015 the pharmacy license was placed on probation for a period of five years with certain terms and conditions.

The Board is pleased to inform you that, upon review of the terms and conditions of your probation, probation has been successfully completed, effective February 7, 2020. Therefore, the probationary period has been terminated and the pharmacy license has been fully restored.

Please be advised that this disciplinary action will remain as part of your license history, which is public information.

If you have any questions, please do not hesitate to contact your probation analyst at (916) 518-3026.

Sincerely,

ANNE SODERGREN
Executive Officer

By

Autumn Ammann
Probation Analyst

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **SUPER CARE, INC. DBA SUPERCARE** **Gabriel Cassar, President;** **Michelline Cassar, Chief Executive Officer;** **John L. Cassar, Vice President;** **Michael Cassar, Shareholder** **Permit No. PHY 45943** **GABRIEL JOHN CASSAR, AKA** **GABRIEL CASSAR** **Pharmacist License No. RPH 25650** **KATHERINE THU LE, AKA** **KATHERINE LE** **Pharmacist-in-Charge** **Pharmacist License No. 57903** **TUAN KIEU NGUYEN** **Pharmacy Technician Registration** **No. TCH 89616** Respondents.	Case No. 4566 OAH No. 2014030278 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER** As to: **SUPER CARE, INC. DBA SUPERCARE, PERMIT No. PHY 45943**

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on February 4, 2015.

It is so ORDERED on January 28, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STAN C. WEISSER, Board President

KAMALA D. HARRIS
Attorney General of California
ARMANDO ZAMBRANO
Supervising Deputy Attorney General
LINDA L. SUN
Deputy Attorney General
State Bar No. 207108
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-6375
Facsimile: (213) 897-2804
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **SUPER CARE, INC. DBA SUPERCARE** **Gabriel Cassar, President;** **Micheline Cassar, Chief Executive Officer;** **John L. Cassar, Vice President;** **Michael Cassar, Shareholder** **16017 Valley Blvd.** **City of Industry, CA 91745** **Permit No. PHY 45943** **GABRIEL JOHN CASSAR, AKA** **GABRIEL CASSAR** **16017 Valley Blvd.** **City of Industry, CA 91745** **Pharmacist License No. RPH 25650** **KATHERINE THU LE, AKA** **KATHERINE LE** **Pharmacist-in-Charge** [redacted] **Rosemead, CA** [redacted] **Pharmacist License No. RPH 57903** **TUAN KIEU NGUYEN** [redacted] **Rowland Heights, CA** [redacted] **Pharmacy Technician Registration No. TCH 89616** Respondents.	Case No. 4566 OAH No. 2014030278 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER** **As to: SUPER CARE, INC. DBA SUPERCARE, Permit No. PHY 45943**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy ("Board"). She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Linda L. Sun, Deputy Attorney General.

2. Respondent Super Care, Inc..dba Supercare; Gabriel Cassar, President; Micheline Cassar, Chief Executive Officer; John L. Cassar, Vice President; Michael Cassar, Shareholder; Katherine Le, Pharmacist-in-Charge (collectively "Respondent Pharmacy" or "Respondent") is represented in this proceeding by attorney Tony J. Park, Esq., whose address is: [redacted] Irvine, CA [redacted]

3. On or about July 23, 2002, the Board issued Permit Number PHY 45943 to Respondent Pharmacy. The Permit was in full force and effect at all times relevant to the charges brought herein and will expire on July 1, 2015, unless renewed.

JURISDICTION

4. Accusation No. 4566 was filed before the Board and is currently pending against Respondent Pharmacy. The Accusation and all other statutorily required documents were properly served on Respondent Pharmacy on January 29, 2014. Respondent Pharmacy timely filed its Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 4566 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent Pharmacy has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 4566. Respondent Pharmacy has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent Pharmacy is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent Pharmacy voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent Pharmacy admits the truth of each and every charge and allegation in Accusation No. 4566.

10. Respondent Pharmacy agrees that its Permit is subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent Pharmacy understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent Pharmacy understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Permit No. PHY 45943 issued to Respondent Pharmacy is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

1. **Obey All Laws**

Respondent Owner shall obey all state and federal laws and regulations.

Respondent Owner shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:

- ☐ an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- ☐ a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
- ☐ a conviction of any crime
- ☐ discipline, citation, or other administrative action filed by any state or federal agency which involves Respondent Pharmacy's permit or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent Owner shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent Owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent Owner shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent Owner shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent Pharmacy's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent Owner shall pay to the Board its costs of investigation and prosecution in the amount of $6,310.80 (six thousand three hundred ten dollars and eighty cents). The costs may be paid on a payment plan approved by the Board. There shall be no deviation from the payment plan schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by Respondent Owner shall not relieve Respondent Pharmacy of their responsibility to reimburse the Board its costs of investigation and prosecution.

6. **Probation Monitoring Costs**

Respondent Owner shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. **Status of License**

Respondent Owner shall, at all times while on probation, maintain current licensure with the Board. If Respondent Owner submits an application to the Board, and the application is approved, for a change of location, change of permit or change of ownership, the Board shall retain continuing jurisdiction over the license, and Respondent shall remain on probation as determined by the Board. Failure to maintain current licensure shall be considered a violation of probation.

If Respondent Owner's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication Respondent Owner's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent Owner discontinue business, Respondent Owner may tender the premise's license to the Board for surrender. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, Respondent Owner shall relinquish the premises wall and renewal license to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent Owner shall further submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer.

///

Respondent Owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the Respondent Pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent Owner shall provide a copy of the written notice to the Board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent Owner may not apply for any new licensure from the Board for three (3) years from the effective date of the surrender. Respondent Owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board.

Respondent Owner further stipulates that he or she shall reimburse the Board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. **Notice to Employees**

Respondent Owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent Owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, Respondent Owner shall submit written notification to the Board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the Board shall be considered a violation of probation.

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"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. **Owners and Officers: Knowledge of the Law**

Respondent Owner shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in Respondent Pharmacy or Respondent Pharmacy's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. **Posted Notice of Probation**

Respondent Owner shall prominently post a probation notice provided by the Board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent Owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. **Violation of Probation**

If Respondent Owner has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent Pharmacy's license, and probation shall be automatically extended until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If Respondent Owner violates probation in any respect, the Board, after giving Respondent Owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary

order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against Respondent Pharmacy during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

13. **Completion of Probation**

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent Pharmacy's license will be fully restored.

14. **Community Services Program**

Within sixty (60) days of the effective date of this decision, Respondent Owner shall submit to the Board or its designee, for prior approval, a community service program in which Respondent shall provide free brown-bag events to the community for at least twenty (20) days per year for the first two (2) years of probation.

Within thirty (30) days of Board approval thereof, Respondent Owner shall submit documentation to the Board demonstrating commencement of the community service program. Respondent Owner shall report on progress with the community service program in the quarterly reports.

Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Tony J. Park, Esq.. I understand the stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12-9-2014

OWNER, SUPER CARE, INC. DBA SUPERCARE
Respondent

I have read and fully discussed with Respondent Super Care, Inc. dba Supercare; Gabriel Cassar; Micheline Cassar; John L. Cassar; Michael Cassar; Katherine Le; the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12/09/2014

Tony J. Park, Esq.
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated: 1/5/2015

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
ARMANDO ZAMBRANO
Supervising Deputy Attorney General

LINDA L. SUN
Deputy Attorney General
Attorneys for Complainant

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Super Care, LLC dba Super Care Health

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MP01363

Physical Address: [redacted] 6380 S VALLEY VIEW BLVD, SUITE 120

City: Las Vegas State: NV Zip: 89118

Mailing Address (if different from physical address): [redacted] 16017 VALLEY BLVD

City: CITY OF INDUSTRY State: CA Zip: 91744

Telephone: (800) 206-4880 Website: https://supercarehealth.com/

Licensing Company Email: compliance@excellere.com

Section 2: Personal Information

First: Michael Middle: David Donald Last: Geldart

Alias(es, nicknames, name changes, etc.): Mike

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Deland State: FL Zip: [redacted]

Telephone: [redacted] Email: mgeldart@excellere.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
UNIVERSITY OF SOUTH FLORIDA			08/83 - 12/85	
Address		City	State	Zip
4202 E. FOWLER AVE		TAMPA	FL	33620
Diploma/Degree obtained, if any				
BA CHEMISTRY				

School Name			From - To (MM/YY – MM/YY)	
SOUTH FLORIDA COLLEGE			08/81 - 05/83	
Address		City	State	Zip
600 W COLLEGE DR		AVON PARK	FL	33825
Diploma/Degree obtained, if any				
AA				

School Name			From - To (MM/YY – MM/YY)	
AVON PARK HIGH SCHOOL			08/77 - 05/80	
Address		City	State	Zip
700 E MAIN ST		AVON PARK	FL	33825
Diploma/Degree obtained, if any				
HIGH SCHOOL DIPLOMA				

School Name			From - To (MM/YY – MM/YY)	
~~N/A~~ UNIVERSITY OF SOUTH FLORIDA			01/15 - 12/16	
Address		City	State	Zip
4202 E FOWLER AVE		TAMPA	FL	33620
Diploma/Degree obtained, if any				
MASTER SCIENCE CYBER SECURITY				

School Name			From - To (MM/YY – MM/YY)	
~~N/A~~ STETSON UNIVERSITY COLLEGE OF LAW			01/86 - 12/88	
Address		City	State	Zip
1401 61st ST S		GULFPORT	FL	33707
Diploma/Degree obtained, if any				
JURIS DOCTORATE				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/16 - Present	[redacted]	Deland	FL	[redacted]
12/15 - 12/16		AVON PARK	FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Excellere Partners			From - To (MM/YY – MM/YY): 11/15 - Present
Business Address: 3033 E. 1st Ave. Suite 700	City: Denver	State: CO	Zip: 80206
Phone: 303-765-2400	Title: Partner, Chief Compliance Officer		
Description of Duties: Partner, Chief Compliance Officer of Excellere Partners, Private Equity			

Business Name: N/A			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name: N/A			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name: N/A			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name: N/A			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4-6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	2/3/2020	ME	Augusta	Kennebec
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2017-PHA-13671		Maine Board of Pharmacy		
Reason/Charge				
See below.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
N/A		N/A		
Name of Business/Industry/Entity				
Bond Pharmacy, Inc. dba Advanced Infusion Solutions				

Provide explanation below:

Consent agreement for administrative action based upon delay in reporting a change in pharmacist-in-charge along with a warning and civil penalty of $250 as the change was reported in seven business days rather than seven calendar days. Fine was paid and all states were notified upon receiving the fully executed order.

Original Signature (electronic, copies or stamps not accepted)

1/6/2026
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4-6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	2/3/2020	OH	Columbus	Franklin
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
A-2019-0158		Ohio Board of Pharmacy		
Reason/Charge				
See below.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
N/A		N/A		
Name of Business/Industry/Entity				
Bond Pharmacy, Inc. dba Advanced Infusion Solutions				

Provide explanation below:

Disciplinary action based upon an alleged single dispensing error which resulted in Advanced Infusion Solutions paying a monetary penalty of $1,500.00. Fine was paid and all states were notified upon receiving the fully executed order.

Original Signature (electronic, copies or stamps not accepted)

1/6/2020
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4-6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	8/20/2020	HI	Honolulu	Honolulu
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
PHA-2020-0040L		Hawaii Board of Pharmacy		
Reason/Charge				
See below.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
N/A		N/A		
Name of Business/Industry/Entity				
Bond Pharmacy, Inc. dba Advanced Infusion Solutions				

Provide explanation below:

Pre-petition settlement agreement which resulted in an administrative fine of $500.00. Based off Ohio allegations. Fine was paid and all states were notified prior to receiving the fully executed order.

Original Signature (electronic, copies or stamps not accepted)

1/6/2026
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4-6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	5/8/2021	AL	Birmingham	Jefferson
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
20-L-0026		Alabama Board of Pharmacy		
Reason/Charge				
See below.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
N/A		N/A		
Name of Business/Industry/Entity				
Bond Pharmacy, Inc. dba Advanced Infusion Solutions				

Provide explanation below:

Consent agreement which resulted in an administrative fine of $5000.00. Based on former matters. Fine was paid and all states were notified upon receiving the fully executed order.

Original Signature (electronic, copies or stamps not accepted)

1/6/2026
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4-6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	1/5/2022	PA	Harrisburg	Dauphin
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
20-54-002960		Pennsylvania Board of Pharmacy		
Reason/Charge				
See below.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
N/A		N/A		
Name of Business/Industry/Entity				
Bond Pharmacy, Inc. dba Advanced Infusion Solutions				

Provide explanation below:

Consent agreement and civil penalty of $750.00 was paid to the Pennsylvania board and all states were notified upon receiving the fully executed order.

Original Signature (electronic, copies or stamps not accepted)

1/6/2026
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 7-6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	5/15/2023	IL	Springfield	Sangamon
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2020-03088		Illinois Board of Pharmacy		
Reason/Charge				
See below.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
Bond Pharmacy, Inc. dba Advanced Infusion Solutions				

Provide explanation below:

Consent agreement was executed resulting in a reprimand of license and disciplinary fine of $1,500.00. Based on former matters. A fine was paid to the Illinois board and all states were notified upon receiving the fully executed order.

Original Signature (electronic, copies or stamps not accepted)

1/6/2026
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4-6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	4/30/2025	OH	Columbus	Franklin
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
A-2023-0119		Ohio Board of Pharmacy		
Reason/Charge				
See below.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
Bond Pharmacy, Inc. dba Advanced Infusion Solutions				

Provide explanation below:

Disciplinary action based upon an alleged single dispensing error that occurred in 2022 for which there is no definitive proof of fault. Advanced Infusion Solutions entered a settlement agreement and agreed to pay a monetary penalty of $8, 000.00. Fine was paid and all states were notified upon receiving the fully executed order.

Original Signature (electronic, copies or stamps not accepted)

1/6/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Geldart

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/6/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Colorado, ss. County of Denver

I, Michael Geldart, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/6/2026

Date

Subscribed and Sworn to before me this 16th day of January 2026

Jordan Amanda Day

Notary Public Signature

JORDAN AMANDA DAY
Notary Public
State of Colorado
Notary ID # 20254020880
My Commission Expires 06-05-2029

(Seal)

7E

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☑ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☑ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG ☑ Ownership Change* ☐ Name Change* ☐ Location Change*	* If making a change, provide current license number: M P03165	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: SuperCare Health

MDEG Physical Address: 380 Freeport Blvd Suite 23

City: Sparks State: NV Zip: 89431

Mailing Address (if different from physical address): 16017 Valley Blvd

City: City of Industry State: CA Zip: 91744

Telephone: 800-206-4880 Website: https://supercarehealth.com/

Email: compliance@excellere.com

Name of MDEG Administrator (NAC 639.694): Matthew Rotter

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
☑ Patients by prescriptions ☐ Pharmacies[a] ☐ Practitioners[a] ☐ Hospitals/Clinics[a] ☐ Clinics[a] ☐ Wholesalers[a] ☐ Other business entities (specify)[a]: This application is ONLY required if MDEG products will be sold to patients by prescription. [a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	☑ Medical Gases** ☑ Respiratory Equipment** ☑ Life-sustaining equipment** ☐ Parenteral and Enteral Equipment** ☐ Assistive Equipment ☐ Diabetic Supplies ☐ Orthotics and Prosthetics ☐ Others: **These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954): Name: Jennifer Ruiz, RT Telephone: 775-842-8942

Document Ref: YF8MK-HUZMX-UAIWC-WE2YW

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9:30am - 5pm	■ Tue: 9:30am - 5pm	■ Wed: 9:30am - 5pm	■ Thurs: 9:30am - 5pm	■ Fri: 9:30am - 5pm
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare: 0261110001, 0261110002, 0282800001, 0282800004, 0282800005, 0282800006, 0282800007, 0282800008,
0282800009, 0282800010, 0282800011, 0282800013, 0282800014, 0282800015, 0282800016, 7071350001
Medicaid: Arizona: 085080, Washington: 2175527, California: 3736735, New Mexico: 47333251, Nevada: 100545354,
Oregon: 500787027

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Document Ref: YF8MK-HUZMX-UAIWC-WE2YW

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): Aether Acquistion, LLC

Corporation/Organization Name: Super Care, LLC

Mailing Address: 3033 E. 1st Ave. Suite 700

City: Denver State: CO Zip: 80206

Telephone: 303-765-2400 Email: compliance@excellere.com

Contact Person Name: Alison Vratil

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Document Ref: YF8MK-HUZMX-UAIWC-WE2YW

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months.**	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Cassar

Print Name of Authorized Person Submitting Application

John Cassar

Original signature of Authorized Person (copies or stamps not accepted)

01 / 09 / 2026

Date

Board Use Only	Date Received: 1/12/26	Amount: $600 Ch 1000002523

Document Ref: YF8MK-HUZMX-UAIWC-WE2YW

CERTIFICATE *of* SIGNATURE

REF. NUMBER
YF8MK-HUZMX-UAIWC-WE2YW

DOCUMENT COMPLETED BY ALL PARTIES ON
10 JAN 2026 00:16:47
UTC

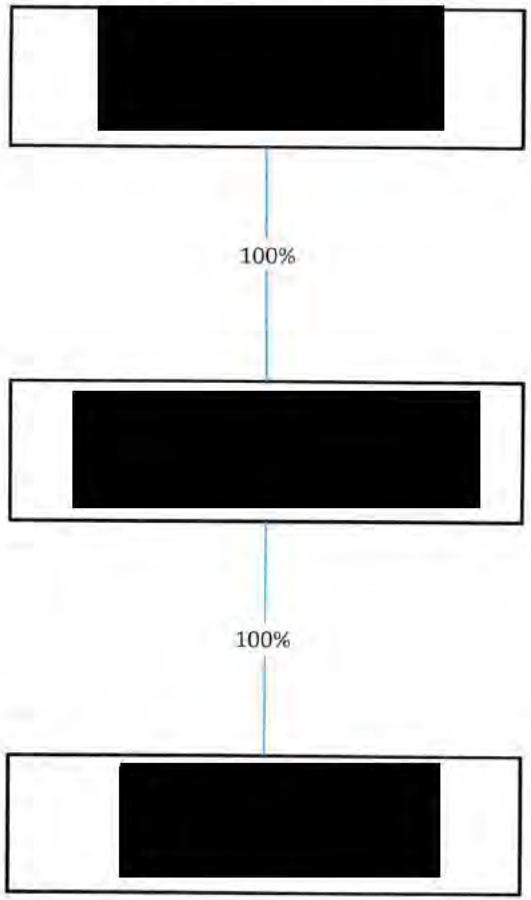
SIGNER	TIMESTAMP	SIGNATURE
JOHN CASSAR EMAIL JOHNC@SUPERCARE.COM	SENT 09 JAN 2026 22:32:01 VIEWED 10 JAN 2026 00:16:26 SIGNED 10 JAN 2026 00:16:47	 IP ADDRESS [redacted] LOCATION RIVERSIDE, UNITED STATES

RECIPIENT VERIFICATION

EMAIL VERIFIED
10 JAN 2026 00:16:26

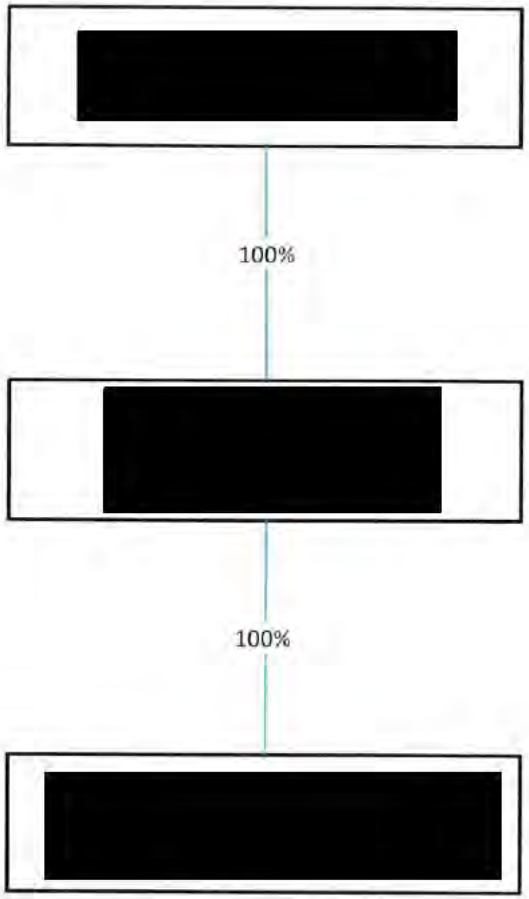
SuperCare Health Entity Structure
(Post-transaction)

Proprietary and Confidential
Not a public record pursuant to
45 CFR Section 5.31



Super Care, Inc. DBA SuperCare Health
Entity Structure (Pre-transaction)

Proprietary and Confidential
Not a public record pursuant to
45 CFR Section 5.31.



CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 1/6/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER ISU Vansa Insurance Services 818-763-9365 710 S Myrtle Ave 511 Monrovia CA 91016-3423 License#: 0B23558	CONTACT NAME: Melisa Nusbaum PHONE (A/C, No, Ext): 818-763-9365 FAX (A/C, No): 818-762-2242 E-MAIL ADDRESS: melisan@isuvansa.com
INSURED SuperCare, Inc. 16017 Valley Blvd. City Of Industry CA 91744 SUPEINC-01	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Pharmacists Mutual Insurance — 13714 INSURER B : INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 450646173 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:	Y	Y	VST0010391 00	1/1/2026	1/1/2027	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 250,000 $ 5,000 $ 1,000,000 $ 3,000,000 $ 2,000,000 $
A	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY X SCHEDULED AUTOS X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY			CAM0006254 01	1/1/2026	1/1/2027	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ 1,000,000 $ $ $ $
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $ 10,000			UCL0162011 07	1/1/2026	1/1/2027	EACH OCCURRENCE AGGREGATE $	$ 5,000,000 $ 5,000,000 $
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		WCC0161914 01	1/1/2026	1/1/2027	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
A	PHARMACY PROFESSIONAL LIABILITY SUPPLMENTAL HEALTHCARE SERVICES			PSP0167224 00	1/1/2026	1/1/2027	EACH OCCURRANCE AGGREGATE RX PRODUCTS	1,000,000 3,000,000 INCLUDED

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

SUPERCARE, INC. LIST OF LOCATIONS: 16017 Valley Blvd, City of Industry, CA 91744 1960 Chicago Ave. Ste E5, Riverside, CA 92507 12176 Industrial Blvd., Ste 4, Victorville, CA 92395-5879 505 Watt Dr., Ste 3, Fairfield, CA 94534 1107 Kansas Ave., Modesto, CA 95351 399 Business Park Ct, Ste 403, Windsor, CA 95492 1637 E. Del Amo Blvd., Carson, CA 90746 14371 Franklin Ave., Tustin, CA 92780 1001 Pecten Ct., Milpitas, CA 95035 1121 Kansas Ave., Modesto, CA 95351 3333 Sunrise Blvd., Ste. J, Rancho Cordova, CA 95742 7243 Engineer Rd. Ste. E, San Diego, CA 92111-1437 2320 Del Monte Ave. Bldg B1, Monterey, CA 93940 870 E. Research Dr. Unit 12, Palm Springs, CA 92262 3335 Pegasus Dr., Ste 308, Bakersfield, CA 93308 710 Ruberta Ave., Glendale, CA 91201 9420 San Mateo NE Ste C, Albuquerque, NM 87113 380 Freeport Blvd, Ste 23, Sparks, NV 89431 3702 E. Roeser Rd., Ste. #7, Phoenix, AZ 85040-9047 6200 Stainless Way, Unit H, Anderson, CA 96007 4175 W. Sierra Madre Ave., Ste. #104, Fresno, CA 93722 5757 Olivas Dr., St. D, Ventura, CA 93003 6380 S. Valley View Blvd., Suites 120 & 122, Las Vegas, NV 89118

CERTIFICATE HOLDER

NPWest
PO Box 100142
Columbia SC 29202

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Melisa Nusbaum

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Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	SUPER CARE, LLC
Entity No.:	1294600
Registration Date:	12/20/1985
Entity Type:	Limited Liability Company - CA
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of February 27, 2026.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 427657836

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

Super Care, LLC		
Officer List		
Name	**Title**	**Address**
John Cassar	Chief Executive Officer	[redacted]
Michael Geldart	Vice President	

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG SuperCare Health MDEG License # (if applicable) MP03165

Physical Address 380 Freeport Blvd Suite 23

City Sparks State NV Zip 89431

Mailing Address (if different from physical address) 16017 Valley Blvd

City City of Industry State CA Zip 91744

Telephone 800-206-4880 Website https://supercarehealth.com/

Licensing Company Email compliance@excellere.com

Section 2: Personal Information

First Matthew Middle _____ Last Rotter

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Reno State NV Zip [redacted]

Telephone [redacted] Email mrotter@supercare.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✓	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

Document Ref: ZKWBN-JBHBX-ECLJX-UCAPV

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Nevada Reno		08/90 - 07/93	
Address	**City**	**State**	**Zip**
164 N Virginia St	Reno	NV	89557
Diploma/Degree obtained, if any			
No Degree			

School Name		From - To (MM/YY – MM/YY)	
Incline High School		08/84 - 07/88	
Address	**City**	**State**	**Zip**
499 Village Blvd	Incline	NV	89451
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/09 to Present	[redacted]	Reno	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				

Document Ref: ZKWBN-JBHBX-ECLJX-UCAPV

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
SuperCare Health			09/25 to present	
Business Address		**City**	**State**	**Zip**
380 Freeport Blvd., Suite 23		Sparks	NV	89431
Phone	**Title**		**Number of Employed Hours**	
800-206-4880	Area Manager		600	
Description of Duties				
Daily operations, oversee the provision of medical equipment and the staff				

Business Name			From - To (MM/YY – MM/YY)	
Owens Healthcare			10/21 - 08/24	
Business Address		**City**	**State**	**Zip**
2600 Mill St., Suite 600		Reno	NV	89431
Phone	**Title**		**Number of Employed Hours**	
775-207-2727	Manager		5760 hours	
Description of Duties				
Managed medical supply company that provided oxygen, ventilators, home medical equipment set-up, and instructed patients on the use of all medical equipment.				

Business Name			From - To (MM/YY – MM/YY)	
Pulmonary Solutions			04/18 - 10/21	
Business Address		**City**	**State**	**Zip**
50 Freeport Blvd., #24		Sparks	NV	89431
Phone	**Title**		**Number of Employed Hours**	
855-881-2254	Manager		6960 hours	
Description of Duties				
Managed medical supply company that provided oxygen, ventilators, home medical equipment set-up, and instructed patients on the use of all medical equipment.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Document Ref: ZKWBN-JBHBX-ECLJX-UCAPV

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Document Ref: ZKWBN-JBHBX-ECLJX-UCAPV

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Matthew Rotter

Original Signature (electronic, copies or stamps not accepted)

01 / 09 / 2026

Date

Document Ref: ZKWBN-JBHBX-ECLJX-UCAPV

I, Matthew Rotter, **certify that as the MDEG Administrator for**

SuperCare Health,

that I (initial that you have read and meet the following requirements):

1. M.R. Have a high school diploma or its equivalent;
2. M.R. Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. M.R. Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. M.R. Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew Rotter

Print Name (First, Last)

Matthew Rotter

Original Signature (electronic, copies or stamps not accepted)

01 / 09 / 2026

Date

Board Use Only	Date Received: 1/12/26

Document Ref: ZKWBN-JBHBX-ECLJX-UCAPV

CERTIFICATE *of* SIGNATURE

REF. NUMBER
ZKWBN-JBHBX-ECLJX-UCAPV

DOCUMENT COMPLETED BY ALL PARTIES ON
09 JAN 2026 21:57:51
UTC

SIGNER	TIMESTAMP	SIGNATURE
MATTHEW ROTTER EMAIL MROTTER@SUPERCARE.COM	SENT 09 JAN 2026 21:49:14 VIEWED 09 JAN 2026 21:49:52 SIGNED 09 JAN 2026 21:57:51	Matthew Rotter IP ADDRESS [redacted] LOCATION RENO, UNITED STATES

RECIPIENT VERIFICATION

EMAIL VERIFIED
09 JAN 2026 21:49:52

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Super Care, LLC dba SuperCare Health

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MP03165

Physical Address: 380 Freeport Blvd Suite 23

City: Sparks State: NV Zip: 89431

Mailing Address (if different from physical address): 16017 Valley Blvd

City: City of Industry State: CA Zip: 91744

Telephone: (800) 206-4880 Website: https://supercarehealth.com/

Licensing Company Email: compliance@excellere.com

Section 2: Personal Information

First: John Middle: Louis Last: Cassar

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Long Beach State: CA Zip: [redacted]

Telephone: [redacted] Email: johnc@supercare.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	NA	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Loyola Marymount University		08/84 to 06/88	
Address	**City**	**State**	**Zip**
1 Loyola Marymount University Dr	Los Angeles	CA	90045
Diploma/Degree obtained, if any			
Bachelor Associates of Business			

School Name		From - To (MM/YY – MM/YY)	
Los Altos High School		09/80 to 06/84	
Address	**City**	**State**	**Zip**
15325 Los Robles Ave	Hacienda Heights	CA	91745
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/22 to Present	[redacted]	Long Beach	CA	[redacted]
09/02 to 02/22		Long Beach	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Super Care Health			2008- Present	
Business Address		**City**	**State**	**Zip**
16017 Valley Blvd		City of Industry	CA	91744
Phone	**Title**			
800-206-4880	Chief Executive Officer			
Description of Duties				
Oversee the growth and direction of the company.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	NA	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4-6 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	2/4/2015	CA	Sacramento	Sacramento
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
AC201200456600		California Board of Pharmacy		
Reason/Charge				
See below.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
Super Care, Inc. dba SuperCare				

Provide explanation below:

On February 4, 2015, SuperCare's pharmacy license number PHY 45943 was placed on probation by the California Board of Pharmacy for a period of five years as a result of the Stipulated Settlement and Disciplinary Order dated January 28, 2015, for:

1. Failure to Maintain Compounding Training Documentation;
2. Misbranded Drugs;
3. Failure to Complete Self-Assessment;
4. Failure to Maintain Records for Compounded Products;
5. Failure to Maintain Compounding Policies and Procedures;
6. Failure to Maintain Licensed Employee Policies and Procedures;
7. Failure to Maintain Facilities and Equipment Records;
8. Failure to Maintain Compounding Quality Assurance Plan;
9. Unprofessional Conduct: Act of Moral Turpitude, Dishonesty, Fraud, Deceit, Corruption;
10. Unprofessional Conduct: False Document/Misrepresentation;
11. Failure to Maintain Security of Dangerous Drugs;
12. Failure to Maintain Operational Standards and Security;
13. Failure to Maintain Operations Policy During Pharmacist Absence;
14. Failure to Maintain Proper Records of Compounded Drug Products/Supervision;
15. Failure to Ensure Compounding Limitations and Requirements;
16. Dispensing/Sale of Expired Drug;
17. Failure to Include Expiration Date on Labels;
18. Purchase of Dangerous Drugs from Unlicensed Entity;
19. Embargoed Misbranded Dangerous Drugs;
20. Failure to Maintain Facility and Equipment Standards; and
21. Drugs Lacking Quality and Strength.

The probation was successfully completed, effective February 7, 2020, and SuperCare's pharmacy license was fully restored.

Original Signature (electronic, copies or stamps not accepted)

01/06/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Cassar

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 01/06/2026

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

See Attached Certificate

Notary Public Signature

(Seal)

JURAT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of LOS ANGELES

Subscribed and sworn to (or affirmed) before me on this 6 day of JANUARY,

20 26 by JOHN LOUIS CASSAR,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature (Seal)

ANN MARIE PROVENCIO
COMM. #2431299
Notary Public - California
Orange County
My Comm. Expires Dec. 17, 2026

OPTIONAL INFORMATION

DESCRIPTION OF THE ATTACHED DOCUMENT

PERSONAL HISTORY
(Title or description of attached document)

APPLICATION
(Title or description of attached document continued)

Number of Pages 7 Document Date 1/6/2026

Additional information

INSTRUCTIONS

The wording of all Jurats completed in California after January 1, 2015 must be in the form as set forth within this Jurat. There are no exceptions. If a Jurat to be completed does not follow this form, the notary must correct the verbiage by using a jurat stamp containing the correct wording or attaching a separate jurat form such as this one with does contain the proper wording. In addition, the notary must require an oath or affirmation from the document signer regarding the truthfulness of the contents of the document. The document must be signed AFTER the oath or affirmation. If the document was previously signed, it must be re-signed in front of the notary public during the jurat process.

- State and county information must be the state and county where the document signer(s) personally appeared before the notary public.
- Date of notarization must be the date the signer(s) personally appeared which must also be the same date the jurat process is completed.
- Print the name(s) of the document signer(s) who personally appear at the time of notarization.
- Signature of the notary public must match the signature on file with the office of the county clerk.
- The notary seal impression must be clear and photographically reproducible. Impression must not cover text or lines. If seal impression smudges, re-seal if a sufficient area permits, otherwise complete a different jurat form.
  - ❖ Additional information Is not required but could help to ensure this jurat is not misused or attached to a different document.
  - ❖ Indicate title or type of attached document, number of pages and date.
- Securely attach this document to the signed document with a staple.

www.NotaryClasses.com 800-873-9865

Disciplinary Questions, Statement of Explanation

Any lawsuit or arbitration, as either a claimant or respondent, that I have been party to as an individual, owner, director, or officer of a corporation, has not been in relation to the practice of pharmacy.

The following California Board of Pharmacy disciplinary action occurred while I was an officer of Super Care, Inc.

Super Care, Inc. dba SuperCare
16017 Valley Blvd
City of Industry, CA 91745

On February 4, 2015, SuperCare's pharmacy license number PHY 45943 was placed on probation by the California Board of Pharmacy for a period of five years as a result of the Stipulated Settlement and Disciplinary Order dated January 28, 2015, for:

1. Failure to Maintain Compounding Training Documentation;
2. Misbranded Drugs;
3. Failure to Complete Self-Assessment;
4. Failure to Maintain Records for Compounded Products;
5. Failure to Maintain Compounding Policies and Procedures;
6. Failure to Maintain Licensed Employee Policies and Procedures;
7. Failure to Maintain Facilities and Equipment Records;
8. Failure to Maintain Compounding Quality Assurance Plan;
9. Unprofessional Conduct: Act of Moral Turpitude, Dishonesty, Fraud, Deceit, Corruption;
10. Unprofessional Conduct: False Document/Misrepresentation;
11. Failure to Maintain Security of Dangerous Drugs;
12. Failure to Maintain Operational Standards and Security;
13. Failure to Maintain Operations Policy During Pharmacist Absence;
14. Failure to Maintain Proper Records of Compounded Drug Products/Supervision;
15. Failure to Ensure Compounding Limitations and Requirements;
16. Dispensing/Sale of Expired Drug;
17. Failure to Include Expiration Date on Labels;
18. Purchase of Dangerous Drugs from Unlicensed Entity;
19. Embargoed Misbranded Dangerous Drugs;
20. Failure to Maintain Facility and Equipment Standards; and
21. Drugs Lacking Quality and Strength.

The probation was successfully completed, effective February 7, 2020, and SuperCare's pharmacy license was fully restored.

I hereby affirm that the above information is true and correct to the best of my knowledge.

John Cassar | 01 / 09 / 2026

Signature | Date

John Cassar
Chief Executive Officer, Super Care, LLC

CERTIFICATE *of* SIGNATURE

REF. NUMBER
RPX8J-JQESZ-NPA4Y-NAOTP

DOCUMENT COMPLETED BY ALL PARTIES ON
09 JAN 2026 21:32:05
UTC

SIGNER	TIMESTAMP	SIGNATURE
JOHN CASSAR EMAIL JOHNC@SUPERCARE.COM	SENT 09 JAN 2026 18:18:50 VIEWED 09 JAN 2026 21:31:50 SIGNED 09 JAN 2026 21:32:05	John Cassar IP ADDRESS [redacted] LOCATION RIVERSIDE, UNITED STATES

RECIPIENT VERIFICATION

EMAIL VERIFIED
09 JAN 2026 21:31:50

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 10, 2020

RECEIVED
FEB 13 2020
By

Supercare
Attention PIC
16017 Valley Blvd
City of Industry, CA 91745
RE: AC 4566

Dear PIC:

This letter is in regard to the above referenced administrative case and the status of the pharmacy license for Supercare, PHY 45943. Effective February 4, 2015 the pharmacy license was placed on probation for a period of five years with certain terms and conditions.

The Board is pleased to inform you that, upon review of the terms and conditions of your probation, probation has been successfully completed, effective February 7, 2020. Therefore, the probationary period has been terminated and the pharmacy license has been fully restored.

Please be advised that this disciplinary action will remain as part of your license history, which is public information.

If you have any questions, please do not hesitate to contact your probation analyst at (916) 518-3026.

Sincerely,

ANNE SODERGREN
Executive Officer

By

Autumn Ammann
Probation Analyst

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **SUPER CARE, INC. DBA SUPERCARE** **Gabriel Cassar, President;** **Michelline Cassar, Chief Executive Officer;** **John L. Cassar, Vice President;** **Michael Cassar, Shareholder** **Permit No. PHY 45943** **GABRIEL JOHN CASSAR, AKA** **GABRIEL CASSAR** **Pharmacist License No. RPH 25650** **KATHERINE THU LE, AKA** **KATHERINE LE** **Pharmacist-in-Charge** **Pharmacist License No. 57903** **TUAN KIEU NGUYEN** **Pharmacy Technician Registration** **No. TCH 89616** Respondents.	Case No. 4566 OAH No. 2014030278 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER** As to: **SUPER CARE, INC. DBA SUPERCARE, PERMIT No. PHY 45943**

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on February 4, 2015.

It is so ORDERED on January 28, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STAN C. WEISSER, Board President

KAMALA D. HARRIS
Attorney General of California
ARMANDO ZAMBRANO
Supervising Deputy Attorney General
LINDA L. SUN
Deputy Attorney General
State Bar No. 207108
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-6375
Facsimile: (213) 897-2804
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **SUPER CARE, INC. DBA SUPERCARE** **Gabriel Cassar, President;** **Micheline Cassar, Chief Executive Officer;** **John L. Cassar, Vice President;** **Michael Cassar, Shareholder** **16017 Valley Blvd.** **City of Industry, CA 91745** **Permit No. PHY 45943** **GABRIEL JOHN CASSAR, AKA** **GABRIEL CASSAR** **16017 Valley Blvd.** **City of Industry, CA 91745** **Pharmacist License No. RPH 25650** **KATHERINE THU LE, AKA** **KATHERINE LE** **Pharmacist-in-Charge** [redacted] **Rosemead, CA** [redacted] **Pharmacist License No. RPH 57903** **TUAN KIEU NGUYEN** [redacted] **Rowland Heights, CA** [redacted] **Pharmacy Technician Registration No. TCH 89616** Respondents.	Case No. 4566 OAH No. 2014030278 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER** **As to: SUPER CARE, INC. DBA SUPERCARE, Permit No. PHY 45943**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy ("Board"). She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Linda L. Sun, Deputy Attorney General.

2. Respondent Super Care, Inc..dba Supercare; Gabriel Cassar, President; Micheline Cassar, Chief Executive Officer; John L. Cassar, Vice President; Michael Cassar, Shareholder; Katherine Le, Pharmacist-in-Charge (collectively "Respondent Pharmacy" or "Respondent") is represented in this proceeding by attorney Tony J. Park, Esq., whose address is: [redacted] Irvine, CA [redacted]

3. On or about July 23, 2002, the Board issued Permit Number PHY 45943 to Respondent Pharmacy. The Permit was in full force and effect at all times relevant to the charges brought herein and will expire on July 1, 2015, unless renewed.

JURISDICTION

4. Accusation No. 4566 was filed before the Board and is currently pending against Respondent Pharmacy. The Accusation and all other statutorily required documents were properly served on Respondent Pharmacy on January 29, 2014. Respondent Pharmacy timely filed its Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 4566 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent Pharmacy has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 4566. Respondent Pharmacy has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent Pharmacy is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent Pharmacy voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent Pharmacy admits the truth of each and every charge and allegation in Accusation No. 4566.

10. Respondent Pharmacy agrees that its Permit is subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent Pharmacy understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent Pharmacy understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Permit No. PHY 45943 issued to Respondent Pharmacy is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

1. **Obey All Laws**

Respondent Owner shall obey all state and federal laws and regulations.

Respondent Owner shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:

- ☐ an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- ☐ a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
- ☐ a conviction of any crime
- ☐ discipline, citation, or other administrative action filed by any state or federal agency which involves Respondent Pharmacy's permit or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent Owner shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent Owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent Owner shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent Owner shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent Pharmacy's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent Owner shall pay to the Board its costs of investigation and prosecution in the amount of $6,310.80 (six thousand three hundred ten dollars and eighty cents). The costs may be paid on a payment plan approved by the Board. There shall be no deviation from the payment plan schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by Respondent Owner shall not relieve Respondent Pharmacy of their responsibility to reimburse the Board its costs of investigation and prosecution.

6. **Probation Monitoring Costs**

Respondent Owner shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. **Status of License**

Respondent Owner shall, at all times while on probation, maintain current licensure with the Board. If Respondent Owner submits an application to the Board, and the application is approved, for a change of location, change of permit or change of ownership, the Board shall retain continuing jurisdiction over the license, and Respondent shall remain on probation as determined by the Board. Failure to maintain current licensure shall be considered a violation of probation.

If Respondent Owner's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication Respondent Owner's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent Owner discontinue business, Respondent Owner may tender the premise's license to the Board for surrender. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, Respondent Owner shall relinquish the premises wall and renewal license to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent Owner shall further submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer.

///

Respondent Owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the Respondent Pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent Owner shall provide a copy of the written notice to the Board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent Owner may not apply for any new licensure from the Board for three (3) years from the effective date of the surrender. Respondent Owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board.

Respondent Owner further stipulates that he or she shall reimburse the Board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. **Notice to Employees**

Respondent Owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent Owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, Respondent Owner shall submit written notification to the Board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the Board shall be considered a violation of probation.

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"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. **Owners and Officers: Knowledge of the Law**

Respondent Owner shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in Respondent Pharmacy or Respondent Pharmacy's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. **Posted Notice of Probation**

Respondent Owner shall prominently post a probation notice provided by the Board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent Owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. **Violation of Probation**

If Respondent Owner has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent Pharmacy's license, and probation shall be automatically extended until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If Respondent Owner violates probation in any respect, the Board, after giving Respondent Owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary

order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against Respondent Pharmacy during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

13. **Completion of Probation**

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent Pharmacy's license will be fully restored.

14. **Community Services Program**

Within sixty (60) days of the effective date of this decision, Respondent Owner shall submit to the Board or its designee, for prior approval, a community service program in which Respondent shall provide free brown-bag events to the community for at least twenty (20) days per year for the first two (2) years of probation.

Within thirty (30) days of Board approval thereof, Respondent Owner shall submit documentation to the Board demonstrating commencement of the community service program. Respondent Owner shall report on progress with the community service program in the quarterly reports.

Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Tony J. Park, Esq.. I understand the stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12-9-2014

OWNER, SUPER CARE, INC. DBA SUPERCARE
Respondent

I have read and fully discussed with Respondent Super Care, Inc. dba Supercare; Gabriel Cassar; Micheline Cassar; John L. Cassar; Michael Cassar; Katherine Le; the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12/09/2014

Tony J. Park, Esq.
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated: 1/5/2015

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
ARMANDO ZAMBRANO
Supervising Deputy Attorney General

LINDA L. SUN
Deputy Attorney General
Attorneys for Complainant

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Super Care, LLC dba Super Care Health

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MP03165

Physical Address: 380 Freeport Blvd Suite 23

City: Sparks, State: NV Zip: 89431

Mailing Address (if different from physical address): ~~Same as above~~ 16017 VALLEY BLVD

City: CITY OF INDUSTRY State: CA Zip: 91744

Telephone: (800) 206-4880 Website: https://supercarehealth.com/

Licensing Company Email: compliance@excellere.com

Section 2: Personal Information

First: Michael Middle: David Donald Last: Geldart

Alias(es, nicknames, name changes, etc.): Mike

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Deland State: FL Zip: [redacted]

Telephone: [redacted] Email: mgeldart@excellere.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF SOUTH FLORIDA		08/83 - 12/85	
Address: 4202 E. FOWLER AVE	City: TAMPA	State: FL	Zip: 33620
Diploma/Degree obtained, if any: BA CHEMISTRY			

School Name		From - To (MM/YY – MM/YY)	
SOUTH FLORIDA COLLEGE		08/81 - 05/83	
Address: 600 W COLLEGE DR	City: AVON PARK	State: FL	Zip: 33825
Diploma/Degree obtained, if any: AA			

School Name		From - To (MM/YY – MM/YY)	
AVON PARK HIGH SCHOOL		08/77 - 05/80	
Address: 700 E MAIN ST	City: AVON PARK	State: FL	Zip: 33825
Diploma/Degree obtained, if any: HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
~~N/A~~ UNIVERSITY OF SOUTH FLORIDA		01/15 - 12/16	
Address: 4202 E. FOWLER AVE	City: TAMPA	State: FL	Zip: 33620
Diploma/Degree obtained, if any: MASTER SCIENCE CYBER SECURITY			

School Name		From - To (MM/YY – MM/YY)	
~~N/A~~ STETSON UNIVERSITY COLLEGE OF LAW		01/86 - 12/88	
Address: 1401 61ST ST S	City: GULFPORT	State: FL	Zip: 33707
Diploma/Degree obtained, if any: JURIS DOCTORATE			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/16 - Present	[redacted]	Deland	FL	[redacted]
12/15 - 12/16	[redacted]	AVON PARK	FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Excellere Partners			11/15 to Present	
Business Address		**City**	**State**	**Zip**
3033 E. 1st Ave. Suite 700		Denver	CO	80206
Phone	**Title**			
303-765-2400	Partner, Chief Compliance Officer			
Description of Duties				
Partner, Chief Compliance Officer of Excellere Partners, Private Equity				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	2/3/2020	ME	Augusta	Kennebec
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2017-PHA-13671		Maine Board of Pharmacy		
Reason/Charge				
See below.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
N/A		N/A		
Name of Business/Industry/Entity				
Bond Pharmacy, Inc. dba Advanced Infusion Solutions				

Provide explanation below:

Consent agreement for administrative action based upon delay in reporting a change in pharmacist-in-charge along with a warning and civil penalty of $250 as the change was reported in seven business days rather than seven calendar days. Fine was paid and all states were notified upon receiving the fully executed order.

Original Signature (electronic, copies or stamps not accepted)

1/6/2026
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	2/3/2020	OH	Columbus	Franklin
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
A-2019-0158		Ohio Board of Pharmacy		
Reason/Charge				
See below.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
Bond Pharmacy, Inc. dba Advanced Infusion Solutions				

Provide explanation below:

Disciplinary action based upon an alleged single dispensing error which resulted in Advanced Infusion Solutions paying a monetary penalty of $1,500.00. Fine was paid and all states were notified upon receiving the fully executed order.

Original Signature (electronic, copies or stamps not accepted)

1/6/2020
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	8/20/2020	HI	Honolulu	Honolulu
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
PHA-2020-0040L		Hawaii Board of Pharmacy		
Reason/Charge				
See below.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
N/A		N/A		
Name of Business/Industry/Entity				
Bond Pharmacy, Inc. dba Advanced Infusion Solutions				

Provide explanation below:

Pre-petition settlement agreement which resulted in an administrative fine of $500.00. Based off Ohio allegations. Fine was paid and all states were notified prior to receiving the fully executed order.

Original Signature (electronic, copies or stamps not accepted)

1/6/2026
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	5/8/2021	AL	Birmingham	Jefferson
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
20-L-0026		Alabama Board of Pharmacy		
Reason/Charge				
See below.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
Bond Pharmacy, Inc. dba Advanced Infusion Solutions				

Provide explanation below:

Consent agreement which resulted in an administrative fine of $5000.00. Based on former matters. Fine was paid and all states were notified upon receiving the fully executed order.

Original Signature (electronic, copies or stamps not accepted)

1/6/2026
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	1/5/2022	PA	Harrisburg	Dauphin
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
20-54-002960		Pennsylvania Board of Pharmacy		
Reason/Charge				
See below.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
Bond Pharmacy, Inc. dba Advanced Infusion Solutions				

Provide explanation below:

Consent agreement and civil penalty of $750.00 was paid to the Pennsylvania board and all states were notified upon receiving the fully executed order.

Original Signature (electronic, copies or stamps not accepted)

1/6/2026
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	5/15/2023	IL	Springfield	Sangamon
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2020-03088		Illinois Board of Pharmacy		
Reason/Charge				
See below.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
Bond Pharmacy, Inc. dba Advanced Infusion Solutions				

Provide explanation below:

Consent agreement was executed resulting in a reprimand of license and disciplinary fine of $1,500.00. Based on former matters. A fine was paid to the Illinois board and all states were notified upon receiving the fully executed order.

Original Signature (electronic, copies or stamps not accepted)

1/6/2026
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	4/30/2025	OH	Columbus	Franklin
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
A-2023-0119		Ohio Board of Pharmacy		
Reason/Charge				
See below.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
Bond Pharmacy, Inc. dba Advanced Infusion Solutions				

Provide explanation below:

Disciplinary action based upon an alleged single dispensing error that occurred in 2022 for which there is no definitive proof of fault. Advanced Infusion Solutions entered a settlement agreement and agreed to pay a monetary penalty of $8, 000.00. Fine was paid and all states were notified upon receiving the fully executed order.

Original Signature (electronic, copies or stamps not accepted)

1/6/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Geldart

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/6/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Colorado, ss. County of Denver

I, Michael Geldart, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/6/2026

Date

Subscribed and Sworn to before me this 6th day of January 2026

Jordan Amanda Day

Notary Public Signature

JORDAN AMANDA DAY
Notary Public
State of Colorado
Notary ID # 20254020880
My Commission Expires 06-05-2029

(Seal)

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8A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☐ New Pharmacy	☐ Retail/Community	☐ Retail/Community
☐ Out-of-Nevada	☒ Ownership Change*	☒ Hospital (# beds 25)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #:
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☒ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH IB01888		☒ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Carson Valley Health

Physical Address: 1107 Highway 395 N

City: Gardnerville State: Nevada Zip: 89410

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 775 782-1683 Toll Free # (NAC 639.708, NRS 639.23286):

Fax: 775 782-1657 Contact Email: bbattis@carsonvalleyhealth.org

Website: www.carsonvalleyhealth.org

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220): Brandon R. Battis

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 18763

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Brandon R. Battis	NV Pharmacist Registration #: 18763
Name: Sieu Long	NV Pharmacist Registration #: 16340
Name: Ryan J. McCloskey	NV Pharmacist Registration #: 15438
Name: Kendra L. Hagood	NV Pharmacist Registration #: 24191
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Barton Memorial Hospital

Corporation/Organization Name: Washoe Barton Medical Clinic DBA Carson Valley Health

Mailing Address: 1107 Highway 395 North

City: Gardnerville State: Nevada Zip: 89410

Telephone: 775-762-8021 Email: bbattis@carsonvalleyhealth.org

Contact Person Name: Brandon Battis

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacy Manager (title) for Carson Valley Health (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Brandon Battis

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

02/1/2026

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Brandon Battis Pharmacist Registration #: 18763

Pharmacy Name: Carson Valley Health

Initial each statement below to indicate you have read and agree with the following:

BB I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

BB I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

BB I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

BB I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

BB I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

2/11/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrea Highfill, CNO

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

CNO — 2/1/26

Original signature of Authorized Person (copies or stamps not accepted) — Date

Board Use Only	Date Received: 2/18/26	Amount: $500 24 00167646

CVH Board of Directors Name	Address	Usual Occupation	Professional Qualifications
Clint Purvance	[redacted]	President and CEO	MD, CPE
Kelly Neiger		CFO	CPA, MBA
Paul Fry III		MD	MD, FAAOS
Jeff Prater		CEO	MHA, FACHE
Colleen Kriss		DO	DO

CVH List of Officers Name	Address	Usual Occupation	Professional Qualifications
Jeff Prater	[redacted]	CEO	MHA, FACHE
Shannon Albert		COO	
Colleen Reid		CFO	CPA
Gina Zink		Clinics Director	
Andrea Highfill		CNO	DNP, RN

Carson Valley is a non-publicly traded corporation and has no individual stockholders. Barton Memorial Hospital is the sole owner.

Top Four Stockholders	Percent Ownership			
Barton Memorial Health	100%			
Additional stockholders that hold 10% or more of the shares				
Non-applicable				

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **WASHOE BARTON MEDICAL CLINIC, A NEVADA NONPROFIT CORPORATION** as a DOMESTIC NONPROFIT CORPORATION (82) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 05/13/1998, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/06/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202602066474208
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Carson Valley Health

Pharmacy/Wholesaler License # (if applicable): IB01888

Physical Address: 1107 Highway 395 N

City: Gardnerville State: Nevada Zip: 89410

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 775 782-1683 Website: www.carsonvalleyhealth.org

Licensing Company Email: bbattis@carsonvalleyhealth.org

Section 2: Personal Information

First: Brandon Middle: Robert Last: Battis

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Rhode Island		06/08 - 05/14	
Address	**City**	**State**	**Zip**
45 Upper College Rd,	Kingston	RI	02881
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Community College of Rhode Island		09/04 - 06/10	
Address	**City**	**State**	**Zip**
400 East Ave	Warwick	RI	02886
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Toll Gate High School		09/00 - 06/04	
Address	**City**	**State**	**Zip**
575 Centerville Rd	Warwick	RI	02886
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/20 - Current Date	[redacted]			
8/19 - 8/20				
2/16 - 8/19				
6/14 - 2/16				
10/12 - 6/14				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Carson Valley Health			02/24 - Current Date	
Business Address		**City**	**State**	**Zip**
1107 Highway 395 N		Gardnerville	NV	89410
Phone	**Title**		**Number of Employed Hours**	
775 762-8021	Pharmacy Manager		4,160	
Description of Duties				
Responsible for the filling, dispensing and distribution of prescription medications. Also, responsible for the proper handling, usage, and storage of medications in the pharmacy. Maintains prescription drug records in accordance to federal and state laws.				

Business Name			From - To (MM/YY – MM/YY)	
Carson Valley Medical Center			05/21 - 02/24	
Business Address		**City**	**State**	**Zip**
1107 US Highway 395 N		Gardnerville	NV	89410
Phone	**Title**		**Number of Employed Hours**	
775 782-1683	Pharmacy Manager		5,540	
Description of Duties				
Responsible for the filling, dispensing and distribution of prescription medications. Also, responsible for the proper handling, usage, and storage of medications in the pharmacy. Maintains prescription drug records in accordance to federal and state laws.				

Business Name			From - To (MM/YY – MM/YY)	
Carson Valley Medical Center			07/15 - 5/21	
Business Address		**City**	**State**	**Zip**
1107 US Highway 395 N		Gardnerville	NV	89410
Phone	**Title**		**Number of Employed Hours**	
775 782-1683	Clinical Pharmacist		12,240	
Description of Duties				
Responsible for the filling, dispensing and distribution of prescription medications. Also, responsible for the proper handling, usage, and storage of medications in the pharmacy. Maintains prescription drug records in accordance to federal and state laws.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Brandon Battis, **certify that as the designated representative for**

Carson Valley Health,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BB I am at least 21 years of age;
3. BB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Brandon Battis

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/1/2020

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brandon Battis

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/9/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Douglas

I, Brandon Battis, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/9/2026

Date

Subscribed and Sworn to before me this 9th day of 2026.

Notary Public Signature

SARA HUNT
Notary Public-State of Nevada
APPT. NO. 23-6849-12
My Appt. Expires 09-22-2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Carson Valley Health

NV Pharmacy or Outsourcing facility license # (if applicable): IB01888

Physical Address: 1107 US Highway 395 N

City: Gardnerville State: NV Zip: 89410

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 775 782-1683 Toll Free # (NAC 639.708, NRS 639.23286):

Fax: 775 782-1657 Contact Email: bbattis@carsonvalleyhealth.org

Website: https://www.carsonvalleyhealth.org/

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220): Brandon Battis

Supervising/Managing Pharmacist NV Pharmacist Registration #: 18763

Name of Designated Person(s) as defined by revised USP-797 guidelines: Brandon Battis

Email of Designated Person(s): bbattis@carsonvalleyhealth.org

Telephone of Designated Person(s): 775 783-3035

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked **"Category 3"**, you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ■ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 09/18/2025

6. What is the frequency of the recertification for the ISO classified areas? every 6 months

7. Were there any follow-up items required from the most recent certification report? ■ Yes ☐ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☐ Yes ■ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? monthly

10. Will you be performing sterile hazardous drug compounding? ■ Yes No

If you marked **"Yes"**, you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Abatacept, Acyclovir, Aminophylline, Amiodarone, Ampicillin, Ampicillin/Sulbactam, Azacitidine, Belimumab, Bendamustine, Bevacizumab, Ceftazidime, Ceftriaxone, Calcium Gluconate, Cangrelor, Cefazolin, Cetuximab, Cefoxitin, Cephalexin, Cisplatin, Clindamycin, Crotalidae, Cyclophosphamide, Daptomycin, Decitabine, Desmopressin, Dexamethasone, Dexmedetomidine, Diltiazem, Dobutamine, Docetaxel, Diphenhydramine, Doxorubicin, Doxorubicin (liposomal), Doxycycline, Efgartigimod, Epinephrine, Ertapenem, Erythromycin, Famotidine, Ferric Carboxymaltose, Ferric Gluconate, Fluconazole, Fluorouracil, Furosemide, Gentamycin, Glucagon, Golimumab, Imipenem/Cilastatin, Infliximab, Ipilimumab, Irinotecan, Irinotecan (liposomal), Iron Sucrose, Ketamine, Labetalol, Leucovorin, Magnesium Sulfate, Methylprednisolone, Micafungin, Milrinone, Nafcillin, Naloxone, Natalizumab, Nicardipine, Nivolumab, Nitroprusside, Norepinephrine, Obinutuzumab, Ocrelizumab, Octreotide, Ondansetron, Oxytocin, Paclitaxel, Paclitaxel (liposomal), Pantoprazole, Pembrolizumab, Pemetrexed, Penicillin G, Pentamidine, Pertuzumab, Phenylephrine, Phenytoin, Piperacillin/Tazobactam, Potassium Chloride, Procainamide, Propofol, Remdesivir, Risankizumab, Rituximab, Sacituzumab Govitecan, Sulfamethoxazole/Trimethoprim, Tobramycin, Tocilizumab, TPN, Valproate Sodium, Vancomycin, Vasopressin, Vecuronium, Vedolizumab, Vincristine, Vinblastine, Voriconazole

12. What laboratory performs your sterility or endotoxin testing?

Name: N/A

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

13. What is your procedure for visual inspection of compounded sterile products?
The pharmacist and compounding personnel will inspect the container for any leaks, defects, signs of tampering, particulate and unexpected color or odor in a well lite area against both a white and black background. The bag is gently squeezed to assess for leaks. The bag is visually inspected to ensure the seals and ports are intact and not leaking. If any unexpected findings are noted (particulates, gas, leaks, damage, tampering), the CSPs are quarantined so they are not inadvertently dispensed to patients. The pharmacy manager is notified immediately, and an investigation and proper disposal occurs.

14. How often do you perform glove fingertip and medial fill testing?
Both are performed before an individual can compound and then at least every 6 months.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
Didactic knowledge and practical training are provided. Several online modules must be completed and each test at the end of each module must be completed with a passing grade. A test regarding calculations, measuring and mixing must be completed with a passing grade of >70%. All individuals must complete media-fill tests and glove fingertip sampling tests in accordance to policy. All individuals must demonstrate competency in preforming hand hygiene and garbing for both non-hazardous and hazardous drugs. All individuals must demonstrate proficiency in aseptic technique by performing aseptic manipulations in an ISO 5 environment and surface samples are taken. All individuals must demonstrate proper use of equipment including the primary engineering controls. They must display proper documentation of the compounding process. Furthermore, demonstrating proper cleaning and disinfection of the cleanrooms occurs. Hazardous drug training regarding garbing, transporting, handling, storing, and compounding using a closed system transfer device also occurs.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Daily cleaning: inside surfaces of ISO Class 5 PECs, using PREempt then Peridox followed by sterile 70% isopropyl alcohol (sIPA) prior to beginning any compounding. Cleaning with sIPA in the PEC occurs at the beginning of shift, prior to each batch, when visibly soiled, after a spill and whenever contamination suspected. Counters, furniture, pass-throughs, easily cleanable work surfaces, and high touch surfaces in the buffer rooms are cleaned using PREempt daily and followed by sIPA. Floors in the non-hazardous buffer and anteroom are cleaned using PREempt daily. On Mondays, Peridox (sporocidial) is added to the daily cleaning. Dwell times are adhered to. PREempt then PeridoxRTU is utilized for monthly cleaning. During monthly cleaning, daily cleaning will occur with the addition of ceilings, walls, the outside of the PECs, refrigerators, carts, storage bins all surfaces. All cleaning procedures are repeated in the anteroom and the hazardous drug buffer room. In the HD buffer room, the same procedures occur except PeridoxRTU is used first for deactivation, then PREempt and sIPA. Decontamination occurs between different types of HDs, prior to performing any cleaning and in the event of a spill inside or outside the PEC. Decontamination, cleaning and disinfection of the surfaces under the work tray of the PEC will be performed monthly using a dual chamber respirator with p100 cartridges.

17. Who performs the sterile compounding process at your facility?

Battis,McCloskey15438,Long16340,Hagood24191,Buckley PT20697,Reinholz PT24029,RogersPT03855,TholenPT31442

18. Who is responsible and accountable for the sterile compounding process at your facility?
Brandon Battis, Pharmacy Manager

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
No products are shipped. All compounded products are utilized within the facility.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? USP 800 compliant Class 2 Biological Safety Cabinet Type B2		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	■ Yes	No
9. If yes, list the name of the device: Equashield		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

No medications are compounded for patient self-administration. Therefore, no patients will have the opportunity to handle or dispose of a hazardous medication that Carson Valley Health compounded. Patients are given information regarding the education of the medications that they are receiving and proper procedures to avoid exposing others to hazardous medications through bodily waste. All medications are handled by our chemotherapy certified nurses. All nurses must complete a hazardous drug education module and pass a test at the end of the module. The nurse must complete the module on a yearly basis. The module discussed the proper handling and disposal of hazardous drugs. Also, it discusses the proper procedures if a hazardous drug spill were to occur.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?
Hazardous drugs training includes didactic knowledge and practical training. Several online modules must be completed and each test at the end of each module must be completed with a passing grade. The aforementioned modules provide education regarding HD overview, HD Primary and Secondary Engineering Controls, HD PPE, Decontamination and Spill Management, and the Receiving, Storage, Compounding, Labeling, Packaging, and Transport of HD. A test regarding calculations, measuring and mixing must be completed with a passing grade of >70%. All individuals must complete media-fill tests and glove fingertip sampling tests in accordance with policy. All individuals must demonstrate competency in preforming hand hygiene and garbing for hazardous drugs. All individuals must demonstrate proficiency in aseptic technique by performing aseptic manipulations in an ISO 5 environment. All individuals must demonstrate proper use of equipment including the primary engineering controls. They must display proper documentation of the compounding process. Furthermore, demonstration of proper deactivation, cleaning and disinfection of the HD buffer room occurs. Additional hazardous drug training includes transporting, handling, storing, and compounding using a closed system transfer device. Demonstration of the correct use of a closed system transfer device must occur. Education regarding how to address a hazardous drug spill is provided.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:
N/A

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?
N/A

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?
N/A

5. What is the frequency for completing surface sampling? N/A		
6. What is the frequency for using sporicidal agents? N/A		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brandon Battis

Name of Person who Completed the Form

Pharmacy Manager

Title

Signature (copies or stamps not accepted)

02/01/2026

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

Authorization Letter

Andrea Highfill DNP, RN

Chief Nursing Officer

Carson Valley Health (formerly Carson Valley Medical Center)

1107 Highway 395 Gardnerville, Nevada 89410

Phone: 775.782.1622

Date: 2/1/26

Nevada State Board of Pharmacy

421 W. Plumb Lane Reno, Nevada 89509

Phone: 775.782.1622

Dear Nevada State Board of Pharmacy,

I, Andrea Highfill, hereby authorize Brandon Battis to appear before the board on behalf of Carson Valley Health.

The authorization pertains to a new pharmacy application that is being submitted due to a change in ownership of Carson Valley Health from dual ownership, which was Renown Regional Medical Center and Barton Memorial Health, to sole ownership of Barton Memorial Health. It is still a non-publicly traded corporation.

Please contact me at 775.782.1622 if there are any questions regarding this authorization.

Sincerely,

Andrea Highfill DNP, RN

Chief Nursing Officer

8B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☑ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☑ Dangerous drugs
	☐ Location Change *	☐ Internet	☑ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: pending
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☑ Non-sterile Compounding
			☑ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Las Vegas Apothecary

Physical Address: 2578 Belcastro Street #104

City: Las Vegas State: NV Zip: 89117

Mailing Address (if different from physical address): 10366 Miners Gulch Ave

City: Las Vegas State: NV Zip: 89135

Telephone: Pending installation prior to opening Toll Free # (NAC 639.708, NRS 639.23286): Pending installation

Fax: Pending installation prior to opening Contact Email: andrew.rx.roth@gmail.com

Website: Pending development prior to opening

Nevada Business License # (if applicable) NV20253308689

Supervising/Managing Pharmacist Name (NRS 639.220): Desiree Roth

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 18832

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Desiree Roth	NV Pharmacist Registration #: 18832
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: Andrew Roth	Credentials: PharmD, NV Rph	%: 100
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: Not Applicable

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): _____

Corporation/Organization Name: Las Vegas Apothecary LLC

Mailing Address: [redacted]

City [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email [redacted]

Contact Person Name: Andrew Roth

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: Not Applicable

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Not Applicable

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Managing Pharmacist (title) for Las Vegas Apothecary (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Desiree Roth

Print Name of Authorized Person

Desiree Roth

Original signature of Authorized Person (copies or stamps not accepted)

2/26/26

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Desiree Roth Pharmacist Registration #: 18832

Pharmacy Name: Las Vegas Apothecary

Initial each statement below to indicate you have read and agree with the following:

DR I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

DR I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

DR I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

DR I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

DR I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	✓	

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:
Pending	NV	01/20/2026	25-421-RPH-S

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Desiree Roth
Original signature of Managing Pharmacist (copies or stamps not accepted)

2-26-26
Date

JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA
BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

January 20, 2026

Via Certified Mail and Email
RPh Desiree Roth, 18832
[redacted]

CITATION-AND-FINE ORDER, Case No. 25-421-RPH-S, Desiree Roth, Unlicensed Technician Activity

Desiree Roth:

The Nevada State Board of Pharmacy (Board) has determined that unlicensed technician activity occurred at ASPN Pharmacy 4, LLC (ASPN). Specifically, Romero Valdez Jr., under your supervision, engaged in technician level tasks at ASPN prior to obtaining registration from the Board. Although Mr. Valdez is a Patient Care Provider, the duties he performed went beyond that role and into the scope of pharmaceutical technician under Nevada law. *See* Nevada Administrative Code (NAC) 6398.245.

Pursuant to NAC 639.240(1), "No person may perform the duties of a pharmaceutical technician until the person has been issued a certificate of registration." A license or registration in another state does not authorize an individual to perform technician-level duties in Nevada without proper registration here.

As the Managing Pharmacist, you are responsible for ensuring that your pharmacy and its personnel comply with all applicable laws. NRS 639.220(1) requires each pharmacy to be managed by a registered pharmacist approved by the Board, who "is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy." Accordingly, pursuant to NRS 639.2895(3), the Board has assessed an administrative fine against you in the amount of **Five Hundred and 00/100 Dollars ($500)** for failing to ensure compliance with Nevada law governing the scope of practice and permissible duties of pharmacy staff.

You have the right to appeal this citation by submitting a written request for a hearing to the Board at the Board's Reno office no later than 30 days after receipt of this citation. NRS 639.2895(2). Unless you submit a timely appeal, the above fine must be paid within the same time frame. Payment must be tendered in the form of a certified check, cashier's check or money

order made payable to "State of Nevada, Office of the Treasurer." Please remit payment to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

If you fail to timely pay the above fine or appeal this citation, as applicable, the Board may take further action, including reporting to the National Practitioner Data Bank and/or referral to the Nevada Controller's Office for collection. See NRS 353C.195; 45 CFR §§ 60.3, 60.5. If you have any questions concerning this citation or your right to appeal the above finding, you may contact the Board's Regulatory Compliance Officer Skylar Young at 702-486-6420, ext. 151, or *via* email at skylaryoung@pharmacy.nv.gov.
Sincerely,

The Nevada State Board of Pharmacy

Signed Statement of Explanation

Re: Personal and Professional History – Questions 3 and 4

I, Desiree Roth, RPh (Nevada License #18832), submit this statement in response to my "Yes" answers to Questions 3 and 4 regarding a board citation or administrative action.

On January 20, 2026, I was issued a Citation-and-Fine Order by the Nevada State Board of Pharmacy (Case No. 25-421-RPH-S) related to an allegation of unlicensed technician activity at ASPN Pharmacies 4, LLC.

At this time, the citation is paused and under formal review by the Nevada State Board of Pharmacy. Counsel for my current employer, ASPN Pharmacies, is actively engaged in communication with the Board regarding this matter. Based on these discussions, the compliance and payment deadlines associated with the citation have been paused, and the matter has not reached a final resolution.

I respectfully assert that the factual basis underlying the citation is inaccurate, and I am cooperating fully with the Board through counsel to clarify the circumstances and resolve the matter appropriately. No final disciplinary action has been imposed, and there has been no suspension, revocation, or restriction placed on my pharmacist license.

I submit this disclosure in the interest of full transparency and in compliance with application requirements, with the understanding that the matter remains pending and under review.

I certify that the information provided above is true and accurate to the best of my knowledge.

Desiree Roth

Desiree Roth, RPh

Nevada License #18832

Date: 2-26-26

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Roth

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

2/26/26

Date

Board Use Only	Date Received: 3/2/26	Amount: $800.00

Las Vegas Apothecary LLC

Section 12 – Required Disclosures and Supporting Statements

(Non-Publicly Traded Pharmacy)

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1. Officers and Directors

(NRS 639.231(2)(b), NAC 639.214(5)(a))

Las Vegas Apothecary LLC is a non-publicly traded limited liability company organized in the State of Nevada.

The following individual serves as the officer and managing member of the company:

- **Andrew Roth, PharmD**
  Managing Member / Officer
  Las Vegas Apothecary LLC

There are no additional officers or directors.

---

2. Top Stockholders / Ownership Interests

(NRS 639.231(3))

Las Vegas Apothecary LLC has one (1) owner.

- **Andrew Roth, PharmD** – 100% ownership interest

No other individuals or entities hold any ownership interest in Las Vegas Apothecary LLC.

---

3. Stockholders Holding 10% or More

(NAC 639.214(4)(b))

- **Andrew Roth, PharmD** – 100% ownership interest

No other stockholders exist.

---

4. Certificate of Good Standing

(Secretary of State Requirement)

A **Certificate of Good Standing** issued by the Nevada Secretary of State (SilverFlume), dated within the last six (6) months, is submitted separately with this application.

---

5. Designated Representative Form

(NAC 639.5005)

Pursuant to NAC 639.5005(c), this requirement **does not apply**, as a majority interest of the applicant is owned by a pharmacist who is:

1. Licensed by the Nevada State Board of Pharmacy; and
2. A resident of the State of Nevada.

---

6. Personal History Record Application

(Non-Publicly Traded Requirement)

A **Personal History Record Application** for the owner, **Andrew Roth, PharmD,** is completed and submitted separately with this application.

---

7. Sterile Compounding Questionnaire

(If Applicable)

Las Vegas Apothecary LLC **will perform sterile compounding.**
A completed **Sterile Compounding Questionnaire** is submitted separately as required.

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8. Pharmacy Inspection, License Verification, DEA Registration

(Non-Nevada Pharmacies Only)

Not applicable.
Las Vegas Apothecary LLC is a **Nevada-located pharmacy.**

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9. Internet Pharmacy Services Certification

(If Applicable)

Las Vegas Apothecary LLC does not provide internet pharmacy services at this time unless otherwise approved and documented.

---

10. Nevada Prescription Monitoring Program (PMP)

Las Vegas Apothecary LLC will comply with all Nevada Prescription Monitoring Program (PMP) reporting requirements for Schedule II–V controlled substances in accordance with NRS 453.162.

Certification

I certify that the information provided in this document is accurate and complete to the best of my knowledge.

Andrew Roth, PharmD

Managing Member / Officer
Las Vegas Apothecary LLC

Date: 2/26/26

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Las Vegas Apothecary LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 03/07/2025, and in good standing in this State.

I further certify that the above DOMESTIC LIMITED-LIABILITY COMPANY (86) has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/27/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202602276515714
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Las Vegas Apothecary

NV Pharmacy or Outsourcing facility license # (if applicable): pending

Physical Address: 2578 Belcastro Street #104

City: Las Vegas State: NV Zip: 89117

Mailing Address (if different from physical address): 10366 Miners Gulch Ave

City: Las Vegas State: NV Zip: 89135

Telephone: Pending installation prior to openin Toll Free # (NAC 639.708, NRS 639.23286): Pending installation

Fax: Pending installation prior to opening Contact Email: andrew.rx.roth@gmail.com

Website: Pending development prior to opening

Nevada Business License # (if applicable) NV20253308689

Supervising/Managing Pharmacist Name (NRS 639.220): Desiree Roth

Supervising/Managing Pharmacist NV Pharmacist Registration #: 18835

Name of Designated Person(s) as defined by revised USP-797 guidelines: Andrew Roth

Email of Designated Person(s): andrew.rx.roth@gmail.com

Telephone of Designated Person(s): 702-250-0177

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ■ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? Not applicable – New pharmacy under construction.

6. What is the frequency of the recertification for the ISO classified areas? N/A– New pharmacy under construction.

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Monthly

10. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Las Vegas Apothecary will compound patient-specific sterile preparations pursuant to valid prescriptions from Nevada-licensed prescribers, in accordance with Section 503A of the Federal Food, Drug, and Cosmetic Act, USP <797>, and Nevada Revised Statutes Chapter 639.Sterile compounded preparations will include, but are not limited to:

Injectable hormone formulations (including hormone replacement therapy); Injectable vitamins and micronutrient preparations; Pain management injections; Anti-infective and immunological preparations; Ophthalmic and otic preparations; Dermatological and aesthetic preparations; Other clinically indicated sterile compounded preparations as requested by prescribers and determined by patient-specific therapeutic need

All bulk drug substances will comply with Section 503A requirements, including current FDA guidance on bulk substance eligibility. The pharmacy will not engage in anticipatory manufacturing, bulk production for non-patient-specific distribution, or outsourcing facility (503B) activities. All preparations will be compounded by trained, qualified personnel under the supervision of Desiree Roth (Managing Pharmacist) and Andrew Roth (Designated Person), following documented standard operating procedures and USP <797> standards for sterile compounding.

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL Bio Pharma

Address: 840 Research Parkway

City: Oklahoma City State: OK Zip: 73104

Telephone: 405-271-1144

13. What is your procedure for visual inspection of compounded sterile products?

All compounded sterile preparations will undergo documented visual inspection by a qualified pharmacist prior to release for dispensing. Inspection will be conducted under appropriate lighting conditions using both light and dark contrasting backgrounds to detect visible particulate matter, cloudiness, discoloration, and container closure defects. For clear solutions, inspection includes verification of clarity and absence of visible particles. For suspensions and opaque preparations, inspection confirms uniform appearance and absence of foreign matter. Additional verification includes proper labeling accuracy and accuracy of the final preparation. All inspections are performed in accordance with USP <797> standards and documented in the compounding record.

14. How often do you perform glove fingertip and medial fill testing?

Glove fingertip and medial fill testing is conducted every 6 months per USP <797> standards for Category 2.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Personnel performing Category 2 sterile compounding will complete initial didactic training on USP <797>, aseptic technique, contamination control, and pharmacy SOPs, followed by supervised hands-on training.
Initial qualification will include hand hygiene, garbing, and donning of sterile gloves three separate and complete times, with gloved fingertip and thumb sampling after each (no growth allowed), and a media fill test representative of the most complex compounding expected to be performed. Ongoing competency will include a single gloved fingertip/thumb sampling after hand hygiene, garbing, and donning of sterile gloves and a media fill test at least every six (6) months, with documentation maintained under Designated Person oversight.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Primary Engineering Controls (PECs):PECs (LAFW or BSC) will be cleaned and disinfected using sterile products only. At the beginning of each shift, before each batch, after spills or contamination, and every 30 minutes during continuous compounding, surfaces will be cleaned using sterile water for injection (or sterile water) as needed to remove residue, followed by sterile 70% isopropyl alcohol (IPA).A sterile sporicidal agent will be applied to PEC surfaces at least monthly and after any known contamination event, in accordance with USP <797>. All cleaning within ISO-classified PEC environments will utilize sterile, low-lint wipes and sterile disinfectants.
Secondary Engineering Controls (SEC – Buffer and Ante Areas):Classified buffer and ante areas will be cleaned and disinfected daily using EPA-registered disinfectants. Floors will be cleaned daily; walls, ceilings, and storage shelving will be cleaned at least monthly. A sporicidal agent will be applied at least monthly and following contamination events.
We intend to utilize Contec cleaning products, including sterile 70% IPA, TB1-3300 disinfectant, Preempt disinfectant, and Peridox sporicidal agent.
All cleaning activities will follow a documented SOP outlining proper contact times, and cleaning sequences (clean to dirty, top to bottom), and will be documented as part of the pharmacy's quality assurance program in compliance with USP <797>. More details of entire cleaning procedures are explained in our SOP.

17. Who performs the sterile compounding process at your facility?

Only personnel who have successfully completed and maintained initial and ongoing USP 797 training and competency.

18. Who is responsible and accountable for the sterile compounding process at your facility?

Andrew Roth, PharmD, Designated Person, and Desiree Roth, PharmD, Managing Pharmacist, are responsible and accountable for oversight and compliance of the sterile compounding process in accordance with USP <797> and Nevada Board of Pharmacy requirements.

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

All products that are shipped or mailed from Las Vegas Apothecary are packaged and transported in full compliance with USP <797> Section 19 (CSP Handling, Storage, Packaging, Shipping, and Transport) and the pharmacy's SOP - Packaging and Transporting Procedure. These procedures ensure that CSP quality, sterility, and stability are maintained.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? LAFWs, BSCs, and CVEs		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	■ Yes	No
9. If yes, list the name of the device: When applicable, we will use the OnGaurd CSTD system.		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

Patients and caregivers are provided with clear instructions on the safe handling, storage, and disposal of hazardous drug products and containers at the time of dispensing.
Education includes verbal counseling and written instructions when applicable.
Specifically, patients are instructed to:
Handle hazardous drugs with care, avoiding exposure to others.
Wash hands before and after handling or applying hazardous drug products.
Prevent secondary exposure by keeping medications and used containers away from children, pregnant individuals, and pets.
Avoid crushing, opening, or manipulating dosage forms unless explicitly directed.
Not flush hazardous drugs or containers down the toilet or sink.
Dispose of empty or partially used containers (estrogen or testosterone gels/creams) by:
Replacing the cap,
Placing the container in a sealed plastic bag, and
Disposing of it in regular household trash (not recycling).
Avoid recycling hazardous drug containers due to potential residual contamination.
Patients are advised that even "empty" containers may contain residual drug and should be handled accordingly.
These instructions are consistent with the intent of United States Pharmacopeia USP <800>, which emphasizes minimizing exposure risk to patients, caregivers, and the public.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

All new employees are trained and qualified before independently compounding sterile hazardous drugs in accordance with USP <797> Section 2 (Personnel Training and Evaluation) and USP <800> Section 9 (Personnel Training). New personnel complete structured didactic training that establishes foundational knowledge prior to any hands-on compounding. Training includes: Principles of aseptic technique and sterile compounding; Review of hazardous drug risks, routes of exposure, and health effects; Familiarization with the facility's NIOSH hazardous drug list; Overview of engineering controls, including ISO Class 5 C-PECs and negative-pressure C-SECs; Personal protective equipment (PPE) requirements specific to sterile hazardous drug compounding; Spill management, waste handling, and exposure response procedures; Review of facility policies, procedures, and SOPs. Following didactic training, personnel receive hands-on instruction and direct observation by a qualified trainer or designated person. This includes: Proper hand hygiene and garbing techniques; Correct donning and doffing of chemotherapy gloves, gowns, and other required PPE; Cleaning, disinfecting, and workflow practices within the sterile hazardous drug compounding area; Safe use of externally vented ISO Class 5 C-PECs used for sterile HD compounding; Personnel are not permitted to compound independently during this phase. Before independent compounding, personnel must successfully complete all required initial competencies, including: Garbing competency, consisting of visual observation and gloved fingertip and thumb sampling; Aseptic manipulation competency, including: Media-fill testing simulating the most challenging sterile compounding processes performed; Post-media-fill gloved fingertip and thumb sampling, Surface sampling of the direct compounding area. Failures result in retraining and re-evaluation prior to authorization. In addition to sterile compounding competencies, personnel receive targeted hazardous drug training that includes: Safe handling and containment of sterile hazardous drugs. Proper PPE selection and use. Spill response procedures and spill kit use. Hazardous drug waste segregation and disposal. Decontamination, deactivation, cleaning, and disinfecting procedures. Medical surveillance and exposure reporting requirements.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?		
6. What is the frequency for using sporicidal agents?		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

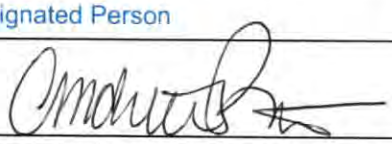
I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Roth

Name of Person who Completed the Form

Designated Person

Title



Signature (copies or stamps not accepted)

2/26/26

Date

Board Use Only	Date Received: 3/2/26 Date Approved: _____ Approved By: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Las Vegas Apothecary

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 2578 Belcastro Street #104

City: Las Vegas State: NV Zip: 89117

Mailing Address (if different from physical addres: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: Pending installation Website: Pending development prior to opening

Licensing Company Email: [redacted]

Section 2: Personal Information

First: Andrew Middle: Oliver Last: Roth

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zi: [redacted]

Telephone: [redacted] Emai: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Western Governors Universitiy		12/23 - 4/24	
Address	City	State	Zip
4001 S 700 E #300	Millcreek	UT	84107
Diploma/Degree obtained, if any			
Masters of Health Administration MHA			

School Name		From - To (MM/YY – MM/YY)	
Roseman University of Health Sciences		08/04 - 06/08	
Address	City	State	Zip
11 Sunset Way	Henderson	NV	89014
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
University of Nevada, Las Vegas		06/03 - 05/04	
Address	City	State	Zip
4505 S Maryland Pkwy	Las Vegas	NV	89154
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
College of Southern Nevada		06/00 - 05/03	
Address	City	State	Zip
6375 W Charleston Blvd	Las Vegas	NV	89146
Diploma/Degree obtained, if any			
Associates - Network Administration and Internetworking Technologies			

School Name		From - To (MM/YY – MM/YY	
Southeast Career and Technical Academy (formerly Vo-Tech High School)		08/95 - 06/00	
Address	City	State	Zip
5710 S Mountain Vista St	Las Vegas	NV	89120
Diploma/Degree obtained, if any			
High School Diploma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Centennial Hills Hospital Pharmacy			12/21 - Present	
Business Address	**City**	**State**	**Zip**	
6900 N Durango Dr	Las Vegas	NV	89149	
Phone	**Title**			
702-629-1300	Pharmacist - USP Specialist/Designated Person			
Description of Duties				
Oversee and train personnel according to USP 797, 800, and 795.				

Business Name			From - To (MM/YY – MM/YY)	
Meta Pharmacy Services			01/26 - 02/26	
Business Address	**City**	**State**	**Zip**	
8352 W Warm Springs Rd	Las Vegas	NV	89113	
Phone	**Title**			
702-754-0172	Pharmacist Per Diem			
Description of Duties				
Verify prescription orders.				

Business Name			From - To (MM/YY – MM/YY)	
Partell Pharmacy			12/25 - 12/25	
Business Address	**City**	**State**	**Zip**	
5835 S Eastern Ave Ste 101	Las Vegas	NV	89119	
Phone	**Title**			
702-791-3800	Pharmacist Per Diem			
Description of Duties				
Verify prescription orders.				

Business Name			From - To (MM/YY – MM/YY)	
Quality Compounding Rx of America			02/25 - 05/25	
Business Address	**City**	**State**	**Zip**	
801 S Rancho Dr STE E7	Las Vegas	NV	89106	
Phone	**Title**			
702-984-6640	Compliance Specialist			
Description of Duties				
Evaluate SOPs and Oversee Compounding Practice				

Business Name			From - To (MM/YY – MM/YY)	
CVS Pharmacy			05/09 - 12/21	
Business Address	**City**	**State**	**Zip**	
6371 N Decatur Blvd	Las Vegas	NV	89130	
Phone	**Title**			
702-515-8541	Pharmacy Manager			
Description of Duties				
Manage retail pharmacy. District manager of CVS Target Channel from 10/20 - 6/21.				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Roth

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/26/26

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Andrew Roth, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/27/26

Date

Subscribed and Sworn to before me this 27 day of FEBRUARY 2026.

Notary Public Signature

Aubrey Caramanica
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 23-9921-01
My Appt. Expires February 6, 2027

8C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada ☐ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☒ Name Change* (if only a Name Change occurred, submit a with the application.) * Current license #: PH 02936	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Specialty Pharmacy and Home Infusion Therapy Pharmacy	☒ Retail/Community ☒ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☒ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: Specialty/Home Infusion

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: ~~Total Infusion Care LLC~~ LUX Infusion 13 *AMENDED* 3/3/26 RCH

Physical Address: 3041 W Horizon Ridge Pkwy, #100

City: Henderson State: NV Zip: 89052

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 702-778-8880 Toll Free # (NAC 639.708, NRS 639.23286): 888-482-2730

Fax: 702-778-8882 Contact Email: ~~mpourteymaur@totalinfusioncare.com~~ *AMENDED*3/3/26

Website: www.biomatrixsprx.com jonathan.chan@totalinfusioncare.com RCH

Nevada Business License # (if applicable) NV20253470488

Supervising/Managing Pharmacist Name (NRS 639.220): ~~Mohammad Pourteymaur~~ Jonathan Chan*AMENDED*3/3/26

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): ~~13750~~ 21072 *AMENDED*3/3/26 RCH

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Mohammad Pourteymaur	NV Pharmacist Registration #: 13759
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): BioMatrix Specialty Pharmacy, LLC

Corporation/Organization Name: Total Infusion Care LLC

Mailing Address: 855 SW 78th Ave, #C200

City: Plantation State: FL Zip: 33324

Telephone: 954-385-7322 Email: morgan.harber@biomatrixsprx.com

Contact Person Name: Morgan Harber

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Chief Executive Officer (title) for Total Infusion Care LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Edward Kramm

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

11/19/21

Date

AMENDED 3/3/26

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: JONATHAN CHAN Pharmacist Registration #: 21072

Pharmacy Name: LUX Infusion 13

Initial each statement below to indicate you have read and agree with the following:

JC I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

JC I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

JC I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

JC I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

JC I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

3/3/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Edward Kramm

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

Date 11/19/25

Board Use Only	Date Received: 11/24/25	Amount: $500 ck 1826

SECTION 3.3.

ATTACHMENT

Edward P. Kramm
Chief Executive Officer

In July of 2018, Mr. Kramm renewed his Kansas Pharmacist license. The due date to complete CE and submit renewal was 6/30/2018. He was out of the country without access to his completed CE and so in July, upon his return to the states, he submitted his completed CE to the CE sponsors. The CE units were dated after the due date so Kansas did not recognize them in the license period which meant he had made an incorrect attestation on his renewal. Inasmuch as Mr. Kramm had not practiced pharmacy since 2008 and pursuant to his request, the Board agreed to retroactively place his license on inactive status beginning July 1, 2018. A Stipulation and Consent Order was executed. The Order included the requirements for changing his license to active status in the future, if desired. Mr. Kramm determined that he would not practice pharmacy at any time in the future so he let his license officially expire on 6/30/2022 and the matter was closed. It is important to note that Mr. Kramm did not practice without a license at any time. **SEE ATTACHED**

Filed By

KANSAS STATE
BOARD OF PHARMACY

BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of the Renewal Application of Edward (Ted) Kramm License No.1-12056	))))))	Case No. 18-750

STIPULATION AND CONSENT ORDER

IT IS HEREBY STIPULATED AND AGREED by and between the Kansas Pharmacy Board (the "Board") and Edward (Ted) Kramm ("Respondent") as follows:

1. The Board is represented herein by its attorney, Randall J. Forbes of Frieden, Unrein & Forbes, 1414 SW Ashworth Place, Suite 201, Topeka, Kansas 66604. The Respondent is represented herein by attorney. N/A.

2. The Board is the Kansas agency vested with the authority to carry out and enforce the provisions of the Kansas Pharmacy Law, K.S.A. 65-1626 *et seq.*, (the "Act") including conducting hearings and proceedings to revoke, suspend, or otherwise discipline a Kansas license to practice pharmacy, including imposing an administrative fine or penalty.

3. The Respondent is presently entitled to engage in the practice of pharmacy in the State of Kansas by reason of the Board having issued Respondent Kansas license number 1-12056 ("Kansas License"). At all times relevant hereto, the Respondent has held a current license to engage in the practice of pharmacy in the State of Kansas.

4. Respondent hereby admits and waives any further proof in this or any other proceeding before or initiated by the Board, and upon motion duly made, seconded and passed, the Board finds as follows:

- On July 25, 2018, Respondent submitted a renewal application to engage in the practice of pharmacy in the State of Kansas.

- In the renewal application, Respondent requested to renew the license on active status.
- At the end of the renewal application, Respondent agreed to the following statement prior to submitting the completed renewal application: "I hereby attest that I have completed all continuing education hours required by law to renew my license."
- Respondent's renewal application was selected for an audit to provide proof of Respondent's continuing education certificates or a transcript of completion of required hours.
- Respondent provided proof of two hours of continuing education to renew Respondent's pharmacy license.
- On May 2, 2019, Respondent indicated he has not practiced pharmacy for several years and wants to retroactively renew his license on inactive status, which does not require continuing education.
- Pursuant to K.A.R. 68-1-1b, 30 hours of continuing education shall be required for renewal of a pharmacist license during each licensure period, which must be obtained in the two-year licensure period ending on the June 30 expiration date of each license.
- Respondent was required to provide proof of completion of 30 hours of continuing education earned between July 1, 2016 and June 30, 2018.

5. Upon motion duly made, seconded and passed, the Board finds and concludes that Respondent's conduct, as described above, violates the Act is therefore grounds for disciplinary action against Respondent's Kansas License pursuant to 65-1627(a)(1) and (a)(9).

6. The Respondent agrees and consents and the Board finds, concludes, and orders that the following disposition is just and appropriate under the circumstances:

A. Respondent's Kansas license to practice pharmacy is retroactively placed on inactive status beginning July 1, 2018.

B. If Respondent seeks to change the license to active status in the future, Respondent shall be required to pay a $2,800 fine and provide proof of an additional 112 hours of completed continuing education for failing to comply with K.S.A. 65-162(a)(1) and (a)(9), in addition to any other fees and requirements established by law. Completion of these hours shall not count toward any subsequent continuing education requirement for Respondent's Kansas license.

7. Respondent agrees that all information in the possession of the Board's Executive Secretary, its staff, its investigators and or its attorney regarding the investigation which lead to this disciplinary action and all information discovered during the pendency of the disciplinary action may be disclosed to and considered by the Board as part of the presentation and consideration of the proposal of settlement in the form of this Stipulation and Consent Order and the Final Order provided for herein, with or without the presence of the Respondent or its attorney. In the event that this Stipulation and Consent Order and the Final Order provided for herein are not accepted and approved by the Board, the Respondent further waives any objection to the Board members' consideration of this Stipulation and Consent Order or the information mentioned in the preceding sentence and further agrees to waive any claim of due process violation or the right to seek the disqualification of any Board member as a result of the Board member's consideration of said document and information.

8. The stipulations contained herein shall not become binding until this Stipulation and Consent Action is approved by the Board and the Final Order provided for herein is entered by the Board. The Respondent acknowledges that the approval of the Board's Executive Secretary or its attorney shall not constitute the approval of the Board or bind the Board to approve this Stipulation and Consent Action or the Final Order provided for herein.

9. The Respondent agrees that this Stipulation and Consent Order is in conformance with Kansas and federal law and the Board has jurisdiction to enter into it and enter the Final Order provided for herein. The Respondent further agrees, for purposes of this matter, that the Kansas Pharmacy Act, K.S.A. 65-1626 *et seq.* is constitutional on its face and as applied in this case.

10. This Stipulation constitutes the entire agreement of the parties and may only be modified by a subsequent writing signed by them. The agreement shall be interpreted in accordance with the laws of the State of Kansas.

11. The Respondent acknowledges that Respondent has the following rights:

(a) To have formal notice of charges served upon him;

(b) To file a response to the charges;

(c) To have notice of and participate in a formal adjudicative hearing with the Board or its designee making specific findings of facts and conclusions of law based only upon evidence admitted at such hearing; and

(d) To take advantage of all applicable provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501 *et seq.* and the Kansas Judicial Review Act, K.S.A. 77-601 *et seq.*

The Respondent freely waives these rights and acknowledges that said waiver is made voluntarily and in consideration of the Board's limiting the disciplinary action taken against him to those provided for herein. The Respondent further waives the right to seek reconsideration or appeal or otherwise contest this Stipulation and Consent Order and the Final Order provided for herein.

12. The Respondent acknowledges that Respondent enters into this Stipulation and Consent Order freely and voluntarily after consultation with counsel of his choosing. The Respondent further acknowledges that Respondent has read this Stipulation and Consent order in its entirety, understands its legal consequences, and agrees that none of its terms are unconscionable, arbitrary, or capricious.

13. Time is of the essence to this Stipulation and Consent Order. Respondent acknowledges and agrees that any violation of this Stipulation and Consent Order shall constitute a willful violation of a lawful Board order and grounds for further disciplinary action against him. The pendency of any disciplinary action arising out of an alleged violation of this Stipulation and Consent Order shall not affect the obligation of Respondent to comply with all terms and conditions of this Stipulation and Consent Order.

14. This Stipulation and Consent Order constitutes the entire and final agreement of the parties. In the event any provision of this Stipulation and Consent Order is deemed invalid or unenforceable by a court of competent jurisdiction, it shall be severed and the remaining provisions of this Stipulation and Consent Order shall be given full force and effect.

15. Upon approval and entry of the Final Order by the Board, this Stipulation and Consent Order shall be a public record in the custody of the Board.

16. This Stipulation and Consent Order shall become effective on the day it is approved, accepted, and made an order of the Board by way of signature of the Board's authorized representative.

17. The Respondent acknowledges that Respondent has been advised by the Board that Respondent would have the right within 15 days after service of the Final Order provided for herein to file a petition for reconsideration with the Board and the right within 30 days after service of the Final Order provided for herein to file a petition for judicial review in the District Court of Shawnee County, Kansas in accordance with the Kansas Judicial Review Act, K.S.A. 77-601 *et seq.* and to serve such a petition for judicial review on the Kansas Board of Pharmacy by serving Alexandra Blasi, JD, MBA, Executive Director, at 800 SW Jackson St., Suite 1414, Topeka, KS 66612. The Respondent hereby waives those rights.

ENTERED AND EFFECTIVE this 10th day of June, 2019.

KANSAS BOARD OF PHARMACY

By: _____
DR. JOHN WORDEN
President

AGREED AND APPROVED BY:

Respondent — Date 6/21/19

Alexandra Blasi
Executive Secretary — Date 6/6/19

Respondent's Attorney's Name & Address — Date

Randall J. Forbes, KS#09089 MO#64335
FRIEDEN, UNREIN & FORBES, LLP
1414 SW Ashworth Place, Suite 201
Topeka, KS 66604
(785) 354-1100 — Date 06/06/2019

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing STIPULATION AND CONSENT ORDER was served by depositing same in the United States mail, postage prepaid, this 10th day of June, 2019 addressed to:

EDWARD (TED) KRAMM
[redacted]
OVERLAND PARK KS [redacted]

Kansas Board of Pharmacy Staff

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

Healthcare Branch
State Board of Pharmacy

December 27, 2016

Mohammad A. Pourteymaur

CERTIFIED AND FIRST CLASS MAIL

RE: Case 2016-3681

Dear Mr. Pourteymaur:

At its November 17, 2016 meeting, the Colorado State Board of Pharmacy ("Board") reviewed the above-referenced complaint. After careful consideration of all the evidence before the Board, the Board determined that upon your initial application for pharmacist licensure in the State of Colorado, you did not attest that you had disciplinary action taken against your license or pending against you in any state when you should have attested to this fact.

The Board hereby admonishes the pharmacy for violation of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act and Board Rules.

This admonishment shall be made a part of the permanent records of the Board and is reportable as a disciplinary action. It may also be considered as an aggravating factor if you incur future violations. You may request that a hearing be initiated by the Board if you wish to dispute the information in this letter. The purpose of such a proceeding would be to adjudicate the propriety of the conduct upon which this letter is based. The Board must receive such a request from you within 20 days after you receive this letter.

If you make a timely request, the letter of admonition shall be deemed vacated pending resolution of formal disciplinary proceedings. Those proceedings involve a hearing conducted in accordance with the State Administrative Procedures Act.

Sincerely,

FOR THE COLORADO STATE BOARD OF PHARMACY

Chris Gassen, R.Ph.
Pharmaceutical Inspector
Acting Program Director

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

MOHAMMAD A. POURTEYMAUR, R.Ph.,
Certificate of Registration #13759,

Respondent.

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

Case No. 08-032-RPH-S

THIS MATTER was heard by the Nevada State Board of Pharmacy (hereinafter Board) at its regular meeting on October 29, 2008, in Las Vegas, Nevada. The Board was represented by Carolyn J. Cramer, General Counsel for the Board. Respondent Mohammad A. Pourteymaur appeared and represented himself. Based on the presentation of Mr. Pourteymaur, and the public records in the possession and control of the Board, the Board issues the following Findings of Fact, Conclusions of Law, and Order:

FINDINGS OF FACT

1. At hearing, Mr. Pourteymaur admitted the facts as plead in the Notice of Intended Action and Accusation were true and correct. At hearing, Mr. Pourteymaur testified by way of explanation and mitigation. Based upon the Respondent's admissions and the evidence presented at hearing, the following are found to be the facts of this matter.

2. Mr. Pourteymaur timely submitted the application for renewal of his pharmacist's license. On his renewal application he indicated that he had completed 30 hours of continuing education. Mr. Pourteymaur's renewal application was included in a random sample to be audited. The audit revealed that Mr. Pourteymaur had completed

zero hours of continuing education between November 1, 2005 and October 31, 2007.

3. At hearing, Mr. Pourteymaur testified that he has been in medical school since August of 2002 and has been taking some pharmacy related courses, but that the classes were not ACPE accredited classes. Additionally, Mr. Pourteymaur testified he had personal matters over the time in question such as deaths and births in his family that took his time. Mr. Pourteymaur also expressed regret that he had answered the question affirmatively stating that he had completed the course work when he knew that he had not and offered classes he took after the renewal period in mitigation to the Board.

CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter and this respondent because Mr. Pourteymaur is a pharmacist licensed by the Board.

2. In indicating on his renewal application that he had completed 30 hours of continuing education on his renewal application when he had taken zero hours of course work, Mr. Pourteymaur violated NRS 639.210(4) and (9) and 639.2174(2) and NAC 639.330 and 639.390.

ORDER

Based upon the foregoing, the Board hereby orders the following:

1. For the renewal period of November 1, 2005 through October 31, 2007, Mr. Pourteymaur shall complete 30 hours of continuing education. Mr. Pourteymaur will not be given credit for any of the continuing education classes he completed prior to October 29, 2008.

2. For the renewal period of November 1, 2007 through October 31, 2009, Mr. Pourteymaur will complete 60 CE's. Mr. Pourteymaur' continuing education hours will

be audited to verify that he has completed the 60 hours of continuing education required by this Order.

3. Mr. Pourteymaur shall pay a fine of $1,000.00 by cashier's or certified check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office within 60 days of the effective date of this Order.

4. Mr. Pourteymaur will not be allowed to inactivate his license.

5. Mr. Pourteymaur must take and pass a written law examination provided by Board staff within 30 days of receipt of the examination.

6. The failure by Mr. Pourteymaur to comply with any term in this order shall result in the immediate suspension of his license and will also result in further discipline, up to and including revocation of the his license.

Signed and effective this 25th day of November, 2008.

Barry Boudreaux, President
Nevada State Board of Pharmacy

EXHIBIT

Total Infusion Care, LLC
A Nevada Limited Liability Company
FEIN #46-1531228

Officers

Name	Title	Business Address
Kathee M. Kramm	President	855 SW 78th Ave #C200 Plantation, FL 33324
Edward P. Kramm	Chief Executive Officer	855 SW 78th Ave #C200 Plantation, FL 33324
Morgan M. Harber	Vice President and Secretary	855 SW 78th Ave #C200 Plantation, FL 33324
Daniel M. Cammarata	Treasurer	855 SW 78th Ave #C200 Plantation, FL 33324

Manager/s

Name	Title	Business Address
BioMatrix Specialty Pharmacy, LLC	Member Manager	855 SW 78th Ave #C200 Plantation, FL 33324

Member/s

Name	Title	Percentage Interest Held	Business Address
BioMatrix Specialty Pharmacy, LLC	Sole Member	100%	855 SW 78th Ave #C200 Plantation, FL 33324

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Total Infusion Care LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 11/05/2025, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 11/21/2025.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202511216296748
You may verify this certificate online at https://www.nvsos.gov/sosentitysearch/

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: LUX Infusion 13

Pharmacy/Wholesaler License # (if applicable): PH 02936

Physical Address: 3041 W Horizon Ridge Pkwy, #100

City: Henderson State: NV Zip: 89502

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 702-778-8880 Website: www.biomatrixsprx.com

Licensing Company Email: rhansen@rchconsult.com

Section 2: Personal Information

First: Jonathan Middle: Ka-Lok Last: Chan

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520 NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Roseman University of Health Sciences		08/18-05/21	
Address	**City**	**State**	**Zip**
11 Sunset Way	Henderson	NV	89014
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of California, Irvine		09/2011-06/2014	
Address	**City**	**State**	**Zip**
260 Aldrich Hall	Irvine	CA	92697
Diploma/Degree obtained, if any			
Bachelor's of Science, Biology			

School Name		From - To (MM/YY – MM/YY)	
Ruben S. Ayala High School		09/14-06/18	
Address	**City**	**State**	**Zip**
14255 Peyton Dr	Chino Hills	CA	91709
Diploma/Degree obtained, if any			
H.S. Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed)

From - To (MM/YY – MM/YY)	[redacted]			
04/23-current				
From - To (MM/YY – MM/YY)				
10/14-04/23				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record-keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Smith's Food and Drug #306			05/25-02/26
Business Address	**City**	**State**	**Zip**
2255 Las Vegas Blvd, N	North Las Vegas	NV	89030
Phone	**Title**		**Number of Employed Hours**
702-642-8092	Pharmacy Manager		1440
Description of Duties			
Managed day-to-day operations in a retail setting			

Business Name			From - To (MM/YY – MM/YY)
Smith's Food and Drug #306			12/21-05/25
Business Address	**City**	**State**	**Zip**
2255 Las Vegas Blvd, N	North Las Vegas	NV	89030
Phone	**Title**		**Number of Employed Hours**
702-642-8092	Staff Pharmacist		7200
Description of Duties			
Dispensed, vaccinations, drug utilization review			

Business Name			From - To (MM/YY – MM/YY)
Total Infusion Care			09/21-01/24
Business Address	**City**	**State**	**Zip**
3041 W. Horizon Ridge Pkwy, #100	Henderson	NV	89052
Phone	**Title**		**Number of Employed Hours**
702-778-8880	Clinical Pharmacist		4680
Description of Duties			
Clinical managed acute patients in infectious disease and chronic patients on specialty medications requiring at-home or AIS infusions.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Jonathan Chan, certify that as the designated representative for

LUX Infusion 13,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JC I am at least 21 years of age;
3. JC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jonathan Chan
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/3/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Chan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/3/2026

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, JONATHAN CHAN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/3/2026

Date

STATE OF NEVADA
COUNTY OF CLARK

Subscribed and Sworn to before me this 3 day of MARCH 2026

Chris Manolidis

Notary Public Signature

Notary Public - State Of Nevada
COUNTY OF CLARK
CHRIS MANOLIDIS
My Appointment Expires
April 1, 2028
No. 22-5076-01

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Total Infusion Care LLC

NV Pharmacy or Outsourcing facility license # (if applicable): PH 02936

Physical Address: 3041 W Horizon Ridge Pkway, #100

City: Henderson State: NV Zip: 89502

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 702-778-8880 Toll Free # (NAC 639.708, NRS 639.23286): 888-482-2730

Fax: 701-778-8882 Contact Email: rhansen@rchconsult.com

Website: www.biomatrixsprx.com

Nevada Business License # (if applicable) NV20253470488

Supervising/Managing Pharmacist Name (NRS 639.220): Mohammad Pourteymaur

Supervising/Managing Pharmacist NV Pharmacist Registration #: 13759

Name of Designated Person(s) as defined by revised USP-797 guidelines: Brianna Morris

Email of Designated Person(s): brianna.morris@biomatrixsprx.com

Telephone of Designated Person(s):

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

   ☑ Category 1 ☑ Category 2 ☐ Category 3

   If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ☑ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☑ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ☑ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 12/4/2025

6. What is the frequency of the recertification for the ISO classified areas? every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ☑ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☑ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? monthly

10. Will you be performing sterile hazardous drug compounding? ☐ Yes ☑ No

    If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

--Antibiotics
--TPN
--Intravenous iron infusions
--Specialty Infusion

12. What laboratory performs your sterility or endotoxin testing?

Name: Technical Safety Services

Address: 4220 Executive Square, Suite 370

City: La Jolla State: CA Zip: 92037

Telephone: 800-877-7742

13. What is your procedure for visual inspection of compounded sterile products?
Visual inspections: components & final CSP, label (including BUD assignment & storage conditions), and container closure system are inspected.

14. How often do you perform glove fingertip and medial fill testing?
Compounding personnel--every 6 months
Overseeing pharmacists (non-compounding)--annually

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
See attached policy 797.16, Section 4.5 which outlines both initial and ongoing training for sterile compounding personnel.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
See attached policy 797.03 which outlines all cleaning frequencies (Sec. 4.1) and agents (Sec. 2.10) used.

17. Who performs the sterile compounding process at your facility?
Names of compounding personnel: Brianna Morris, Justin Estella, Kalvin Edquiban, and Michean Heffron

18. Who is responsible and accountable for the sterile compounding process at your facility?
Designated person: Brianna Morris
Responsible PIC: Mo Pourtemayer

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
See attached policy 797.05 which outlines transport of CSPs and the required packaging utilized (Sec 4.3)

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Are you complying with all USP 800 guidelines?	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding:)

1. List the specific Category 3 sterile products that your facility compounds:

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?		
6. What is the frequency for using sporicidal agents?		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

CASEY COOPER, PHARM.D.

Name of Person who Completed the Form

DIRECTOR, PHARMACY POLICY + STANDARDS

Title

C. Cooper Pharm.D.

Signature (copies or stamps not accepted)

1/26/26

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

[BIOMATRIX]

Policy Title: Quality Assurance & Quality Control Program – Sterile Compounding

Department: Pharmacy

Effective Date: 1/1/2026

Policy Number: 797.16

Applicability:

This policy applies to (1) BioMatrix and its wholly-owned subsidiaries and affiliates (each, an "Affiliate"); (2) any other entity or organization in which BioMatrix or an Affiliate owns a direct or indirect equity interest of greater than 50%; and (3) any entity in which an Affiliate either manages or controls the day to day operations of the facility each, a "BioMatrix Entity" (collectively, "BioMatrix" or "Company").

Purpose:

- This policy describes the Sterile Compounding Program quality assurance and quality control responsibilities and processes for BioMatrix Infusion Pharmacies where Compounded Sterile Preparations (CSPs) are compounded, verified, and stored prior to dispensing. The policy serves as BioMatrix Infusion Pharmacies' written Quality Assurance and Control Program ("Quality Program") consisting of:
  - **Quality Assurance (QA)**: The procedures, activities, and oversight that ensures the compounding process consistently meets quality standards
  - **Quality Control (QC):** The sampling, testing, and documentation of results that, when taken together, ensure CSP specifications have been met prior to release and dispensing
- The Quality Program is a comprehensive system that supports continual quality improvement within the Sterile Compounding Program and is designed to ensure:
  - Regulatory and statutory compliance
  - Adherence to policies and procedures
  - Prevention and detection of errors or other quality deficiencies
  - Evaluation and handling of complaints and adverse events
  - Appropriate investigations and corrective actions
- The Quality Program integrates information and data collected from patients, caregivers, and providers; compounding and support personnel; technical, mechanical, and scientific professionals; and supporting organizational and industry experts with the ultimate goal of ensuring patient safety through consistent and repeatable high quality CSPs prepared in a safe and controlled compounding environment.

Scope:

This policy applies to all clinical and administrative personnel involved in the provision, coordination, and support of services provided by BioMatrix Specialty Pharmacy.

Definition(s):

- **Cycle parameters**: A description of the unique sterilization or depyrogenation parameters used for a defined purpose or process including temperature, duration, and pressure (if appropriate).
- **Cycle validation indicators**: including biological indicators and endotoxin challenge vials (ECVs) used to validate the respective sterilization or depyrogenation cycles achieved the conditions necessary to achieve the desired result in the CSPs or items included in the cycle; is not absolute proof of sterility (or depyrogenation).
- **Load characteristics**: A description and visual representation/diagram of each sterilization or depyrogenation process such as maximum number of items loaded, configuration and placement of items inside the load, and wrapping, if any, of the loaded items
- **Oversight:** The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available for consultation if and when needed even if not physically present.
- **Quality assurance (QA):** A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
- **Quality control (QC)**: The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.
- **Release inspection and testing:** Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
- **Specification:** The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.
- **Verify:** To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use

Roles & Responsibilities:

1. The Designated Person(s) (DP):
   - Partner with Director of Clinical operations and Supervising Pharmacist to develop, implement, and manage the Sterile Compounding Quality Program
   - Educate Compounding Personnel on the Quality Program including individual and team quality related responsibilities, processes, documentation, and tools
   - Alert and engage the Director of Clinical Operations and Supervising Pharmacist of issues impacting quality or regulatory and/or statutory changes impacting the Quality Program
   - Ensure quality assurance audits of the Sterile Compounding Practice compliance and related documentation are conducted on a timely basis
   - Oversee remediation and documentation of any deficiencies found in QA audit process
2. Compounding Personnel:
   - Understand individual and compounding team role and responsibilities in supporting sterile practice quality assurance and control through compliance with all the Sterile Compounding Program policies and procedures (i.e., Standard Operating Procedures or SOPs)
   - Alert DP or compounding supervisor of any known or suspected deficiencies, failures, or out of specification results related to any aspect of sterile compounding operations and assist with remediation efforts if appropriate, including, but not limited to issues with:
     Facilities operations or certification

Engineering controls (e.g., PECs/SECs)
Environmental controls for compounding and drug storage locations (e.g., pressure differentials, temperatures, humidity; functioning of HVAC or airflow systems)
Equipment, supplies, components, containers
Cleaning, disinfecting, or application of sporicidal disinfectants
Materials movement and personnel conduct with controlled areas
Sterile compounding and release inspections and tests
Personnel training and competency evaluations
Documentation of compliance activities

3. Director of Policy and Supervising Pharmacist:

- Partner with DP to understand sterile practice regulatory and statutory requirements, how to locate and interpret compliance documentation, QA/QC audit parameters, and specifics of BioMatrix Infusion Pharmacies' sterile compounding Quality Program
- Conduct and document findings of independent sterile compounding QA audits per policy
- Communicate QA audit results to DP and pharmacy staff.

Partner with DP to resolve audit deficiencies; conduct follow up verification of corrective actions taken to resolve deficiencies

Policy:

1. [USP 1163] The Director of Clinical Operations is responsible to define, implement, and oversee BioMatrix Infusion Pharmacies' Quality Program and ensure it includes, at a minimum, the following integrated components:

   i. Compounding Personnel Training & Competency Evaluation
   ii. Standard Operating Procedures (SOPs)
   iii. Compliance Documentation Review & Audit
   iv. CSP Verification
   v. CSP Release Inspections & Testing
   vi. Controlled Area(s) Cleaning, Disinfecting, & Safety
   vii. CSP Containers, Packaging, Repackaging, Labeling, and Storage Practices
   viii. Responsible Personnel
   ix. [Compounding at outsourced vendors, suppliers & laboratories only] Outsourcing Documentation Supporting BUD Assignments and Release Testing Results

2. [USP 797] Sterile Compounding Program compliance related activities and documentation (e.g., inspection or analytical laboratory reports, competency forms and checklists, electronic and written records, and supporting documentation) are reviewed and audited at least once annually to ensure:

   i. All required regulatory and statutory sterile compounding requirements are successfully completed within the appropriate timeframe, memorialized with the appropriate documentation, and reviewed by the DP (if appropriate)
   ii. Out of specification findings, occurrences, and events are investigated and remediated
   iii. Corrective actions are fully documented, and data collected in response to corrective actions is reviewed to confirm action taken have been effective
   iv. Opportunities of continual process improvement are identified and initiated

3. [Best Practice] Sterile compounding personnel performance and technique are audited on a regular and ongoing basis to validate compliance with procedures, workflows, and conduct as defined in Sterile Compounding Program policies and procedures designed to maintain a state of control in the compounding environment and ensure patient safety through the preparation of sterile, accurate, and consistent CSPs.
4. The pharmacy will perform 2 separate sterility tests on compounded Total Parenteral Nutrition (TPN) every 6 months. These will be from separate days and are done to validate BioMatrix Infusion Pharmacy use of automated compounding device for compounding TPN therapy.
    a. From 01 MAY 2024 – Using QI Medical QuickTest System – QT3000 – per manufacturer instructions. Incubated at 20 to 25°C for 14 days per manufacturer.
    b. Prior to 01 MAY 2024 – Using QI Medical QT Junior System – TJ3100 – per manufacturer instructions. Previously incubated at 30 to 35C for 14 days; updated as of 2/20/2024 to incubate per manufacturer instructions at 20 to 25°C for 14 days. An 8mL sample of a TPN without lipid emulsion was aseptically extracted from a compounded TPN within the PEC and added to the QT Junior system.

Procedure:

[USP 797] **Sterile Program Quality Assurance Compliance Review & Audit**

1. [USP 797] Review Sterile Compounding Program compliance activities and audit at least once annually to ensure all regulatory and statutory requirements and supporting documentation are effectively and fully completed within the appropriate timeframe(s) and per policy. This audit also confirms DP and compounding personnel compliance with policies and procedures and allows for the detection and potential prevention of other quality deficiencies.
2. Confirm compliance documentation is retained in a readily retrievable electronic and/or written format and can be easily located with minimal instruction.
3. **Facilities and environmental controls QA audit parameters** follow criteria in the table below. Refer to the **Facilities & Environmental Controls policy** and **Certification & Recertification policy** for additional information regarding these regulatory requirements.

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
FACILITIES & ENGINEERING CONTROLS		
Sterile facilities certification / recertification	Initially & every 6 months* *Performed by a qualified certification vendor*	• Formal sterile suite certification report & ISO classification certificate for each sterile suite/area; includes: ○ Total particle count testing under dynamic conditions (SECs only) ○ Airflow testing results demonstrating air velocity, room air exchange rate, and room pressure differentials at doorways (SECs only) ○ HEPA filter integrity testing (SECs & PECs) ○ Dynamic airflow smoke pattern test (PECs only) • Certificate of compliance posted on each PEC

[BIOMATRIX]

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
Total particle counts / ISO classifications		• Sampling plan diagram • ISO Class 5 (PEC): < 3520/m^3 • ISO Class 7 (Buffer Room & Ante Room to a Hazardous Buffer Room): < 352,000/m^3
SEC air exchanges per hour (ACPH)		• ISO Class 7 Areas: ≥ 30 ACPH *(must show contribution of ACPH from HVAC system and PECs separately plus total ACPH)* • ISO Class 8 Areas: ≥ 20 ACPH
SEC pressure differentials (at doorways)		• Positive pressure to neutral areas (Ante to Non-classified Area): +0.02 in. w.c. • Positive pressure to positive pressure area (Ante to Buffer): +0.02 in. w.c. • Positive pressure to negative pressure area (Ante to Hazardous Ante/Drug Storage/Buffer): -0.01 to -0.03 in. w.c. • Negative pressure to negative pressure area (Hazardous Ante/Drug Storage to Hazardous Buffer): -0.01 to -0.03 in. w.c.
SEC & PEC HEPA filter integrity testing		• 99.97% efficacy documented for each HEPA filter • Description of patch size applied to HEPA filter *(PEC HEPA filters should not exceed 2% of filter surface area)*
PEC dynamic airflow smoke patter test & video		• Documented and video evidence of successful completion of airflow smoke pattern test performed *"under dynamic operating conductions demonstrating unidirectional airflow and sweeping action over and away from the preparation"*
OOS or Failure Investigation & Corrective Action Plans	As needed	• Documentation of facilities or engineering controls OOS or failures, investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken have been effective
ENVIRONMENTAL CONTOLS		
SEC pressure differentials (at doorways)	Measured by continuous monitoring device	• Daily review and documentation of pressure differentials every day compounding occurs (see above for required pressure differential values/ranges)
SEC and drug storage location temperatures	Measured by continuous monitoring device or recorded manually	• Daily review and documentation of compounding room and drug storage location temperatures every day compounding occurs ○ Compounding areas: ≤ 20°C *(recommended for compounder comfort; not a firm requirement)* ○ Ambient Drug Storage Areas (Controlled Room Temp): 20 - 25°C ○ Refrigerated Drug Storage Areas: 2 - 8°C ○ Frozen Drug Storage Areas: -25 to -10°C
SEC humidity		• Daily review and documentation of compounding room humidity every day compounding occurs ○ Compounding areas: ≤ 60% *(recommended for compounder comfort; not a firm requirement)*
Calibration, maintenance, and certification records	Every 12 months	For each continuous monitoring system, device, or gauge monitoring pressure differentials, temperatures (room and drug storage locations), and humidity: • Documentation of annual calibration and certification by a qualified technician • Documentation of maintenance as needed
OOS or Failure Investigation &	As needed	• Documentation of daily pressure differential, temperature, or humidity monitory OOS or failures results, investigation to

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
Corrective Action Plans		determine root cause(s), corrective action plan, and review of remediation to confirm actions taken have been effective

*Facilities are also recertified after events impacting the quality of the environment including, but not limited to redesign, construction/major repairs, relocation or replacement of PEC, or room configuration/traffic pattern changes that could affect airflow or air quality.

4. **Microbial air and surface sampling QA audit parameters** follow criteria in the table below. Refer to the **Microbial Air & Surface Sampling policy** and **Out of Specification policy** for additional information regarding these regulatory requirements.

<table>
<tr><th>Requirement</th><th>Compliance Activity Frequency</th><th>Quality Assurance Parameter</th></tr>
<tr><td colspan="3">MICROBIAL AIR & SURFACE SAMPLING</td></tr>
<tr><td>Viable Air Sampling Results</td><td>Every 6 months</td><td rowspan="2">• Viable sampling diagram (including sites within PECs and SECs sufficient to adequately characterize the state of microbial control within area)
• Sampling results reports:
○ Date, time, & person performing sampling
○ Identification of sampling locations and person/entity who performed sampling
○ Media incubation dates and temperatures
○ Media used: manufacturer, lot number, expiration date, and validation of growth promotion (e.g., control plate results)
○ Sampling equipment used: manufacturer, model, certification
○ CFU enumeration per site (reported as a single number per site if only TSA media plates used; reported as 2 separate numbers if two types of media plates are used per site)
○ Microbial identification of CFUs to the genus level (not required unless action levels are exceeded)
<table><tr><th>ISO Class</th><th>Viable Air Sample
CFU/m³ of air per plate (1000L sample)</th><th>Viable Surface Sample
CFU per sampling plate</th></tr><tr><td>ISO 5</td><td>> 1</td><td>> 3</td></tr><tr><td>ISO 7</td><td>> 10</td><td>> 5</td></tr><tr><td>ISO 8</td><td>> 100</td><td>> 50</td></tr></table></td></tr>
<tr><td>Surface Sampling Results</td><td>Every Month</td></tr>
<tr><td>[Best Practice]
Sampling results after OOS events</td><td>As needed and for major air handling system maintenance</td><td>• OOS event written description including:
○ Date, time, and location (e.g., area(s) impacted)
○ Impact to environmental controls (e.g., pressure differentials, temperatures, and/or humidity)
○ Impact to operations of PECs, if applicable
○ Impact to compounding operations and immediate remediation steps taken (e.g., restricting compounding operations, temporarily reclassifying sterile suite as a SCA or Category 1 compounding with BUDs limited to a maximum of 12 hours room temp or 24 hours refrigerated, etc.)
○ Remedial cleaning after event, if applicable
○ Validation of restored state of microbial control (e.g., sampling results report)</td></tr>
<tr><td>OOS or Failure Investigation &</td><td>As needed</td><td>• Documentation of OOS results (e.g., CFUs exceeding action levels at any site, pathogenicity of microorganisms identified, or trends</td></tr>
</table>

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
Corrective Action Plans		of actionable results, etc.), investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken were effective • Resampling report results confirming successful remediation
COAs for media used onsite	Media ordered for environmental sampling	For each lot of media used: • Manufacturer (or internal) lot number and expiration date • Manufacturer COA verifying media has been tested and meets expected microbial growth promotion, media pH within acceptable limits, and sterilization requirements

5. **Personnel training and competency QA audit parameters** follow criteria in the table below. Refer to the **Personnel Training & Evaluation policy** for additional information regarding these regulatory requirements.

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
PERSONNEL TRAINING & COMPETENCY EVALUATIONS		
Compounding Personnel	Initially & every 6 or 12 months depending on evaluation	**For each employee:** • Competency documentation showing successful completion initially (prior to compounding) and <u>every 12 months</u> of: 1. **Foundational and job-related knowledge exam** – ▪ <u>Initially & Ongoing</u>: minimum 80% passing score 2. **Observed validation of core skills** in maintaining the quality of the sterile compounding environment (e.g., cleaning, materials movement, etc.) ▪ <u>Initially & Ongoing</u>: 100% observed skills assessment • Competency documentation showing successful completion initially (prior to compounding) and <u>every 6 months</u> of: 3. **Observed Hand Hygiene & Garbing Competency** including gloved fingertip (GFT) results – ▪ <u>Initially</u>: performed three (3) times with zero (0) CFUs detected & 100% passing score ▪ <u>Ongoing</u>: performed once with zero (0) CFUs detected & 100% observed skills assessment 4. **Observed Aseptic Technique Competency** including media fill (MF) and post media fill GFT and surface sample (SS) results ▪ Initial & Ongoing: no turbidity in MF, <u>≤</u> 3 CFU on GFT, & <u>≤</u> 3 CFU on SS & 100%% observed skills assessment • Documentation of media manufacturer, lot number, & expiration date plus incubation dates and temperatures for competencies using media (i.e., #3 & #4) • Evaluation date, time, and evaluator name for all observed competencies (i.e., #2, #3, & #4)
Personnel directly overseeing compounding	Initially & every 12 months	See above <u>Exception</u>: #3 & #4 competencies are performed initially and once every 12 months
Personnel performing	Initially & every 12 months	See above

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
Allergenic Extract Compounding		Exception: #3 & #4 competencies are performed initially and once every 12 months. If employee does not compound AEs for > 6 consecutive months, employee successfully repeats all initial evaluations (#1 - #4) prior to compounding independently
Personnel performing Immediate Use Compounding	Initially & every 12 months	See above Exception: personnel who exclusively perform immediate use compounding are only perform job-related knowledge exam (#1) & observed core skills assessment (#2)
Personnel providing supporting roles	Initially & every 12 months	• Personnel who exclusively performing supporting roles located outside of controlled compounding areas (e.g., Pharmacy coordinators and drivers are evaluated on placing items onto the anteroom cart and removing items from the anteroom cart to ensure no outside packaging/corrugated cardboard and that only one cleanroom site door is open at a time.)
Compounding Personnel performing specialized roles	Initially and every 12 months	For each compounder performing a specialized role (e.g., Assigned Sterile Trainers and personnel performing air and/or surface sampling, managing incubation of media): • The DP observes and documents competency in the specific skills and knowledge needed to perform the specialized role
Competency Failure & Corrective Action Plans	As needed	• Documentation and description of failed results, investigation, prescribed remedial training and/or corrective action plan, and review of remediation to confirm actions taken were effective • Results of repeated competencies (required for failures, refer to policy for more information)
COAs for media used onsite	Media/media fill components ordered for personnel sampling	For each lot of media used: • Manufacturer (or internal) lot number and expiration date • Manufacturer COA verifying media has been tested and meets expected microbial growth promotion, media pH within acceptable limits, and sterilization requirements

6. **Cleaning of controlled compounding area QA audit parameters** follow criteria in the table below. Refer to the **Cleaning, Disinfecting, & Application of Sporicidal Agent policy** for additional information regarding these regulatory requirements.

<table>
<tr><th>Requirement</th><th>Compliance Activity Frequency</th><th>Quality Assurance Parameter</th></tr>
<tr><td colspan="3">CLEANING & DISINFECTING</td></tr>
<tr><td>Cleaning, Disinfecting, & Application of Sporicidal Agents</td><td>Per Policy</td><td>Refer to the policy for a detailed description of the cleaning tasks, frequency, and agents to be used; in general, the following occurs:
<table>
<tr><th>Minimum Frequency</th><th>Task/Area</th><th>Cleaning Agent</th></tr>
<tr><td>Daily</td><td>Cleaning & disinfecting:
• Interior of each PEC (including work tray)
• Equipment resident in PEC
• Pass Through(s)
• Work surfaces outside of PEC and with SECs (or SCA)</td><td>EPA registered one step disinfectant cleaner or separate agents</td></tr>
</table>
</td></tr>
</table>

Requirement	Compliance Activity Frequency	Quality Assurance Parameter		
			• Floors • Sinks	
		Monthly	• All daily tasks (above) • Underneath PEC work tray • Walls & Ceilings • All surfaces outside of PEC (not only high touch) • Storage bins & shelves • Equipment outside of PECs	Sporicidal Agent (with cleaning & disinfecting activity)
		Ad Hoc	As determined by the DP or per policy for Out of Specification (OOS) occurrences	
		• Timely and complete documentation of regularly scheduled and ad hoc cleaning tasks that occur including identification of person completing task		
OOS or Failure Investigation & Corrective Action Plans	As needed	• Documentation of OOS results (e.g., incomplete or undocumented cleaning tasks, cleaning agent defects, etc.), investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken were effective		

7. **Sterile supplies, components, and compounding equipment QA audit parameters** follow criteria in the table below. Refer to the **Equipment, Supplies, & Components for Sterile Compounding policy** for additional information regarding these regulatory requirements.

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
STERILE SUPPLIES & COMPONENTS		
Verification of FDA Approved Manufacturer	Prior to initial order	Per new manufacturer used for nonsterile APIs (and recommended for components used in nonsterile compounding): • Verify manufacturing facility is FDA-registered
COAs for nonsterile APIs & components	Upon receipt of item(s)	Per component or Active Pharmaceutical Ingredient (API) received for use in nonsterile to sterile compounding: • Verify APIs and components conform with sterility, apyrogenicity, and physical and/or chemical specifications and conform with USP-NF monograph criteria (if monograph exists)
STERILE COMPOUNDING EQUIPMENT		
Sterile Equipment Calibration, Maintenance, & Certification	Per Manufacturer's Instructions	Per each piece of sterile compounding equipment (e.g., ACDs, analytical balances, incubators, autoclave, dry heat oven, etc.): • Documentation of calibration and certification by a qualified technician • Documentation of maintenance as needed
OOS or Failure Investigation & Corrective Action Plans	As needed	• Documentation of OOS results (e.g., substandard APIs, components, or supplies), investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken were effective

8. **Compounding records and CSP release inspection QA evaluation parameters** follow criteria in the table below. Refer to the **Master Formulation Record & Compounding Record policy, Release**

Inspections & Testing policy, CSP Sterilization & Equipment Depyrogenation policy, and **CSP Sterility and Bacterial Endotoxin Testing for Extended BUDs policy** for additional information regarding these regulatory requirements.

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
Compounding Records		
Master Formula Record (MFR) & Compounding Record (CR) Creation; BUD/storage/stability reference	CR: For every CSP	For each Category 1 or 2 CSP: • CR: refer to policy for the required data included in each CR ○ *For CSPs not requiring a MFR*, the CR can be prescription or medication order or representation of the same stored in a workflow management system, ACD, or similar
Release Inspections & Tests		
Visual Inspections, Measurements, Physiochemical Tests, & Calculations	Every CSP	Results documented on CR or implied by RPh final verification: • Visual inspections: components & final CSP, label (including BUD assignment & storage conditions), and container closure system • Measurements: component and/or final CSP weights, volumes, etc. • Physiochemical Tests: CSP pH, osmolarity, refractive index, etc. if applicable • Calculations/Conversions: per formulation
OOS or Failure Investigation & Corrective Action Plans	As needed	• Documentation of OOS results (e.g., failed release inspections or tests, sterilization failures, etc.), investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken were effective

9. **Standard operating procedure, complaints and adverse drug reaction (ADR) handling, and CSP recalls QA evaluation parameters** follow criteria in the table below. Refer to the **Good Documentation policy** and **Complaints, Adverse Reactions, and CSP Recall Handling policy** for additional information regarding these regulatory requirements.

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
SOPs, Complaint and ADR Handling, & Recalls		
Sterile Practice SOPs & Annual Review	Every 12 months	• SOPs meeting USP <797> documentation requirements • Annual review, revisions, updates by Designated Person • Staff communication regarding SOP updates
Complaints & Adverse Drug Reaction (ADR) Handling	As needed per reports by patients, providers, staff, public	For each compliant or ADR: • Reported, documented, and tracked per policy • Patient/public harm risk assessment including severity and response urgency determination • Root cause analysis and investigation description • Corrective action(s) description, timeline, and evaluation criteria if appropriate • Evaluation of data collected in response to corrective action; determination if corrective action was successful
Recalls	As needed	• Description of specific failures and impacted CSPs and/or CSP compounding processes (e.g., CSP sterility, strength, endotoxin burden, or other quality attribute)

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
		• List of patients and prescribers effected (or potentially effected) • Description of recall process and timeline for unused dispensed CSPs • Communication to prescribers (and patients/caregivers) • Assessment of undispensed CSPs for inclusion in recall • Disposal documentation for recalled CSPs • Investigation, corrective action, and follow up to ensure failure has been remedied and recall process has been concluded • Reporting of ADR to appropriate regulatory bodies and required follow up

[Best Practice] **Personnel Compliance Audits**

10. Conduct compliance audits for compounding personnel and personnel performing supporting roles that require entry into controlled compounding areas to ensure adherence to policies and procedures, accountability for individual impacts on the state of control within controlled areas, and individual and team responsibility for patient safety.

    - Whenever possible, perform audits remotely or in a manner that is undetected by personnel to allow for observation of a more accurate representation of everyday behaviors and habits
    - Schedule audits to occur separately from competency assessments and, whenever possible, at intervals that occur between scheduled competencies

Personnel Category	Audit Topics	Audit Frequency
Compounding Personnel	• Hand hygiene & garbing including preparation prior to entering controlled areas • Materials movement into controlled areas • Aseptic manipulations & technique • Use of compounding equipment • CSP labeling and BUD/storage assignment • Cleaning, disinfecting, & applying sporicidal agents • Movement and conduct within controlled areas • Compounding and compliance documentation	Per individual compounder: Every 6 (six) months
Direct Compounding Supervisors	• Hand hygiene & garbing including personal preparation prior to entry into controlled areas • In process and final CSP verifications • Release inspections & tests • Compounding and compliance documentation • Oversight of controlled areas and entry of visitors	Per individual compounding supervisor: Every 6 (six) months
Compounders Performing Specialized Roles/Tasks:	Compliance with SOPs for: • Assigned Trainers • Viable air and/or surface sampling • Media incubation	Per individual: Every 6 (six) months

Document audit results in a level of detail that allows the DP and/or Pharmacy Management to effectively follow up with personnel to provide feedback, coaching, and corrective actions if needed. Retain audit

documentation in a readily retrievable format and review and trend individual and/or team results to identify quality improvement, educational, and training opportunities.

[USP 797] **Evaluation and Handling of Complaints and Adverse Events**

Refer to the **Complaint, Adverse Drug Reaction, & CSP Recall Handling** policy.

[USP 797] **Investigations and Corrective Actions**

When OOS, failures, complaints, or adverse drug reactions occur in any facet of the Sterile Compounding Program, perform an investigation that is consistent with the extent of the deviation and include an evaluation of historical trends for areas of concern.

Document the OOS, failure, complaint, or ADR per policy and ensure investigation findings, corrective action plans, and data collected to validate effectiveness of corrective actions is documented and retained in a readily accessible electronic or written format.

Investigations and immediate and longer-term corrective action plans may include but are not limited to the following: *[USP does not specify investigation and corrective actions. The following table is intended to be a starting point. Revise as appropriate.]*

Area of Compliance	Investigation	Potential Corrective Actions	
		Immediate	Longer Term
Facilities & Engineering Controls (PECs / SECs; HEPA Filters; airflow & exhaust systems)	• Verification of current certifications • Certification report review for deficiencies or discrepancies • Evaluation of engineering & technical systems, equipment, HEPA filters for needed repairs or replacement • Evaluation of external factors that could impact function (e.g., power surges) • Trends	• Risk assessment to current compounding operations & CSPs • Halt or limit compounding in effected PEC or SEC • If SEC, reclassify to SCA until resolved • Staff communication	• Repair or replacement of equipment or systems • Assessment of certification vendor, certification report, and OOS or potential OOS communication • Assessment of and revisions to certification report review and sign off process
Environmental Controls (HVAC-controlled Temperatures & Humidity; Pressure Differentials)	• Verification that maintenance, calibration, and certification of monitoring of airflow and monitoring systems and gauges are current • Evaluation of systems and gauges for needed repairs or replacements • Assessment of proper staff reading and documenting data • Trends	• Risk assessment to current compounding operations, CSPs, & compounding staff • Halt or limit compounding or drug storage in effected area • If pressure differential issue, reclassify to SCA until resolved • Staff communication	• Repair or replacement of equipment or systems • Placement of additional monitoring devices • Staff education about daily monitoring and maintenance of gauges • SOP changes & revised work instructions for vendors/personnel performing sampling
Personnel Competencies, Conduct, & Compounding Performance	• Review of training process and progress • Review of performance records and previous competency results (if applicable) • Interview of trainer and compounding supervisors • Interview with trainee • Live or video QA audits	• Risk assessment of previously compounded CSPs • Determine compounding status of individual (e.g., removal or limited work duties)	• Additional training, observed skill, and competency evaluations • QA live or video audits • Coaching or Performance improvement Plan • SOP changes & staff communication/training

[BIOMATRIX]

Area of Compliance	Investigation	Potential Corrective Actions	
		Immediate	Longer Term
	• CSP QC testing • Trends	• Immediate training & competency evaluations • Ad hoc QA audits • Staff communication	
Cleaning, Disinfecting, & Application of Sporicidal Agents	• Review of personnel training & competency records • Review of cleaning logs, agents, & dwell times used • Review of cleaning procedures • Live or video QA audits	• Risk assessment of previously compounded CSPs • Remedial cleaning with appropriate agent(s) • Coaching or training • Staff Communication	• Additional training, observed skill, and competency evaluations • QA live or video audits • Coaching or training • SOP changes & staff communication/training
Environmental Monitoring (Viable Air &/or Surface Sampling)	• Review operating conditions when samples taken (e.g., trainees or visitors present • Review of types of organisms, locations, CFU counts, & trends • Review personnel data (e.g., training records, visual observations, competencies) • Review of cleaning practices & documentation • Review of HEPA filter efficacy & ACPH as reported in cert. report • Review of materials movement • Review of media COAs, expiration, & proper storage • Confirmation of air sampler maintenance & certification • Review of sampler's training, competency, and technique	• Risk assessment to current compounding operations & CSPs • Remedial cleaning with appropriate agent(s) • Perform and/or reschedule retesting ASAP • Individual coaching or retraining if appropriate • Staff communication	• Staff education and retraining, if needed • Assessment of appropriateness of engineering & environmental controls for current conditions (e.g., volume, number of personnel, etc.) • Smoke studies to find airflow eddies, turbulence, and/or staled airflow • Consider redesigning workflows, traffic patterns, & personnel congestion points • SOP changes & staff communication/training
Sterile Equipment, Components, & Supplies	• Review of COAs and sign off upon receipt and/or before use • For equipment, confirmation of current maintenance, calibration, & certification • For ACDs, review of daily accuracy measurement records • Review of manufacturer information or recalls • Review of proper use or operation by compounding staff • Trends	• Risk assessment to current compounding operations & CSPs • Removal of equipment, components, supplies until issue resolved • Individual or team coaching or training • Staff communication	• Repair or replacement of equipment • Source components or supplies for alternative vendors • SOP changes & staff communication • Additional training, competency, and/or quality audits
CSP Quality and/or Release Testing Failures	• Review release test procedure & compliance with SOP • Review facilities, engineering and environmental controls certifications • Review compounding process including supplies, components, & equipment used	• Patient risk assessment & recall determination if CSPs dispensed prior to final results • Investigation for other CSPs potentially impacted by quality issue; CSP recall consideration	• SOP changes & staff communication • Additional training, competency, and/or quality audits

[BIOMATRIX]

Area of Compliance	Investigation	Potential Corrective Actions	
		Immediate	Longer Term
	• Review personnel records of compounder(s) & QA audits of compliance • Review of analytical laboratory credentials & protocols • Trends	• Individual or team coaching or training • Staff communication	
Complaints & Adverse Drug Reaction Reports	Review of all areas of sterile practice for possible contributory or causative factors; prioritize investigation by the most likely causes; ***see above***	• Risk assessment to current compounding operations & CSPs up to and including halting or restricting compounding operations, limiting BUDs to SCA or immediate use until issue resolved • Reassigning personnel involved pending investigation • Staff communication	Corrective actions appropriate to address the suspected or known root cause(s); ***see above*** • Enhanced QA/QC monitoring to ensure corrective actions have been effective • Staff communication

Supporting Documents/References:

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.
- United States Pharmacopeial Convention, Inc. <1163> Quality Assurance in Pharmaceutical Compounding. Current version.

Related Accreditation Standard(s):

DRX

Approved by:

Allison Croft, Compliance Officer — 01/21/2026 (Date)

Kimberly Jensen Moore (Jan 22, 2026 09:24:20 PST)

Kim Moore, SVP Pharmacy Operations — 01/22/2026 (Date)

[BIOMATRIX]

Casey Cooper, Dir.of Pharmacy Policy and Standards

Date

Original Policy & Procedure Date: 1/1/2026

REVISION/REVIEW	DATE	BRANCH LEVEL APPROVAL (NAME AND TITLE)
Revised	1/16/2026	Casey Cooper, PharmD Director of Pharmacy Policy and Standards

[BIOMATRIX]

Policy Title: Cleaning and Disinfecting Sterile Compounding Areas

Department: Pharmacy

Effective Date: 1/1/2026

Policy Number: 797.03

Applicability:

This policy applies to (1) BioMatrix and its wholly-owned subsidiaries and affiliates (each, an "Affiliate"); (2) any other entity or organization in which BioMatrix or an Affiliate owns a direct or indirect equity interest of greater than 50%; and (3) any entity in which an Affiliate either manages or controls the day to day operations of the facility each, a "BioMatrix Entity" (collectively, "BioMatrix" or "Company").

Purpose:

This policy describes the procedures for cleaning and disinfecting compounding areas where Compounded Preparations (CSP) are prepared within BMX pharmacies.

[USP 797] Surfaces in classified areas and segregated compounding areas are potential sources of microbial contamination. To reduce the risk of contact contamination, surfaces within classified areas used to prepare Category 1 and Category 2 are cleaned, disinfected, and have sporicidal disinfectants applied according to the processes and frequencies described in this procedure.

Cleaning involves removing organic and inorganic materials (e.g., dirt, debris, microbes, and residual drugs or chemicals) form surfaces with the use of a cleaning agent and manual or mechanical action.
Disinfecting involves using a chemical or physical agent on surfaces to destroy microorganisms including fungi, viruses, and bacteria.
Sporicidal disinfectants are chemical or physical agents that destroy all vegetative microorganisms including bacterial and fungal spores while applied at a sufficient concentration and for a specified contact time.

[USP 797] **Sterile 70% isopropyl alcohol (sIPA)** is a staple in day-to-day compounding activities and plays a critical role in sanitizing and reducing the bioburden on gloved hands, surfaces, and materials through both chemical application and physical wiping. sIPA, however, is not a cleaning or disinfecting agent. While it does have some disinfectant properties, it does not possess the broad-spectrum coverage of cleaning, disinfecting, or sporicidal agents and requires a lengthy (and impractical) contact time to truly convey bactericidal or fungicidal activity.

Scope:

This policy applies to all clinical and administrative personnel involved in the provision, coordination, and support of services provided by BioMatrix Specialty Pharmacy.

Definition(s):

- **Classified area**: An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class).

- **Cleaning agent**: An agent for the removal of residues (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
- **Compounding area:** The area where compounding is occurring (i.e., a cleanroom suite or inside the perimeter of the SCA).
- **Garb:** Items such as gloves, garments (e.g., gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).
- **IPA:** Isopropyl alcohol.
- **Low-lint wiper**: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from, the wiper material in a dry condition.
- **One-step disinfectant cleaner**: A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.
- **Pass-through**: An enclosure with sealed doors on both sides that should be interlocked. The pass-through is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.
- **Primary engineering control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
- **Secondary engineering control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
- **Segregated compounding area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only.
- **Sporicidal disinfectant**: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms
- **Triple clean:** consists of two separate and distinct applications of an approved one-step disinfectant cleaner (allowing for full contact time between applications) followed by a separate application of an approved sporicidal disinfectant; remove cleaning agent residue with sIPA.

Roles & Responsibilities:

[USP 797] The Designated Person(s) (DP):

- Ensures cleaning staff receives appropriate training and maintains current cleaning and related competencies.
- Oversees selection of appropriate EPA-registered cleaning, disinfecting, and sporicidal agents and ensures staff understands and adheres to appropriate contact times for each agent.
- Ensures the organization or facility maintains access to a current SDS for each cleaning agent and ensures cleaning personnel understand how to access and use the SDS in case of a spill or accident.
- Determines appropriate remedial cleaning requirements for ad hoc and out-of-specification occurrences up to and including a triple clean of affected compounding areas including the following circumstances:
  1. Actionable environmental findings from total particle counts, viable air sampling, or surface sampling results and/or trends.

2. Scheduled and unscheduled power and/or airflow disruptions directly impacting sterile compounding area(s).
3. Certification of sterile compounding area(s).
4. New or major construction or maintenance work performed within or adjacent to the sterile compounding area(s).

2. Compounding personnel:

- Undergo training and demonstrate competency initially and at least once annually in skills and competencies related to cleaning and disinfecting.
- Adhere to all cleaning procedures including cleaning agent selection, frequency, method, and sequence of cleaning activities (i.e., cleanest to dirtiest).
- Ensure appropriate use of sterile 70% IPA before, during, and after the compounding process.
- Complete timely documentation of all cleaning activities performed.

Policy:

1. [USP 797] Cleaning and disinfecting of all surfaces inside compounding areas, including sinks, as well as the application of a sporicidal disinfectant occur on a regular basis and at a minimum frequency as specified in *USP <797> Pharmacecutical Compounding – Sterile Preparations 2023* and according to this policy (see Section 4.1).
2. [USP 797] Surfaces in compounding areas are cleaned prior to being disinfected with an EPA-registered (or equivalent outside of the US) agent. An EPA-registered (or equivalent) one-step disinfectant cleaner is an appropriate alternative that allows both processes to occur in one step.
3. [USP 797] Sporicidal disinfecting agents are EPA-registered (or equivalent outside of the US) and allow for cleaning, disinfecting, and sporicidal activity concurrently in a single step.
4. [USP 797] Manufacturer's directions or published data for the minimum contact time is followed for each of the cleaning, disinfecting, and sporicidal agents used to ensure the agents have full microbial destroying action.
5. [USP 797] Cleaning and sanitizing is completed daily on each day that compounding occurs.
6. [USP 797] Cleaning and sanitizing is repeated when spills occur and when surfaces are visibly soiled.
7. [USP 797] All personnel involved in cleaning and disinfecting of classified compounding and segregated compounding areas receive training and demonstrate competency in Hand Hygiene and Garbing initially and at least annually. Refresher training is provided as needed and when changes in procedures or agents occur.
8. [USP 797] All cleaning and disinfecting activities are performed by appropriately garbed personnel using facility-approved agents and procedures including frequency, method, and location of cleaning activity.

9. [USP 797] Sterile cleaning agents are used to clean the interior of, and all equipment housed inside of PECs.

10. [Best Practice] Cleaning agents and supplies used in PECs and SECs are assigned an expiration (or "in-use") date once opened or prepared; expiration dates are clearly and permanently written on the bottle, container, or wrapping of the supply and do not exceed manufacturer expiration dates or recommended "in-use" dates.

Cleaning Agent or Supply	Location Used	Dwell Time	Expiration Date* (from initial puncture, use, or preparation)
Peridox RTU (Hydrogen Peroxide; Peroxyacetic Acid) One-step Cleaner, Disinfectant, *Sporicide*	**Sterile: Cleaning interior of PECs and equipment within PECs (when allowed by manufacturer)** Non-Sterile: All Surfaces of SECs; Exterior of PECs	**3 minutes for sporicidal and decontamination action; 2 minutes for bactericidal action**	**6 months or manufacturer expiration, whichever is sooner**
PREempt Plus (Accelerated Hydrogen Peroxide) One-step Cleaner, Disinfectant	All Surfaces of SECs; Exterior of PECs	**1 minute for bactericidal/virucidal action; 5 minutes for tuberculocidal; 10 minutes for fungicidal**	**3 years or manufacturer expiration date, whichever is sooner**
Contec Sterile IPA Sterile Isopropyl Alcohol 70%	All surfaces of PECs, equipment, and SECs	**10-15 seconds, or until dry**	**45 days or manufacturer expiration date, whichever is sooner**
Pharma-Hol Sterile Isopropyl Alcohol 70%	All surfaces of PECs, equipment, and SECs	**10-15 seconds, or until dry**	**45 days or manufacturer expiration date, whichever is sooner**
STERILE Low-Lint Dry Wipes	Inside PECs; Exterior of PECs; All surfaces in SECs	**N/A**	**15 days**
Sterile Cleaning Pads for EasyReach Cleaning Tools	Inside PECs	**N/A**	**15 days**

*Consult the manufacturer for dates for specified products in use at your facility or define a more conservative expiration date.

Safety Data Sheets (SDSs) are retained electronically for all cleaning supplies, included in training cleaning personnel, and are readily retrievable by all compounding staff members.

[BIOMATRIX]

Procedure:

1. Frequency of Cleaning, Disinfection, and Application of Sporicidal Disinfectants – Adapted from USP <797> 2023Table 10

	Cleaning and Disinfecting		Applying Sporicidal Disinfectant	
	Frequency	**Who**	**Frequency**	**Who**
Inside PECs – including all surfaces, direct compounding area and work tray, and equipment used inside the PEC	Daily on days when compounding occurs and when surface contamination is known or suspected	Compounding Pharmacy Technician or Compounding Pharmacist	Monthly	Compounding Pharmacy Technician or Compounding Pharmacist
Surfaces Underneath Removable PEC Work Tray *(if applicable)*	Monthly - surfaces under the tray	Compounding Pharmacy Technician or Compounding Pharmacist	Monthly	Compounding Pharmacy Technician or Compounding Pharmacist
Work Surfaces Outside of PEC	Daily on days when compounding occurs - all "high touch" surfaces daily	Compounding Pharmacy Technician or Compounding Pharmacist	Monthly – all surfaces including high touch and underneath of tables, chairs, and carts plus wheels.	Compounding Pharmacy Technician or Compounding Pharmacist
Floors	Daily on days when compounding occurs	Compounding Pharmacy Technician or Compounding Pharmacist	Monthly	Compounding Pharmacy Technician or Compounding Pharmacist
Sinks	Daily on days when compounding occurs	Compounding Pharmacy Technician or Compounding Pharmacist	Monthly	Compounding Pharmacy Technician or Compounding Pharmacist
Walls, Door(s), and Door Frame(s)	Monthly	Compounding Pharmacy Technician or Compounding Pharmacist	Monthly	Compounding Pharmacy Technician or Compounding Pharmacist
Ceilings of Sterile Suite	Monthly	Compounding Pharmacy Technician or Compounding Pharmacist	Monthly	Compounding Pharmacy Technician or Compounding Pharmacist
Storage Shelves and Bins	Monthly	Compounding Pharmacy Technician or	Monthly	Compounding Pharmacy Technician or

	Cleaning and Disinfecting		Applying Sporicidal Disinfectant	
	Frequency	Who	Frequency	Who
		Compounding Pharmacist		Compounding Pharmacist
Equipment Outside of the PEC(s)	Monthly	Compounding Pharmacy Technician or Compounding Pharmacist	Monthly	Compounding Pharmacy Technician or Compounding Pharmacist

- [USP 797] Cleaning activities occur from cleanest to dirtiest areas.
- [USP 797] If cleaning and disinfecting are performed as separate steps, cleaning is performed prior to disinfecting.
- [USP 797] After the application of a disinfectant, cleaning agent, or sporicidal disinfectant, the agent is allowed to dwell, or maintain a contact time, for the minimum duration specified by the manufacturer or published data to ensure full bactericidal, fungicidal, virucidal, and/or sporicidal action.
- [USP 797] Daily cleaning and disinfecting occurs on days when compounding occurs. If compounding does not occur for more than 24 hours (e.g., over a weekend or holiday):

a. Complete daily cleaning and disinfecting prior to the start of compounding on the day compounding resumes.

b. [Best Practice] [Conservative: If pharmacy or specific facility(ies) compounds Category 1 and/or 2 CSPs] Monthly cleaning and application of sporicidal disinfectants occurs at least every 30 days to ensure a regular and consistent cleaning schedule and is completed as one continuous process or, at a minimum, is completed with 72 hours to minimize the risk of cross-contaminating already cleaned areas.

- [Best Practice] Cleaning and disinfection of the inside of a PEC and any equipment housed and used inside a PEC occurs prior to and at the conclusion of daily and/or shift compounding.

2. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants in the PEC

- [USP 797] If needed, remove visible particles, debris, or residue with an appropriate solution (e.g., Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers.
- [USP 797] **For cleaning and disinfecting**: Use a sterile low-lint wiper and apply a sterile cleaning agent followed by a sterile disinfecting agent or apply an EPA-registered (or equivalent) one-step disinfectant cleaner to equipment and all interior surfaces of the PEC. Only sterile cleaning products shall be used to clean inside of ISO Class 5 spaces. Use easy-reach tools to minimize entry of personnel head or upper body inside the PEC. Change wiper or disposable cleaning product when changing cleaning agents (i.e., one easy reach tool cover for disinfectant, then new cover for sIPA.
- [USP 797] **For application of a sporicidal disinfectant**: After cleaning and disinfecting, apply a sterile sporicidal disinfectant using a sterile low-lint wiper to all equipment, interior surfaces, and the area underneath the work tray; if the sporicidal disinfectant is an EPA-registered (or equivalent) one-step disinfectant sporicidal cleaner, separate cleaning and disinfecting steps are not required.
- [USP 797] Ensure the contact time specified by the manufacturer is achieved.

- [USP 797] After the application of cleaning, disinfecting, and/or sporicidal agent inside PEC, apply sIPA to equipment and all interior surfaces to remove residue. sIPA should also be used elsewhere in the clean room suite following sporicidal agent use (glass windows, horizontal surfaces, floors, etc), to remove residue.
- [USP 797] Allow the surface to dry completely before beginning compounding.

3. Use of Sterile 70% IPA inside of a PEC

- Do not spray cleaning solutions, including sIPA, inside of a PEC to avoid deteriorating the integrity of the HEPA filter. Wet a sterile low-lint wiper with the sIPA and apply directly with mechanical/manual action to the interior hood surfaces and equipment.
- [USP 797] Apply sIPA to the horizontal work surface of each PEC and allow to dry before compounding:

a. Immediately before initiating compounding or a new compounding process
b. At least every 30 minutes if the compounding process takes 30 minutes or less
c. After completing a compounding process if the process takes more than 30 minutes

[BIOMATRIX]

4. Other Cleaning Considerations

1. Clean high touch surfaces outside of PECs on a daily basis and all other surfaces plus the high touch surfaces on a monthly frequency, including but not limited to:

High Touch Surfaces (Daily Clean)	Other Surfaces (Monthly Clean)
Horizontal work surfaces, tables, counters, or carts Chair seats, arms, and backs RF scanner, touch screen monitor, Pinnacle Compounder Repeater Pump Communication devices (Intercom and doorbell buttons) Light switches, door handles or hands- free activator Sink surfaces, drain, and faucet Gowning bench and garb storage handles EasyReach Cleaning Tools	Exterior of PECs Legs, underside of horizontal surfaces, and feet/wheels of work surfaces, tables, counters, carts, chairs, or benches Trash bins and hazardous waste disposal containers Doorframes, window ledges, and other irregular surfaces Vial Roller

[BEST PRACTICE] Cleaning, disinfecting, and the application of a sporicidal agent does not take place while active compounding is occurring.

[USP 797] Perform cleaning from cleaner to dirtier areas (e.g. ISO 5, ISO 7, and then ISO 8 areas).

For all sites, clean and disinfect as needed after spills and when surface contamination (e.g., splashes) is known or suspected.

Replace all garb after cleaning and prior to resuming compounding duties.

Use appropriate respiratory support, such as a full face respirator with eye protection when applying a sporicidal agent to surfaces within the compounding area, including the following cleaning tasks:

Inside PECs, including under the work tray of a Biological Safety Cabinet (BSC)

Walls, ceilings, floors

Surfaces outside of PECs

Refer to USP <800> and related policies for decontamination steps if hazardous drugs are used.

5. Remedial Cleaning for Out of Specification Conditions

a. As directed by the Designated Person or designee, perform and document remedial cleaning on an as needed basis. Remedial cleaning ranges from cleaning and disinfection to application of a sporicidal disinfectant to triple cleaning affected compounding areas.

b. A **triple clean** consists of two separate and distinct applications of an approved one-step disinfectant cleaner (allowing for full contact time between applications) followed by a separate application of an approved sporicidal disinfectant; remove cleaning agent residue with sIPA.

c. Triple Clean Key Techniques:

Order of cleaning: 'Top to bottom, back to front':

1.Ceiling

2. Walls

3. Horizontal Work Surfaces/Shelving/Exteriors of PECs/Pass-thrus

4. Floors; work starting from back of room furthest from anteroom door to finish at anteroom door with each step. Begin by mopping side edge, then utilize the S-curve method, using side-to-side, overlapping strokes while maintaining a clean leading edge.

a. Video demonstration here (YouTube Contec mopping training video; S-curve technique at 0:51): https://www.youtube.com/watch?v=9cKnnpshk5w

5. Finish full clean with designated agent per round in ISO 5 PEC space.
6. Use low-linting wipes.
7. Allow cleaning agent to sit per 'Dwell Time' recommendations according to package insert prior to residue removal
8. Use linear, overlapping strokes with wipers/cleaning agent
9. Common Reasons for need for a Triple Clean:

    a. Loss of Airflow/Positive Pressure/excessive temp/humidity excursions >30 min due to power outage or any other mechanical event.

    b. After any non-passing certification or environmental sampling results (surface sampling or air viable sampling).

    c. After any alterations or changes to clean room environment (ie welded floor repair, new hood added, old hood removed) which modify the SECs of the clean room suite.

    d. Any other scenario in which the DP deems a 3x cleaning is warranted (flooding, extended room pressure issues, etc

    e. At a minimum, document purpose, date, and cleaning agent(s) used when conducting remedial cleaning. Ensure remedial cleaning documentation is retained and readily retrievable.

6. Selection and Use of Cleaning Agents

- [USP 797] Select and use cleaning and disinfecting agents with careful consideration of compatibilities, effectiveness, and user safety including, but not limited to, antimicrobial activity, inactivation by organic matter, residue, shelf life, preparation requirements of the agent, and suitability for surfaces being disinfected.
- [Best Practice] Use of ready-to-use and one-step disinfectant cleaner solutions is preferred over those requiring dilution or separate cleaning and disinfection steps.
- [USP 797] Clean and disinfect sterile cleaning agent containers prior to introduction into the ISO 5 environment. Assembly of sterile agent bottles shall be conducted inside the ISO 5 area and bottles should remain closed when removing from the PEC.
- Sterile cleaning and disinfecting supplies (e.g., closed containers of sterile wipers, bottles of 70% sterile IPA) can be used for up to the time listed in the chart 2.10 once opened. Permanently and legibly write or label the expiration date on all cleaning supplies.
- [Best Practice] Store open packages of sterile wipes inside the PEC. If removed from a PEC once opened, they are no longer considered sterile and can only be used in ISO Class 7 and 8 areas. Disinfect sterile cleaning solution bottles stored outside of a PEC prior to introduction and use inside of the PEC with sIPA. Permanently and legibly write or label sterile cleaning agent bottles as "ISO 5 use".

7. Selection and Use of Cleaning Supplies and Tools

- [USP 797] Use sterile cleaning supplies and tools inside a PEC whenever possible; clean and disinfect prior to use (e.g., tool handles and holders). Store easy-reach tools inside the PEC

when not in use by hanging from IV bar via hook. Store mops not in use on hooks mounted on clean side of anteroom.

- [USP 797] Dedicate and do not remove reusable cleaning tools (e.g. mop frames and handles) to specific classified areas or segregated compounding areas.

- Use either dedicated mop frames in buffer and ante rooms or use the mop in the buffer room before using in the ante area.
- Dedicated mops and cleaning tools are used in hazardous areas.
- Dispose of cleaning tools in a method that minimizes the chance of dispersing contaminants in the air.
  - [USP 797] Cleaning and disinfecting supplies such as wipers, sponges, pads, and mop heads are made of low lint materials and, whenever possible, are disposable.
- Disposable cleaning supplies are discarded after use.
- Reusable cleaning tools are made of cleanable materials that are nonporous (excluding wood) are are cleaned and disinfected before and after each use.
  - [Best Practice] Use the dedicated sink for cleaning compounding equipment and supplies.

Documentation of Cleaning

[USP 797] Document all cleaning, disinfecting, and application of sporicidal disinfectants electronically after completion of the task by the personnel performing the work. Detailed cleaning records are retained and readily accessible

Supporting Documents/References:

3. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
4. United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

[BIOMATRIX]

Pharma-Choice™
by: Acute Care Pharmaceuticals

Pharma-Hol sterile IPA "45 day in Use Expiration Dating"

Thank you for your inquiry about the "In Use Expiration" dating for our Pharma-Hol sterile alcohol products. We know that "In Use Expiration" dating is very important not just for your sterile alcohol but for all of the cleaning and disinfecting products used in the pharmacy environment.

Premise of Testing- To determine if the spray mechanism and the contents of the IPA in the spray bottle remain sterile up to 45 days.

Testing Facility-With our customer's needs in mind we have put our Pharma-Hol sterile alcohol products through some rigorous real time, real world sterility testing. We submitted several representative samples and lot #s of our 16 oz. and 32 oz. Pharma-Hol Sterile Alcohol (with trigger sprayers) to an independent analytical testing laboratory. Our analysis was performed by Aerobiology Laboratory Associates Inc. Certificate of Analysis AIHA-LAP EMLAP# 218951. They are a well- known national Laboratory group that has expertise in a wide variety of USP 797 surface, air, bacterial, fungal and water related testing services.

Testing Protocol-The environment the bottles are to be stored for use up to 45 days and sprayed in a known area of contamination **(Non-Sterile Non-ISO class)** working production area of an environmental microbiology laboratory. The representative bottles were used daily (sprayed several times per day) over a 45-day period. The contents of each bottle were then tested at regular intervals (day 0, day 14, day 30 and day 45) to determine if the contents had in fact remained sterile. Air samples for bacteria and fungi will be taken on the same days the product is challenged.

Conclusion-At the conclusion of the testing period of 45 days, our Pharma-Hol sterile IPA with trigger sprayers remained sterile and did not promote or sustain bacterial or fungal growth within the bottles. Based on normal use in the Pharmacy environment and since testing was conducted in a non-ISO area, we conclude that you can safely and confidently use a 45 day "In use expiration" on all your Pharma-Hol sterile IPA bottles. This 45-day timing of course commences only after the Pharma-Hol has been activated from first use.

Disclaimer
Our stated "In Use Expiration" is solely a guideline and is not intended to change the written protocol within your facility. If the product is being used in a **Non-ISO** area of your facility "In Use Expiration" dating for your specific environment should be determined based on your facility's individual testing results. This is based on the fact that there are a multitude of factors that can influence the expiration date, i.e. foot traffic, size, ventilation, cleaning protocol, etc.

We hope you find this information helpful. Please do not hesitate to contact us if you need any additional information or copies of our independent study results.

12225 World Trade Dr., Suite A, San Diego, CA 92128 // 888-909-7700

[BIOMATRIX]

Related Accreditation Standard(s):

DRX

Approved by:

Allison Croft, Compliance Officer — 01/21/2026 — Date

Kimberly Jensen Moore (Jan 22, 2026 09:24:20 PST)

Kim Moore, SVP Pharmacy Operations — 01/22/2026 — Date

Casey Cooper (Jan 22, 2026 08:16:21 CST)

Casey Cooper, Dir.of Pharmacy Policy and Standards — 01/22/2026 — Date

Original Policy & Procedure Date: 1/1/2026

REVISION/REVIEW	DATE	BRANCH LEVEL APPROVAL (NAME AND TITLE)
Revised	1/16/2026	Casey Cooper, PharmD Director of Pharmacy Policy and Standards

[BIOMATRIX]

Policy Title: Handling, Storage, Packaging, Shipping, & Transport of CSPs

Department: Pharmacy

Effective Date: 1/1/2026

Policy Number: 797.05

Applicability:

This policy applies to (1) BioMatrix and its wholly-owned subsidiaries and affiliates (each, an "Affiliate"); (2) any other entity or organization in which BioMatrix or an Affiliate owns a direct or indirect equity interest of greater than 50%; and (3) any entity in which an Affiliate either manages or controls the day to day operations of the facility each, a "BioMatrix Entity" (collectively, "BioMatrix" or "Company").

Purpose:

1. This policy describes the handling, storage, packaging, shipping, and transportation requirements and procedures for Compounded Sterile Preparations (CSPs) prepared at Biomatrix Infusion Pharmacies.
2. CSP quality and integrity can be adversely affected by inappropriate handling, storage, packaging, shipping, & transport methods. Care and consideration are given to the determination and selection of these methods and personnel and/or vendors to carry out these duties. Proper training, processes, and quality assurance and control measures are integral to maintaining the quality of CSP during these processes.
3. Refer to **Label, Packaging, and Transport of Hazardous Drugs policy** for procedures to hazardous medication handling, storage, packaging, transporting, and shipping.

Scope:

This policy applies to all clinical and administrative personnel involved in the provision, coordination, and support of services provided by BioMatrix Specialty Pharmacy.

Definition(s):

- **Closure:** A material that seals an otherwise open space of a *Container* and provides protection for the contents. It also provides access to the contents of the *Container* (e.g., screw caps and stoppers).
- **Container:** A receptacle that holds an intermediate compound, API, excipient, or dosage form, and is in direct contact with the article (e.g., ampules, vials, bottles, syringes, and pen injectors).
- **Controlled room temperature:** The temperature maintained thermostatically that encompasses the usual and customary working environment of 20°–25° (68°–77° F).
- **Freezer:** A place in which the temperature is controlled between −25° and −10° (−13° and 14° F)

- **Room temperature** (also referred to as ambient temperature): The temperature prevailing in a working environment.
- **Tamper-evident packaging:** A *Packaging system* that may not be accessed without obvious destruction of the seal or some portion of the *Packaging system*

Roles & Responsibilities:

1. The Designated Person(s) (DP):
   - Provide appropriate training and competency evaluations for personnel performing CSP handling, storage, packaging, and transport
   - Ensure CSP storage locations are appropriately monitored, and temperature is recorded daily or readily accessible
   - Research CSP stability and integrity when drug storage temperature excursions occur and determine if CSPs have retained quality and can be dispensed or must be destroyed due to a lack of uncertainty in the available stability and sterility data in the event of an excursion
   - Ensure packaging procedures and materials are appropriate to help retain the quality of the CSP

2. Internal Personnel Handling, Storing, Packaging, & Transporting CSPs:
   - Personnel successfully complete and remain current on training and competency assessments required to perform job functions. Refer to **Sterile Compounding Personnel Training & Evaluation policy** for further information.

3. Third Party Delivery and Shipping Vendors:
   - Maintain appropriate CSP storage conditions during transit, per labeling and delivery or shipping instructions.

Policy:

1. [USP 797] Personnel handling, storing, packaging, and transporting CSPs are trained in the knowledge and skills needed to perform job-related responsibilities Refer to **Sterile Compounding Personnel Training & Evaluation policy** for further information.

2. [USP 797] CSPs are handled in a manner that maintains CSP quality and packaging integrity and are stored in temperature controlled designated storage areas to ensure storage temperatures remain within the appropriate range.

3. Designated CSP storage area temperatures are monitored and logged daily on days of operation by a continuous recording device.

4. [USP 797] Temperature monitoring systems are verified for accuracy at least every 12 months or as required by the manufacturer.

5. [USP 797] Temperature excursions above or below the required limits are investigated and CSPs are discarded if available literature or analytical testing does not verify the affected CSP(s) are expected to retain integrity or quality.

6. [USP 797] CSP packaging materials protect CSPs from damage, leakage, contamination, degradation, and adsorption as well as prevent accidental exposure to transport personnel.

7. [USP 797] Tamper evident closures are used for all controlled substance CSPs and all other CSPs shipped outside of Biomatrix Infusion Pharmacies.

8. [USP 797] Light-resistant packaging materials are used for light-sensitive CSPs.

9. [USP 797] Shipping and transportation methods and vendors are selected that reasonably and reliably deliver properly packaged CSPs in an undamaged, sterile, and stable condition.

10. [USP 797] CSPs delivered or shipped outside of Biomatrix Infusion Pharmacies bear the appropriate visible and legible labeling on the outer packaging or container conveying in-transit storage requirements, special handling instructions (if applicable), and immediate storage requirements (if appropriate) upon receipt. Refer to the **Labeling** of **CSPs policy** for further information.

Procedure:

1. [USP 797] CSP Handling and Storage

   - After CSPs have been compounded and transferred to final dispensing containers, minimize jostling, shaking, or inverting CSPs unless labeling or literature promotes these actions to maintain or reestablish homogeneity of mixture.
   - Transport CSPs to drug storage locations on carts or in sanitized bins to minimize the risk of jostling, dropping, or damaging packaging and container closure systems and, as result, potentially impacting CSP integrity.
   - Move CSPs to the designated storage areas within controlled compounding areas corresponding with the labeled storage conditions upon pharmacist final verification, when delays in final verification exceed 30 minutes from completion of compounding for CSPs requiring refrigerated or frozen storage or pending release testing results.
   - Move CSPs to designated storage areas within or outside of controlled areas when CSPs have been released for dispensing or administration, packaging, transport, or shipping.
   - Store CSPs in the following storage locations:

Storage Condition	Within Controlled Area(s)	Outside of Controlled Area(s)
Prior to Final Verification *(including CSPs that have not undergone final verification or pending release testing results)*		
Controlled Room Temperature: 20°C - 25°C	General Pharmacy	N/A
Refrigerated: 2°C - 8°C	Pharmacy Refrigerator 4 or 5	N/A
Frozen: -25°C to -10°C	Pharmacy Freezer 6	N/A
After Final Verification *(CSPs released for dispensing, delivery, or shipping)*		
Controlled Room Temperature: 20°C - 25°C	General Pharmacy	Pharmacy, Shipping Warehouse, or with CNYIS Nursing staff if properly packaged and labeled for delivery

Refrigerated: 2°C - 8°C	Pharmacy Refrigerator 4 or 5	Pharmacy, Shipping Warehouse, or with CNYIS Nursing staff if properly packaged and labeled for delivery
Frozen: -25°C to -10°C	Pharmacy Freezer 6	Pharmacy, Shipping Warehouse, or with CNYIS Nursing staff if properly packaged and labeled for delivery

2. [USP 797] CSP Packaging

- Select CSP container closure systems and packaging that do not interact physically or chemically (e.g., adsorption) with the CSP and that protect the CSP's sterility, identity, potency, purity, and similar quality criteria (e.g., light sensitivity).
  - Refer to the USP-NF drug monograph, manufacturer's packaging data, or similar literature to determine appropriate container closure systems and packaging.
  - Record container closure system and packaging requirements and references on the Master Formulation Record (MFR), if applicable, for future reference.
- Use tamper evident CSP containers or closure systems for the following:
  - Controlled substance CSPs
  - Ophthalmic and otic CSPs
  - CSPs for use via high-risk routes of administration (e.g., intrathecal, epidural, intravenous)
  - CSPs transported or shipped to an offsite administration site or directly to the patient
  - CSPs delivered, transported, or shipped by a third-party vendor
- Prior to transport outside of the pharmacy, package CSPs in packaging materials that minimize the risk of damage, leakage, or contamination and are designed to maintain the integrity of the requisite storage conditions for each CSP. Acceptable packaging includes, but is not limited to:
  - **Containers**: Hard-sided coolers, insulated containers, and/or refrigerated or frozen storage units
  - **Cooling Source**: Ice packs, refrigerant cooling blocks
- [Biomatrix Practice] Prior to use of packaging containers and/or cooling sources to transport and/or ship CSPs, perform a test of the materials to ensure they effectively and consistently maintain the desired storage conditions. Additionally, assess the duration of efficacy to determine the timeframe during which the materials and packaging method remain viable. Retain written records of the packaging material efficacy tests.

3. [USP 797] CSP Transport, Delivery, & Shipment

- Transport CSPs to drug storage locations within the immediate facility on well-organized carts to minimize the risk of jostling, dropping, or damaging packaging and container closure systems and potentially impacting CSP integrity.
  - If multiple CSP deliveries occur simultaneously, sort CSPs into sanitized and labeled bins or totes to reduce the risk of mix-up or missed delivery of time-sensitive medications.
  - Transport medications in appropriate packaging and storage conditions (see table below).
- For transport and delivery outside of the immediate facility, package CSPs individually in clear zippered bags to minimize the risk of contamination or spill exposure to transport personnel and use appropriate packaging and devices (e.g., insulated cooler) to maintain storage conditions during transport.

[BIOMATRIX]

Transport Scenario / Storage Conditions	Required Packaging Materials		
	Controlled Room Temp 20°C to 25°C	**Refrigerated: 2°C to 8°C**	**Frozen: -25°C to - 10**
Transport within immediate facility via cart	• CSP(s) placed in sanitized bins	• CSP(s) placed in clear zippered bag • Transported in cooler with ice packs	• CSP(s) placed in clear zippered bag • Transported in cooler with ice packs
Transport or delivery to locations outside of immediate facility	• **CSP(s) placed in clear zippered bag** • **Transported in cooler with ice packs if necessary, based on weather conditions**	• **CSP(s) placed in clear zippered bag** • **Transported in cooler with ice packs**	• **CSP(s) placed in clear zippered bag** • **Transported in cooler with ice packs**
Shipping via Common Courier	• **CSP(s) placed in clear zippered bag** • **Packaged in box (may be insulated) with ice packs if necessary, based on weather conditions**	• **CSP(s) placed in clear zippered bag** • **Packaged in insulated container with sufficient ice packs**	• **CSP(s) placed in clear zippered bag** • **Packaged in insulated container with sufficient ice packs**

- When transporting or shipping CSPs outside of the immediate facility, package CSPs in shipping containers designed to protect and maintain the quality of the contents and secured in a manner that allows for immediate detect of tampering or unauthorized entry into the shipping container.
- When shipping refrigerated CSPs outside of immediate facility, packages will include disposable temperature sensors. These sensors will determine if packaged CSP have maintained proper temperatures and will indicate if temperature excursions have occurred. For this purpose, the pharmacy will use **WarmMark ® Time-Temperature Sensors** produced by **SpotSee®.** These monitors will provide visible indication if packages exceed 8°C (with +/- 1°C sensitivity) for designated time windows. These time windows are as follows; brief (2 hours), moderate (12 hours) and prolonged (48 hours). *Additional information is provided in Appendix One of this policy.*
- [BEST PRACTICE] For temperature sensitive CSPs, package the CSP in a moisture resistant clear, zippered bag placed inside of an appropriate insulated shipping container. Transport or ship CSP with the necessary quantity of ice packs to reasonably ensure controlled storage conditions for 24 hours from packaging of shipping container until delivery to final recipient.
- Select transportation and shipping modes that reasonably and reliably allow for delivery of temperature sensitive CSPs within the timeframe that corresponds to the useable life of ice packages inserted into insulated storage containers for temperature control.
- [USP 797] Label external shipping containers special handling instructions, in-transit storage requirements and, immediate storage requirements upon receipt if appropriate. Refer to common courier policies and instructions on proper containing labeling.

4. [USP 797] Monitoring & Logging Storage Temperatures
   - Monitor and log temperatures of all drug storage locations and devices daily on days of operation or via continuous monitoring device.
   - Temperatures are recorded manually on temperature log in Simplifi 797 and continuously by iMonnit software, which is accessible via internet login from any computer.
   - Temperature monitoring devices are maintained, and accuracy validated at least once every 12 months or per manufacturer instructions.
   - Retain readily retrievable records of temperature logs and accuracy validations.

5. [USP 797] CSP Storage Location Temperature Excursions
   - Report out of range temperatures or continuous temperature monitoring system alarms immediately to the Designated Person, or Pharmacy Manager. Temperature deviations in drug storage locations are considered urgent maintenance events and are remediated as quickly as possible.
   - When deviations exceed **± 5°C** of the required storage conditions for *longer than 30 minutes,* quarantine CSPs located in the affected drug storage areas(s) in appropriate comparable storage conditions. Refer to the **Release Inspections & Testing policy** for CSP quarantine procedures.
   - As soon as possible, the DP or responsible party conducts necessary research to determine if the affected CSP quality and integrity has been compromised.
     - If CSPs are determined to have retained quality and integrity, move CSPs back to the appropriate storage location.
     - If CSP quality or integrity cannot be determined or has been compromised, log or remove CSPs from dispensable inventory and destroy and/or dispose of per facility drug disposal policy.
   - Investigate the temperature excursion to determine root cause(s) and implement corrective actions if appropriate. Consider historical trends in the investigation. Refer to the **Quality Assurance and Quality Control policy** for procedures related to conducting investigations and corrective actions.

6. CSPs Exposed to Temperature Deviation during Transport or Shipping
   - Provide delivery personnel and vendors transporting CSPs within and outside of the immediate facility with training and instructions regarding:
     - Monitoring CSP temperatures, packaging, and storage conditions before, during, and immediately after transit
     - Managing and reporting temperature deviations and excursions
   - Insert instructions in shipping containers or in labeling materials for the evaluation of CSP temperature upon receipt, if appropriate. Instructions should also include pharmacy contact information for further information.
   - When temperature excursions are reported to the Pharmacy, log the issue per the Complaints, Adverse Drug Reactions, & CSP Recall policy. May also considering checking with drug manufacturers and extended stability references as well to see if drug is

salvageable to prevent patient from going without therapy until a new drug shipment is made, depending on patient's location to pharmacy and other circumstances for a new delivery. Patient safety will be kept as top priority and out of specification medication would only be used when deemed necessary involving discussion between the DP/supervising pharmacist and Director of Clinical Operations or Chief Operating Officer

Supporting Documents/References:

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.
- United States Pharmacopeial Convention, Inc. <659> Packaging and Storage Requirements. Current version.
- Spotsee Warm Mark Temperature Sensors Data Sheet. Accessible through: https://2072862.fs1.hubspotusercontent-na1.net/hubfs/2072862/Product%20Files/WarmMark/WarmMark_Data%20Sheet.pdf

Related Accreditation Standard(s):

DRX

Approved by:

Allison Croft, Compliance Officer — 01/21/2026 (Date)

Kimberly Jensen Moore (Jan 22, 2026 09:24:20 PST)

Kim Moore, SVP Pharmacy Operations — 01/22/2026 (Date)

Casey Cooper (Jan 22, 2026 08:16:21 CST)

Casey Cooper, Dir.of Pharmacy Policy and Standards — 01/22/2026 (Date)

Original Policy & Procedure Date: 1/1/2026

REVISION/REVIEW	DATE	BRANCH LEVEL APPROVAL (NAME AND TITLE)
Revised	1/16/2026	Casey Cooper, PharmD Director of Pharmacy Policy and Standards

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Total Infusion Care LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH 02936

Physical Address: 3041 W Horizon Ridge Pkwy, #100

City: Henderson State: NV Zip: 89502

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 702-778-8882 Website:

Licensing Company Email: rhansen@rchconsult.com

Section 2: Personal Information

First: Mohammad Middle: Ali Last: Pourteymaur

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] Stat[redacted] Zip [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF THE PACIFIC		08/94-5/97	
Address	City	State	Zip
3601 PACIFIC AVE	STOCKTON	CA	95211
Diploma/Degree obtained, if any			
PHARM. D.			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF COLORADO		8/92 – 5/94	
Address	City	State	Zip
1775 CENTRAL CAMNS MALL	BOULDER	CO	80309
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
ABRAHAM LINCOLN HIGH SCHOOL		08/88 – 6/92	
Address	City	State	Zip
2285 SOUTH FEDERAL	DENVER	CO	80219
Diploma/Degree obtained, if any			
DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/24 - NOW	[redacted]			
8/00 - 9/24				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Total Infusion Care LLC f/k/a Total Infusion Care Inc.			04/13 - now
Business Address	**City**	**State**	**Zip**
855 SW 78th Ave, #C200	Plantation	FL	33324
Phone	**Title**		
954-385-7322	PHARMACY MANAGER / STAFF PHARMACIST		

Description of Duties ACHC ACCREDITATION, NV BOP INSPECTION REPORTS, USP 797, PAYROLL COMPLIANCE, CHECKING TECHNICIANS, SUPERVISE PHARMACISTS

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9, Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8: 5 & 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

SEE ATTACHED

Original Signature (electronic, copies or stamps not accepted)

11/17/05
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

MOHAMMAD POURTEYMAUR

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/17/25

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, MOHAMMAD ALI POURTEYMAUR, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/20/25

Date

Subscribed and Sworn to before me this 20th day of November 2025

Notary Public Signature

Meghan Missick
Notary Public, State of Nevada
My Commission Expires: 05-14-28
Certificate No: 24-3528-01

(Seal)

Third-Party Revenue Cycle Management Litigation Overview

The following is a summary of the litigation between Total Infusion Care Inc. ("TIC") and a third-party revenue cycle management provider (the "Provider"), which commenced on May 30, 2024, and was resolved and dismissed on October 15, 2024.

TIC is a small home infusion pharmacy owned by four individuals -- Ali Pourmola, Naghme "Nicki" Saedi, Mohammad Pourteymaur and Michael Houske. TIC provides, among other things, antibiotics, immune deficiency medications, iron supplements and nutrition that are administered to patients intravenously. The location where these infusions are provided is usually in a patient's home or in TIC's on-site infusion suite. To get reimbursed for its services, TIC bills either a patient's pharmacy benefits plan, e.g., Medicare Part D, CVS, ExpressScripts, OptumRx, or the patient's medical benefits plan such as United Healthcare, Health Plan Nevada, Aetna, Cigna and Anthem for the medication and other services like nursing and supplies depending on the patient's coverage. Based on its increasing volume of business in 2022, TIC decided to seek out an outside billing company to help meet its billing needs. The Provider was such a medical billing company. The Provider represented its people had thirty-one years of billing experience including billing for home infusion pharmacy services. TIC and the Provider entered into a contract effective November 1, 2022, for the Provider to provide billing services regarding some, but not all, of TIC's medical benefit claims for certain assigned payers. A dispute arose between TIC and the Provider in July 2023, based on the Provider's incompetent billing, and TIC terminated the contract. This dispute was not limited to a dispute regarding a contract alone, but the dispute also involved the Provider's misrepresentations that enticed TIC to enter into the contract with the Provider in the first place. The dispute also involved the Provider's extreme negligence in performing under the contract. The Provider's misrepresentations and negligence caused damage to TIC in lost revenue and lost profits.

Despite TIC's attempt to mediate this matter without incurring the expense of formal litigation and to allow the parties to part ways, the Provider commenced litigation in state court in Nevada on May 30, 2024, and TIC removed the matter to United State District Court in Nevada on June 7, 2024. The parties, however, continued to discuss settlement. On September 23, 2024, the parties reached an agreement for an undisclosed payment from TIC to the Provider. The matter was dismissed on October 15, 2024. Despite the validity and strength of its claims, TIC made a business decision to resolve the matter for far less than the potential legal fees that would have been incurred to litigate the matter to conclusion.

SETTLEMENT AGREEMENT AND RELEASE OF ALL CLAIMS

This Settlement Agreement and Release of all Claims (the "Agreement") is entered into this 10th day of September, 2024, by and between Plaintiff Med-Strategies, Inc. ("MSI") and Defendant Total Infusion Care, Inc. ("TIC"), and any of their affiliates, agents, servants, employees, parents, subsidiaries, and any person or entity acting by, through, under or in concert with each of them (collectively referred to as the "Parties" or "Settling Parties").

RECITALS

A. On September 27, 2022, MSI and TIC entered into a Services Agreement wherein MSI agreed to provide various management services to TIC, including, but not limited to, billing and collection services and as further described in the Services Agreement. Prior to the Lawsuit (defined below) being filed, TIC paid MSI $50,000 towards amounts owed under the Services Agreement (the "Initial Payment") which MSI agrees was received and deposited by MSI.

B. On May 30, 2024, MSI filed a Complaint in the Eighth Judicial District Court of Nevada, Case No. A-24-894368-B which was subsequently removed to the United States District Court for the District of Nevada, Case No. 2:24-cv-01060-GMN-MDC pertaining to the Services Agreement and alleging that TIC breached its obligations to MSI (the "Lawsuit"). The allegations pertaining MSI's claims are set forth in more detail in the MSI's Complaint in the Lawsuit. Therein, TIC planned to assert counterclaims against TIC in the Lawsuit, which shall be considered and defined as part of the Lawsuit.

C. Collectively all claims and causes of action that the Parties have against one another, whether alleged or otherwise, whether known, unknown, past, present, or future claims, demands, damages, causes of action, complaints, counterclaims, controversies, costs, debts, expenses, obligations, losses, promises, charges, and any liability whatsoever related to the Services Agreement, the Lawsuit, or otherwise are known as the "Dispute." The Dispute shall be broadly construed to fulfill the parties' intent that this Agreement resolve any and all issues between the Parties.

D. Without admitting liability as to any claim, counterclaim, allegation, or defense raised or asserted in the Lawsuit and the Dispute, the Parties desire to settle, resolve, and compromise all claims and potential claims, counterclaims, rights of action, and disputes that relate to the Lawsuit and the Dispute.

AGREEMENT

Based upon the foregoing, and in consideration of the terms set forth in this Agreement, and for other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. Consideration. Upon execution by the Parties to this Agreement, and in consideration for each of the terms of this Agreement, the sufficiency of which is acknowledged by the Parties, the Parties agree as follows: 1) TIC shall make a payment to MSI in the amount of $450,000.00 (the "Settlement Payment"); 2) the Settlement Payment shall be paid by wire transfer to the The Law Offices of Timothy Elson, Inc. 3) the Settlement Payment shall be

transferred to The Law Offices of Timothy Elson within 20 days after the settlement agreement is fully executed, a W9 is provided by The Law Offices of Timothy Elson and TIC's receipt of wiring instructions; and 4) the funds shall not be released to MSI until dismissal has been entered. The Settlement Payment is in addition to the Initial Payment.

2. Mutual Release. For good and valuable consideration, the Settling Parties do hereby fully and finally settle, release, acquit, and forever discharge the other Settling Parties and their respective successors, predecessors, representatives, directors, members, officers, employees, servants, agents, partners, attorneys, insurers, and assigns, as to any and all claims in any way arising out of or related to the Services Agreement, the Lawsuit, and/or the Dispute. Such claims include, but are not limited to, any and all manner of action or actions, cause or causes of action, in law or in equity, suits, claims, controversies, demands, assignments, covenants, obligations, debts, liens, contracts, agreements, promises, judgments, orders, liability, damages, losses, attorney fees or costs, any and all costs or expenses, fixed or contingent of whatsoever kind or nature, at equity or otherwise, which have existed or may have existed, or which do exist, or which hereafter can, shall, or may exist with respect to the Settling Parties, the Services Agreement, the Lawsuit, the Dispute, and any and all claims that were or might have been, or which could have been, alleged against any of the Settling Parties by any of the Settling Parties.

3. Dismissal of the Action. Within five business days of receipt of the Settlement Payment, the Parties shall collectively work together to dismiss the Lawsuit in its entirety and with prejudice, each party to bear their own attorneys' fees and costs. The funds shall not be released to MSI from its attorney until dismissal has been entered. The Parties shall take no steps to have any orders entered in the action other than the order dismissing the action with prejudice.

4. Non-Assignment. The Parties warrant and represent that they have not pledged, sold, assigned, conveyed or otherwise transferred, in whole or in part, any claim or cause of action that they may have against each other.

5. Disputed Claims. This Agreement is the result of a compromise among the Settling Parties of disputed claims. This Agreement or any payment made pursuant to it shall never, at any time or for any purpose, be considered an admission of liability and/or responsibility on the part of any of the Settling Parties, as they continue to deny such liability and disclaim any responsibility.

6. Confidentiality. The Settling Parties and their counsel shall keep the terms of this settlement confidential. One thousand dollars of the settlement amount shall be allocated as consideration for this confidentiality. Notwithstanding the foregoing, the Settling Parties may disclose such terms of this Agreement as required to their respective attorneys, accountants, tax preparers, insurers, or insurance agents. In addition, the Settling Parties may disclose such terms of this Agreement as required by a valid court order or a validly issued subpoena provided that prior notice is provided to the non-disclosing party at least ten days before disclosure unless such notice is prohibited by law. The Settling Parties hereby state, warrant, and represent that they have not already disclosed the terms of this

settlement or the existence of this pending settlement of this matter to anyone or any entity or any agency other than their attorneys or insurer.

7. Non-Disparagement. The Settling Parties agree not to make negative or disparaging remarks maligning, ridiculing, defaming or otherwise speaking ill of each other and each other's principals to third parties, in any forum (including but not limited to orally, in writing, on social media, the Internet, to the media, persons engaged in radio, television or Internet broadcasting, or to persons or entities that gather or report information on trade and business practices). However, this provision does not apply to any communications that are protected by the litigation privilege. In addition, this provision does not apply when the parties are responding to a validly issued subpoena or court order provided that prior notice is provided to the non-disclosing party at least ten days before disclosure unless such notice is prohibited by law.

8. Indemnification. The Parties agree to indemnify and hold one another harmless from and against any and all loss, costs, damages, or expenses, including without limitation, attorney fees, arising out of any party's breach of this Agreement or the fact that any representation made herein was false when made and such false representation results in further litigation against or involving each Party.

9. Review by Parties and Counsel. The Parties acknowledge that each of them, and their respective counsel, has had the opportunity to review the Agreement, that the terms of the Agreement have been completely read by them and explained to them, that the terms are fully understood and voluntarily accepted by them, and that the Agreement will not be construed against any Party merely because such party prepared the Agreement. The Parties hereby represent to each other that they have reviewed this Agreement with competent legal counsel and that no Party shall deny the validity of this Agreement on the grounds that the Party did not understand the nature and consequences of this Agreement or did not have the opportunity to seek the advice of independent counsel prior to executing it.

10. Complete Agreement and Understanding. This Agreement contains the entire understanding between the Parties, and supersedes, if any, all prior and contemporaneous agreements and understandings, inducements or conditions, express or implied, oral or written, except as herein contained. The Parties agree that any purported reliance on oral representations would be unreasonable.

11. Binding Nature of Agreement. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors, heirs, representatives, and assigns.

12. Enforcement of Agreement. In any action brought to enforce, interpret, or determine the validity of the obligations, terms, covenants, or conditions of the Agreement, the prevailing Party shall be entitled to recover from the other party its costs (including but not limited to the costs incurred in connection with the use of any necessary expert witness) and reasonable attorney fees.

13. Attorney Fees and Costs. The Parties to the Agreement agree that, except as to an action to enforce the Agreement set forth above, each Party shall bear its own costs (including but not

limited to the cost incurred in connection with the use of any necessary expert witnesses), attorney fees and other expenses.

14. Captions. The paragraph captions set forth in the Agreement are for the convenience of the Parties and do not modify, limit, or otherwise affect the express provisions of the Agreement.

15. Governing Law. The Agreement and all questions relating to its validity, interpretation, performance and enforcement shall be governed by and construed in accordance with the laws of the State of Nevada.

16. Forum Selection Clause. In the event of any litigation that in any way relates to or arises out of the subject matter of this Agreement, the Parties hereby consent to the personal jurisdiction of the federal and state courts of Nevada, and further agree that the venue of any such litigation shall be exclusively limited to the state or federal courts located in Clark County, Nevada.

17. Severability. Should any provision of this Agreement be declared or determined by any court to be illegal or invalid, the validity of the remaining parts, terms or provisions shall not be affected thereby and said illegal or invalid part, term or provision shall be deemed not to be a part of this Agreement.

18. Modification. This Agreement may not be modified or amended other than by a written agreement signed by authorized representatives of all Parties.

19. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, and it shall not be necessary in making proof of this Agreement to produce or account for more than one such counterpart.

Med-Strategies, Inc.	Total Infusion Care, Inc.
By: S. M	By: M. H
Print Name: Ramesh Goginenl	Print Name: Michael Hooske
Its (Position): CEO	Its (Position): General Counsel & EVP
Date: 10/2/2024	Date: 3 October 2024

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

Healthcare Branch
State Board of Pharmacy

December 27, 2016

Mohammad A. Pourteymaur

CERTIFIED AND FIRST CLASS MAIL

RE: Case 2016-3681

Dear Mr. Pourteymaur:

At its November 17, 2016 meeting, the Colorado State Board of Pharmacy ("Board") reviewed the above-referenced complaint. After careful consideration of all the evidence before the Board, the Board determined that upon your initial application for pharmacist licensure in the State of Colorado, you did not attest that you had disciplinary action taken against your license or pending against you in any state when you should have attested to this fact.

The Board hereby admonishes the pharmacy for violation of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act and Board Rules.

This admonishment shall be made a part of the permanent records of the Board and is reportable as a disciplinary action. It may also be considered as an aggravating factor if you incur future violations. You may request that a hearing be initiated by the Board if you wish to dispute the information in this letter. The purpose of such a proceeding would be to adjudicate the propriety of the conduct upon which this letter is based. The Board must receive such a request from you within 20 days after you receive this letter.

If you make a timely request, the letter of admonition shall be deemed vacated pending resolution of formal disciplinary proceedings. Those proceedings involve a hearing conducted in accordance with the State Administrative Procedures Act.

Sincerely,

FOR THE COLORADO STATE BOARD OF PHARMACY

Chris Gassen, R.Ph.
Pharmaceutical Inspector
Acting Program Director

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

MOHAMMAD A. POURTEYMAUR, R.Ph.,
Certificate of Registration #13759,

Respondent.

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

Case No. 08-032-RPH-S

THIS MATTER was heard by the Nevada State Board of Pharmacy (hereinafter Board) at its regular meeting on October 29, 2008, in Las Vegas, Nevada. The Board was represented by Carolyn J. Cramer, General Counsel for the Board. Respondent Mohammad A. Pourteymaur appeared and represented himself. Based on the presentation of Mr. Pourteymaur, and the public records in the possession and control of the Board, the Board issues the following Findings of Fact, Conclusions of Law, and Order:

FINDINGS OF FACT

1. At hearing, Mr. Pourteymaur admitted the facts as plead in the Notice of Intended Action and Accusation were true and correct. At hearing, Mr. Pourteymaur testified by way of explanation and mitigation. Based upon the Respondent's admissions and the evidence presented at hearing; the following are found to be the facts of this matter.

2. Mr. Pourteymaur timely submitted the application for renewal of his pharmacist's license. On his renewal application he indicated that he had completed 30 hours of continuing education. Mr. Pourteymaur's renewal application was included in a random sample to be audited. The audit revealed that Mr. Pourteymaur had completed

zero hours of continuing education between November 1, 2005 and October 31, 2007.

3. At hearing, Mr. Pourteymaur testified that he has been in medical school since August of 2002 and has been taking some pharmacy related courses, but that the classes were not ACPE accredited classes. Additionally, Mr. Pourteymaur testified he had personal matters over the time in question such as deaths and births in his family that took his time. Mr. Pourteymaur also expressed regret that he had answered the question affirmatively stating that he had completed the course work when he knew that he had not and offered classes he took after the renewal period in mitigation to the Board.

CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter and this respondent because Mr. Pourteymaur is a pharmacist licensed by the Board.

2. In indicating on his renewal application that he had completed 30 hours of continuing education on his renewal application when he had taken zero hours of course work, Mr. Pourteymaur violated NRS 639.210(4) and (9) and 639.2174(2) and NAC 639.330 and 639.390.

ORDER

Based upon the foregoing, the Board hereby orders the following:

1. For the renewal period of November 1, 2005 through October 31, 2007, Mr. Pourteymaur shall complete 30 hours of continuing education. Mr. Pourteymaur will not be given credit for any of the continuing education classes he completed prior to October 29, 2008.

2. For the renewal period of November 1, 2007 through October 31, 2009, Mr. Pourteymaur will complete 60 CE's. Mr. Pourteymaur' continuing education hours will

be audited to verify that he has completed the 60 hours of continuing education required by this Order.

3. Mr. Pourteymaur shall pay a fine of $1,000.00 by cashier's or certified check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office within 60 days of the effective date of this Order.

4. Mr. Pourteymaur will not be allowed to inactivate his license.

5. Mr. Pourteymaur must take and pass a written law examination provided by Board staff within 30 days of receipt of the examination.

6. The failure by Mr. Pourteymaur to comply with any term in this order shall result in the immediate suspension of his license and will also result in further discipline, up to and including revocation of the his license.

Signed and effective this 25th day of November, 2008.

Barry Boudreaux, President
Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Total Infusion Care LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH 02936

Physical Address: 3041 W Horizon Ridge Pkwy, #100

City: Henderson State: NV Zip: 89502

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 702-778-8882 Website:

Licensing Company Email: rhansen@rchconsult.com

Section 2: Personal Information

First: Daniel Middle: Mark Last: Cammarata

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Florida Atlantic University		1980 - 1982	
Address	**City**	**State**	**Zip**
777 Glades Road	Boca Raton	FL	33431
Diploma/Degree obtained, if any			
Bachelor of Science in Business Administration with major in Accounting			

School Name		From - To (MM/YY – MM/YY)	
Broward Community College		1978 -1980	
Address	**City**	**State**	**Zip**
3501 Davie Road	Davie	FL	33314
Diploma/Degree obtained, if any			
Associates Degree			

School Name		From - To (MM/YY – MM/YY)	
Hollywood Hills High School		1974 - 1978	
Address	**City**	**State**	**Zip**
5400 Stirling Road	Hollywood	FL	33021
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/86 - present	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
BioMatrix Specialty Pharmacy, LLC and affiliates			05/20 - present	
Business Address	**City**		**State**	**Zip**
855 SW 78th Ave, #C200	Plantation		FL	33324
Phone	**Title**			
954-385-7322	Treasurer (previously CFO and Secretary)			
Description of Duties				
Performed duties commensurate with those of a CFO and Treasurer of a large company with numerous subsidiaries, several licensed pharmacies, AICs, and licensed nursing agencies.				

Business Name			From - To (MM/YY – MM/YY)	
Integrated Dermatology			06/18 - 04/20	
Business Address	**City**		**State**	**Zip**
4700 Exchange Court, Suite 110	Boca Raton		FL	33431
Phone	**Title**			
561-314-2000	Chief Executive Officer			
Description of Duties				
Responsible for accounting, finance, risk management, RCM, human resources and acquisition due diligence and integrations.				

Business Name			From - To (MM/YY – MM/YY)	
Orangetherapy Fitness			10/15 - 06/18	
Business Address	**City**		**State**	**Zip**
4216 Jackson Street	Hollywood		FL	33021
Phone	**Title**			
954-604-9384	Franchise Owner			
Description of Duties				
Responsible for all aspects of owning and operating a fitness studio.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniel Cammarata

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/25

Date

Please have this section completed in the presence of a Notary Public.

State of FLORIDA, ss. County of Brevard

I, DANIEL CAMMARATA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/19/25

Date

Subscribed and Sworn to before me this 19 day of November.

Kimberly Deese

Notary Public Signature

Notary Public State of Florida
Kimberly Deese
My Commission HH 504324
Expires 3/14/2028

(Seal)

* Original sent under separate cover

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Total Infusion Care LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH 02936

Physical Address: 3041 W Horizon Ridge Pkwy. #100

City: Henderson State: NV Zip: 89502

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 702-778-8382 Website:

Licensing Company Email: rhansen@rchconsult.com

Section 2: Personal Information

First: Morgan Middle: Means Last: Harber

Alias(es, nicknames, name changes, etc.): Means (maiden name)

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zi: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Loyola University of Chicago School of Law		08/08 - 05/11	
Address	**City**	**State**	**Zip**
25 E Pearson St	Chicago	IL	60611
Diploma/Degree obtained, if any			
Juris Doctor			

School Name		From - To (MM/YY – MM/YY)	
University of Florida		06/04 - 05/08	
Address	**City**	**State**	**Zip**
210 Gerson Hall	Gainesville	FL	32611
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Melbourne Central Catholic School		08/00 - 05/04	
Address	**City**	**State**	**Zip**
154 E Florida Ave	Melbourne	FL	32901
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
05/15 - present				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
BioMatrix Specialty Pharmacy, LLC and affiliates			12/16 - present	
Business Address		**City**	**State**	**Zip**
855 SW 78th Ave, #C200		Plantation	FL	33324
Phone	**Title**			
954-385-7322	Vice President & Secretary (previously Chief Administrative Officer, General Counsel)			
Description of Duties				
Oversee all legal matters associated with nationwide business operations for licensed pharmacies, nursing agencies, and AICs, including Human Resources, Corporate Compliance, Risk Management and all merger and acquisition activities.				

Business Name			From - To (MM/YY – MM/YY)	
Healthcare District of Palm Beach County			09/12 - 12/16	
Business Address		**City**	**State**	**Zip**
1515 N Flagler Dr, #101		West Palm Beach	FL	33401
Phone	**Title**			
561-804-5600	Chief Compliance Officer			
Description of Duties				
Leadership of the District's Compliance Program across all lines of business, including an acute care hospital, skilled nursing facility, managed care program, trauma program, aeromedical program, and school health programs.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Total Infusion Care LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH 02936

Physical Address: 3041 W Horizon Ridge Pkwy, #100

City: Henderson State: NV Zip: 89502

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 702-778-8882 Website:

Licensing Company Email: rhansen@rchconsult.com

Section 2: Personal Information

First: Kathee Middle: Marie Last: Kramm

Alias(es, nicknames, name changes, etc.): Deem (maiden name), Rhea (previous married name)

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Kansas University		1981 - 1986	
Address	**City**	**State**	**Zip**
1450 Jayhawk Blvd	Lawrence	KS	66045
Diploma/Degree obtained, if any			
Bachelor of Science in Nursing			

School Name		From - To (MM/YY – MM/YY)	
Shawnee Mission High School (Northwest)		1979 - 1981	
Address	**City**	**State**	**Zip**
12701 West 67th Street	Shawnee	KS	66216
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/23 - present	[redacted]			
05/21 - 06/23				
07/17 - 05/21				
11/03/07/17				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
BioMatrix Specialty Pharmacy, LLC and affiliates			06/23 - present
Business Address	**City**	**State**	**Zip**
855 SW 78th Ave, #C200	Plantation	FL	33324
Phone	**Title**		
954-385-7322	Board Member and President (previously CEO)		
Description of Duties			
Performed duties commensurate with those of a Board Member and Executive Officer of a large company with numerous subsidiaries, several licensed pharmacies, AICs, and licensed nursing agencies.			

Business Name			From - To (MM/YY – MM/YY)
Superior Biologics			05/22 - 09/22
Business Address	**City**	**State**	**Zip**
505 Elmwood Ave	Sharon Hill	PA	19079
Phone	**Title**		
800-314-0182	Chief Executive Officer		
Description of Duties			
All duties and responsibilities commensurate with those of a CEO.			

Business Name			From - To (MM/YY – MM/YY)
Optum Infusion Services			11/15 - 02/20
Business Address	**City**	**State**	**Zip**
11000 Optum Circle	Eden Prairie	MN	55344
Phone	**Title**		
877-342-9352	SVP Infusion Services		
Description of Duties			
Responsible for sales and operational efforts for a 10 person payor contracting team.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order? See Note	* ✓	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Unknown	Unknown	Kansas	Fairway	Johnson
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Possibly N/A		City, County or State Police		
Reason/Charge				
Pulled over for expired tag, failed sobriety test				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

In approximately 1987 or 1988 I was pulled over in Fairway, Kansas for an expired tag. During the stop I was asked to do a sobriety test and the results were "just at the limit". I was taken to the police station and picked up by a friend. I was required to take a class on impaired driving, which I completed. I do not remember if any formal charges were made against me, if there were, the records were expunged. I have searched the court records and have not found any records related to the incident, nor does my FBI Background Report have any mention of the incident. I do not have access to any other information or documents regarding the incident.

Original Signature (electronic, copies or stamps not accepted)

11/19/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kathee Kramm

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-19-25

Date

Please have this section completed in the presence of a Notary Public.

State of Kansas, ss. County of Johnson

I, Kathee Kramm, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11-19-25

Date

Subscribed and Sworn to before me this 19 day of November 2025

Alexandria Miller

Notary Public Signature

NOTARY PUBLIC
STATE OF KANSAS
ALEXANDRIA MILLER
My Appointment Expires: 6-11-29

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Total Infusion Care LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH 02936

Physical Address: 3041 W Horizon Ridge Pkwy, #100

City: Henderson State: NV Zip: 89502

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 702-778-8882 Website:

Licensing Company Email: rhansen@rchconsult.com

Section 2: Personal Information

First: Edward Middle: Paul Last: Kramm

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Philadelphia College of Pharmacy and Science		09/83 - 05/88	
Address	**City**	**State**	**Zip**
600 S 43rd Street	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
Bachelor of Science in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Exeter Township Senior High School		09/80 - 06/83	
Address	**City**	**State**	**Zip**
201 E 37th Street	Reading	PA	19606
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/23 - present	[redacted]			
05/21 - 06/23				
07/17 - 05/21				
11/03/07/17				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
BioMatrix Specialty Pharmacy, LLC and affiliates		12/23 - present	
Business Address	**City**	**State**	**Zip**
855 SW 78th Ave, #C200	Plantation	FL	33324
Phone	**Title**		
954-385-7322	Board Member and Chief Executive Officer		
Description of Duties			
Performed duties commensurate with those of a Board Member and Executive Officer of a large company with numerous subsidiaries, several licensed pharmacies, AICs, and licensed nursing agencies.			

Business Name		From - To (MM/YY – MM/YY)	
Molecular Designs LLC		10/21 - 12/23	
Business Address	**City**	**State**	**Zip**
2 Perimeter Park South, Suite 160	Birmingham	AL	35243
Phone	**Title**		
800-314-0182	Chief Executive Officer		
Description of Duties			
Overall management of design development and implementation of molecular testing.			

Business Name		From - To (MM/YY – MM/YY)	
Optum Infusion Services		11/15 - 04/20	
Business Address	**City**	**State**	**Zip**
11000 Optum Circle	Eden Prairie	MN	55344
Phone	**Title**		
877-342-9352	SVP Infusion Services		
Description of Duties			
Oversight of all aspects of the infusion services division of Optum Rx.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	✔	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 & 9. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
07/25/2018	06/10/2019	Kansas	Topeka	Shawnee
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
18-750		Kansas State Board of Pharmacy		
Reason/Charge				
Misrepresentation of CE obtained for renewal of Kansas Pharmacist License				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				

Provide explanation below:

In June of 2018, I renewed my Kansas Pharmacist license. The due date to complete the required CE and sumbit the renewal was 6/30/2018. I was out of the country without access to my completed CE information at the time of the renewal. Upon my return in July, I submitted my completed CE to the CE sponsors. All CE units were dated after the due date of 6/30/2018 so the Kansas State Board of Pharmacy did not recognize them in the renewal license period so my attestation to obtaining all required CE was unintentionally incorrect. I was given the opportunity to renew my license, however, inasmuch as I had not practiced as a pharmacist since 2008, I requested that my Kansas pharmacist license not be renewed but rather be retroactively placed on inactive status. The Board executed a Stipulation and Consent Order which included placing my Kansas Pharmacist license on inactive status beginning 7/1/2018. I then reinstated my license effective 06/10/2019 and voluntarily surrendered it on 6/30/2022.

Original Signature (electronic, copies or stamps not accepted)

11/19/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Edward Kramm

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/25

Date

Please have this section completed in the presence of a Notary Public.

State of Kansas, ss. County of Johnson

I, Edward Kramm, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/19/25

Date

Subscribed and Sworn to before me this 19 day of November 2025.

Alexandria Miller

Notary Public Signature

NOTARY PUBLIC
STATE OF KANSAS
ALEXANDRIA MILLER
My Appointment Expires: 6-11-29

(Seal)

SECTION 8.6. & 9.

ATTACHMENT

Edward P. Kramm
Chief Executive Officer

In July of 2018, Mr. Kramm renewed his Kansas Pharmacist license. The due date to complete CE and submit renewal was 6/30/2018. He was out of the country without access to his completed CE and so in July, upon his return to the states, he submitted his completed CE to the CE sponsors. The CE units were dated after the due date so Kansas did not recognize them in the license period which meant he had made an incorrect attestation on his renewal. Inasmuch as Mr. Kramm had not practiced pharmacy since 2008 and pursuant to his request, the Board agreed to retroactively place his license on inactive status beginning July 1, 2018. A Stipulation and Consent Order was executed. The Order included the requirements for changing his license to active status in the future, if desired. Mr. Kramm determined that he would not practice pharmacy at any time in the future so he let his license officially expire on 6/30/2022 and the matter was closed. It is important to note that Mr. Kramm did not practice without a license at any time. **SEE ATTACHED**

Filed By

KANSAS STATE
BOARD OF PHARMACY

BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of the Renewal Application of Edward (Ted) Kramm License No.1-12056	))))))	Case No. 18-750

STIPULATION AND CONSENT ORDER

IT IS HEREBY STIPULATED AND AGREED by and between the Kansas Pharmacy Board (the "Board") and Edward (Ted) Kramm ("Respondent") as follows:

1. The Board is represented herein by its attorney, Randall J. Forbes of Frieden, Unrein & Forbes, 1414 SW Ashworth Place, Suite 201, Topeka, Kansas 66604. The Respondent is represented herein by attorney. N/A.

2. The Board is the Kansas agency vested with the authority to carry out and enforce the provisions of the Kansas Pharmacy Law, K.S.A. 65-1626 *et seq.*, (the "Act") including conducting hearings and proceedings to revoke, suspend, or otherwise discipline a Kansas license to practice pharmacy, including imposing an administrative fine or penalty.

3. The Respondent is presently entitled to engage in the practice of pharmacy in the State of Kansas by reason of the Board having issued Respondent Kansas license number 1-12056 ("Kansas License"). At all times relevant hereto, the Respondent has held a current license to engage in the practice of pharmacy in the State of Kansas.

4. Respondent hereby admits and waives any further proof in this or any other proceeding before or initiated by the Board, and upon motion duly made, seconded and passed, the Board finds as follows:

- On July 25, 2018, Respondent submitted a renewal application to engage in the practice of pharmacy in the State of Kansas.

- In the renewal application, Respondent requested to renew the license on active status.
- At the end of the renewal application, Respondent agreed to the following statement prior to submitting the completed renewal application: "I hereby attest that I have completed all continuing education hours required by law to renew my license."
- Respondent's renewal application was selected for an audit to provide proof of Respondent's continuing education certificates or a transcript of completion of required hours.
- Respondent provided proof of two hours of continuing education to renew Respondent's pharmacy license.
- On May 2, 2019, Respondent indicated he has not practiced pharmacy for several years and wants to retroactively renew his license on inactive status, which does not require continuing education.
- Pursuant to K.A.R. 68-1-1b, 30 hours of continuing education shall be required for renewal of a pharmacist license during each licensure period, which must be obtained in the two-year licensure period ending on the June 30 expiration date of each license.
- Respondent was required to provide proof of completion of 30 hours of continuing education earned between July 1, 2016 and June 30, 2018.

5. Upon motion duly made, seconded and passed, the Board finds and concludes that Respondent's conduct, as described above, violates the Act is therefore grounds for disciplinary action against Respondent's Kansas License pursuant to 65-1627(a)(1) and (a)(9).

6. The Respondent agrees and consents and the Board finds, concludes, and orders that the following disposition is just and appropriate under the circumstances:

A. Respondent's Kansas license to practice pharmacy is retroactively placed on inactive status beginning July 1, 2018.

B. If Respondent seeks to change the license to active status in the future, Respondent shall be required to pay a $2,800 fine and provide proof of an additional 112 hours of completed continuing education for failing to comply with K.S.A. 65-162(a)(1) and (a)(9), in addition to any other fees and requirements established by law. Completion of these hours shall not count toward any subsequent continuing education requirement for Respondent's Kansas license.

7. Respondent agrees that all information in the possession of the Board's Executive Secretary, its staff, its investigators and or its attorney regarding the investigation which lead to this disciplinary action and all information discovered during the pendency of the disciplinary action may be disclosed to and considered by the Board as part of the presentation and consideration of the proposal of settlement in the form of this Stipulation and Consent Order and the Final Order provided for herein, with or without the presence of the Respondent or its attorney. In the event that this Stipulation and Consent Order and the Final Order provided for herein are not accepted and approved by the Board, the Respondent further waives any objection to the Board members' consideration of this Stipulation and Consent Order or the information mentioned in the preceding sentence and further agrees to waive any claim of due process violation or the right to seek the disqualification of any Board member as a result of the Board member's consideration of said document and information.

8. The stipulations contained herein shall not become binding until this Stipulation and Consent Action is approved by the Board and the Final Order provided for herein is entered by the Board. The Respondent acknowledges that the approval of the Board's Executive Secretary or its attorney shall not constitute the approval of the Board or bind the Board to approve this Stipulation and Consent Action or the Final Order provided for herein.

9. The Respondent agrees that this Stipulation and Consent Order is in conformance with Kansas and federal law and the Board has jurisdiction to enter into it and enter the Final Order provided for herein. The Respondent further agrees, for purposes of this matter, that the Kansas Pharmacy Act, K.S.A. 65-1626 *et seq.* is constitutional on its face and as applied in this case.

10. This Stipulation constitutes the entire agreement of the parties and may only be modified by a subsequent writing signed by them. The agreement shall be interpreted in accordance with the laws of the State of Kansas.

11. The Respondent acknowledges that Respondent has the following rights:

(a) To have formal notice of charges served upon him;

(b) To file a response to the charges;

(c) To have notice of and participate in a formal adjudicative hearing with the Board or its designee making specific findings of facts and conclusions of law based only upon evidence admitted at such hearing; and

(d) To take advantage of all applicable provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501 *et seq.* and the Kansas Judicial Review Act, K.S.A. 77-601 *et seq.*

The Respondent freely waives these rights and acknowledges that said waiver is made voluntarily and in consideration of the Board's limiting the disciplinary action taken against him to those provided for herein. The Respondent further waives the right to seek reconsideration or appeal or otherwise contest this Stipulation and Consent Order and the Final Order provided for herein.

12. The Respondent acknowledges that Respondent enters into this Stipulation and Consent Order freely and voluntarily after consultation with counsel of his choosing. The Respondent further acknowledges that Respondent has read this Stipulation and Consent order in its entirety, understands its legal consequences, and agrees that none of its terms are unconscionable, arbitrary, or capricious.

13. Time is of the essence to this Stipulation and Consent Order. Respondent acknowledges and agrees that any violation of this Stipulation and Consent Order shall constitute a willful violation of a lawful Board order and grounds for further disciplinary action against him. The pendency of any disciplinary action arising out of an alleged violation of this Stipulation and Consent Order shall not affect the obligation of Respondent to comply with all terms and conditions of this Stipulation and Consent Order.

14. This Stipulation and Consent Order constitutes the entire and final agreement of the parties. In the event any provision of this Stipulation and Consent Order is deemed invalid or unenforceable by a court of competent jurisdiction, it shall be severed and the remaining provisions of this Stipulation and Consent Order shall be given full force and effect.

15. Upon approval and entry of the Final Order by the Board, this Stipulation and Consent Order shall be a public record in the custody of the Board.

16. This Stipulation and Consent Order shall become effective on the day it is approved, accepted, and made an order of the Board by way of signature of the Board's authorized representative.

17. The Respondent acknowledges that Respondent has been advised by the Board that Respondent would have the right within 15 days after service of the Final Order provided for herein to file a petition for reconsideration with the Board and the right within 30 days after service of the Final Order provided for herein to file a petition for judicial review in the District Court of Shawnee County, Kansas in accordance with the Kansas Judicial Review Act, K.S.A. 77-601 *et seq.* and to serve such a petition for judicial review on the Kansas Board of Pharmacy by serving Alexandra Blasi, JD, MBA, Executive Director, at 800 SW Jackson St., Suite 1414, Topeka, KS 66612. The Respondent hereby waives those rights.

ENTERED AND EFFECTIVE this 10th day of June, 2019.

KANSAS BOARD OF PHARMACY

By: _____
DR. JOHN WORDEN
President

AGREED AND APPROVED BY:

Respondent

Date 6/21/19

Alexandra Blasi
Executive Secretary

Date 6/6/19

Respondent's Attorney's Name & Address

Date

Randall J. Forbes, KS#09089 MO#64335
FRIEDEN, UNREIN & FORBES, LLP
1414 SW Ashworth Place, Suite 201
Topeka, KS 66604
(785) 354-1100

Date 06/06/2019

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing STIPULATION AND CONSENT ORDER was served by depositing same in the United States mail, postage prepaid, this 10th day of June, 2019 addressed to:

EDWARD (TED) KRAMM
[redacted]
OVERLAND PARK KS [redacted]

Kansas Board of Pharmacy Staff

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing STIPULATION AND CONSENT ORDER was served by depositing same in the United States mail, postage prepaid, this 10th day of June, 2019 addressed to:

EDWARD (TED) KRAMM
[redacted]
OVERLAND PARK KS [redacted]

Kansas Board of Pharmacy Staff

8D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☐ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.) * Current license #: PH 03705	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Saint Mary pharmacy

Physical Address: 4180 S Rainbow blvd, Ste 808

City: Las Vegas State: NV Zip: 89103

Mailing Address (if different from physical address): NA

City: NA State: NA Zip: NA

Telephone: 702-722-3707 Toll Free # (NAC 639.708, NRS 639.23286): NA

Fax: 702-848-5574 Contact Email: Pharmacy050522@outlook.com

Website: NA

Nevada Business License # (if applicable) NV 20222344792

Supervising/Managing Pharmacist Name (NRS 639.220): TEGEST TILAHUN

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20171

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: TEGEST TILAHUN	NV Pharmacist Registration #: 20171
Name: Soyoung Zom	NV Pharmacist Registration #: 18126
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA
Parent Company (if any): NA
Corporation Name: NA
Mailing Address: NA
City: NA State: _____ Zip: _____
Telephone: NA Email: _____
Contact Person Name: NA

Date of SEC Registration: NA	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: S Corp
Parent Company (if any): NA
Corporation/Organization Name: Remedies pharmacy INC.
Mailing Address: 4180 S. Rainbow Blvd, ste 808
City: Las Vegas State: NV Zip: 89103
Telephone: 702-722-3707 Email: pharmacy050522@outlook.com
Contact Person Name: Baraa Talebs
Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: NA
Mailing Address: NA
City: NA State: _____ Zip: _____
Telephone: NA Email: _____
Contact Person Name: NA
Please check type of partnership (NAC 639.214) ☐ General ☐ Limited
Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: NA
Business Name: NA
Business Address: NA
City: NA State: _____ Zip: _____
Telephone: NA Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist in Charge (title) for SAINT MARY Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

TEGEST TILAHUN

Print Name of Authorized Person

Tegest Tilahun

Original signature of Authorized Person (copies or stamps not accepted)

1/23/2026

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, TEGEST TILAHUN hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist In Charge (PIC) (title) for Saint Mary Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Tegest Tilahun
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 3rd day of February, 2026

Notary Public
State of Nevada, County of Clark

Linda M Abrams
Notary Public - State of Nevada
County of Clark
APPT. NO. 19-6625-01
My Appt. Expires: Sept. 3, 2027

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: TEGEST TILAHUN Pharmacist Registration #: 20171

Pharmacy Name: SAINT MARY PHARMACY

Initial each statement below to indicate you have read and agree with the following:

T.T I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

T.T I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

T.T I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

T.T I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

T.T I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		X
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		X

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

1/23/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Baraa Jaleb

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1/28/2026

Date

Board Use Only	Date Received: 2/9/26	Amount: $500.00

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

CORPORATION, INDICATE THE Secretary:

BARAA M HAMOUDI TALEB — Name
USA — Country
[redacted] — Address / City / State / Zip/Postal Code

CORPORATION, INDICATE THE Treasurer:

BARAA M HAMODI TALEB — Name
USA — Country
[redacted] — Address / City / State / Zip/Postal Code

CORPORATION, INDICATE THE Director:

BARAA M HAMODI TALEB — Name
USA — Country
[redacted] — Address / City / State / Zip/Postal Code

CORPORATION, INDICATE THE President:

BARAA M HAMODI TALEB — Name
USA — Country
[redacted] — Address / City / State / Zip/Postal Code

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.

X BARAA TALEB
Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Subscriber, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

President — Title
01/23/2026 — Date

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Remedies pharmacy Inc.** as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 02/02/2022, and in good standing in this State.

I further certify that the above DOMESTIC CORPORATION (78) has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 03/03/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202603036528873
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Saint Mary Pharmacy
Pharmacy/Wholesaler License # (if applicable) PH03705
Physical Address 4180 S Rainbow Blvd #808
City Las Vegas State NV Zip 89103
Mailing Address (if different from physical address) Same
City _____ State _____ Zip _____
Telephone _____ Website _____
Licensing Company Email _____

Section 2: Personal Information

First TEGEST Middle _____ Last TILAHUN
Alias(es, nicknames, name changes, etc.) _____
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X
Mailing Address [redacted]
City [redacted] State [redacted] Zip [redacted]
Telephone [redacted] Email [redacted]
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

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Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: MCPHS - Worcester		From - To (MM/YY – MM/YY): 09/03 - 06/06	
Address: 19 Foster St.	City: Worcester	State: MA	Zip: 01608
Diploma/Degree obtained, if any: Pharm. D			
School Name: Concordia University		From - To (MM/YY – MM/YY): 08/86 - 06/90	
Address: 1455 Blvd. De Maisonneuve	City: Montreal	State:	Zip: Canada
Diploma/Degree obtained, if any: B.Sc. Biochemistry			
School Name: Vanier College		From - To (MM/YY – MM/YY): 08/84 - 06/86	
Address: 821 Sainte-Croix Ave	City: Montreal, PQ	State:	Zip: Canada
Diploma/Degree obtained, if any: Dip. Health Science			
School Name: Bialik High School		From - To (MM/YY – MM/YY): 10/80 - 06/84	
Address: 6500 Kildare Rd.	City: Montreal, PQ	State: ~~Mon~~	Zip: Canada
Diploma/Degree obtained, if any:			
School Name:		From - To (MM/YY – MM/YY):	
Address:	City:	State:	Zip:
Diploma/Degree obtained, if any:			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/25 - Present	[redacted]			
~~08/19~~ 09/22 - 05/				
08/18 - 09/22				
~~08/11~~ 09/13 - 05				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: QHR Pharmacy			From - To (MM/YY – MM/YY): 09/22 - 08/25
Business Address: 765 N Nellis Blvd #7	City: Las Vegas	State: NV	Zip: 89110
Phone: 702-331-6388	Title: PIC	Number of Employed Hours: 6240	
Description of Duties: Data entry, filling, verifying scripts, ordering medications, assuring pharmacy followed DEA + BOP rules etc			
Business Name: CVS Pharmacy			From - To (MM/YY – MM/YY): 09/06 - 04/13
Business Address:	City: Washington	State: DC	Zip:
Phone:	Title: Staff Pharmacist	Number of Employed Hours: ~13500	
Description of Duties: Data entry, verifying scripts			
Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:	Number of Employed Hours:	
Description of Duties:			
Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:	Number of Employed Hours:	
Description of Duties:			
Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:	Number of Employed Hours:	
Description of Duties:			

Continue on next page if additional space is needed.

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Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

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I, TEGEST TILAHUN, certify that as the designated representative for

_____,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

TEGEST TILAHUN

Print Name (First, Last)

Tegest Tilahun

Original Signature (electronic, copies or stamps not accepted)

2/23/26

Date

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I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

TEGEST TILAHUN

Print Name (First, Last)

Tegest Tila

Original Signature (electronic, copies or stamps not accepted)

2/23/26

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, TEGEST TILAHUN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Tegest Tila

Original Signature

2/23/26

Date

Subscribed and Sworn to before me this 23rd day of February 2026

Notary Public Signature

Linda M Abrams
Notary Public - State of Nevada
County of Clark
APPT. NO. 19-6625-01
My Appt. Expires: Sept. 3, 2027

(Seal)

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler SAINT MARY PHARMACY

Pharmacy/MDEG/Wholesaler License # (if applicable) PH 03 705

Physical Address 4180 S Rainbow Blvd

City LAS VEGAS State NV Zip 98103

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (702)-722-3707 Website _____

Licensing Company Email pharmacy050522@outlook.com

Section 2: Personal Information

First Baraa Middle M Hamodi Last Taleb

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
University of Petra Faculty of Pharmacy			3/2004 - 6/2010
Address	**City**	**State**	**Zip**
Airport Rd. Amman - Jordan	Amman		
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Mutamayiz al High school-			
Address	**City**	**State**	**Zip**
Al-Khadraa	Baghdad / Iraq		
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/10/2013	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
ST.MARY COMMUNITY PHARMACY			01/25- Present
Business Address	**City**	**State**	**Zip**
13641 CENTRAL AVE STE E	CHINO	CA	91710
Phone	**Title**		
(714) 541-8150	PHARMACY OWNER %65		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
D&B PHARMACUETICAL			4/2024- Present
Business Address	**City**	**State**	**Zip**
1272 Amaryllis way	Corona	CA	92882
Phone	**Title**		
(951)-603-4424	Pharmacist consultant		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
WALMART PHARMACY			9/2024-2/2025
Business Address	**City**	**State**	**Zip**
4210 Highland Ave	Highland	CA	92346
Phone	**Title**		
(909) 425-8687	PHARMACIST		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
ADVANCED CARE PHARMACY			3/2018-5/2021
Business Address	**City**	**State**	**Zip**
BO320 BONNIE CIR	CORONA	CA	92878
Phone	**Title**		
(951)-256-8800	PHARMACIST INTERN		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		/
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		/
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		/
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		/
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		/
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		/
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		/

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Baraa Taleb
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/6/2026
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Baraa Taleb, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/6/2026
Date

Subscribed and Sworn to before me this 6th day of Feb. 2026.

Notary Public Signature

Linda M Abrams
Notary Public - State of Nevada
County of Clark
APPT. NO. 19-6625-01
My Appt. Expires: Sept. 3, 2027

(Seal)

8E

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☐ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-Nevada	☒ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 03749		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: PBC LLC DBA Specialty Care Rx

Physical Address: 801 S Rancho Dr Ste D1A

City: Las Vegas State: NV Zip: 89106

Mailing Address (if different from physical address): 200 E Katella Ave Ste C

City: Orange State: CA Zip: 92867

Telephone: 702-790-4404 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 702-790-4406 Contact Email: infovegas@myscrx.com

Website: www.myscrx.com

Nevada Business License # (if applicable) NV20131503868

Supervising/Managing Pharmacist Name (NRS 639.220): Kharen Lopez

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 18439

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Kharen Lopez	NV Pharmacist Registration #: 18439
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NV

Parent Company (if any): BPJ LLC

Corporation/Organization Name: PBC LLC

Mailing Address: 200 E Katella Ave Ste C

City: Orange State: CA Zip: 92867

Telephone: 702-790-4404 Email: infovegas@myscrx.com

Contact Person Name: Blanca Monterroza

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☒ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Managing Member (title) for PBC LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Brenda Brown

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

12/19/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Brenda Brown hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Managing Member (title) for PBC LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

B. A. B.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 19th day of December, 2025

Notary Public

DOMENICA PUENTE
Notary Public, State of Texas
Comm. Expires 08-05-2028
Notary ID 135023944

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Kharen Lopez Pharmacist Registration #: 18439

Pharmacy Name: PBC LLC DBA Specialty Care Rx

Initial each statement below to indicate you have read and agree with the following:

KML I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

KML I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

KML I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

KML I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

KML I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History:	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

12/15/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brenda Brown

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

12/19/2025

Date

Board Use Only	Date Received: 1/7/26	Amount: $1000-ck 2145

Specialty Care Rx
Excellence is Our Specialty

200 E. Katella Ave, Suite A
Orange, CA 92867
T (714) 941-6177
www.myscrx.com

January 6, 2026

RE: Change of Ownership-PGBB LLC (License PH03634) and PBC LLC (License PH03749)

Dear Nevada Board of Pharmacy:

This is to further notify you of the change in ownership of our 2 locations specified above. The initial notification was given on December 12, 2025, when I spoke with Kristy at extension 131.

The change involves the current ownership being bought by a parent/holding company (BPJ LLC). However, the TIN, DBA and legal business name will not change. I have attached an organizational chart within the documents included and have summarized below the CHOW for your reference and convenience when reviewing our application.

Previous: Owner/License/DBA	**Change: New Parent Company**
PGBB LLC/ PH03634	BPJ LLC
Specialty Care Rx	All other information Same as previous

Previous: Owner/License/DBA	**Change: New Parent Company**
PBC LLC/ PH03749	BPJ LLC
Specialty Care Rx	All other information Same as previous

Please let me know if you have any questions or need further information to process the application.

Thank you,

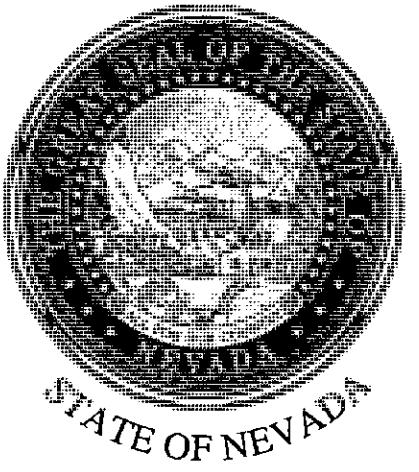
Specialty Care Rx
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Specialty Care Infusion Center
Care for life

Chat with me on Teams

Blanca Monterroza
Director of Contracts and Regulatory Affairs, CPhT/PRS
Specialty Care Rx
(949) 506-1300 Ext.270
(310) 909-9786
(866) 511-4654
bmonterroza@myscrx.com

We keep our patients at the center of everything we do!

SECRETARY OF STATE



CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational or qualification, as applicable, documents on file in this office for

PBC L.L.C.

Organizational Documents on File	Filing Date
Amendment	03/15/2017
Certificate of Revival	10/05/2015
Articles of Organization	08/22/2013

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence PBC L.L.C., as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, and by virtue of the laws of the State of Nevada since 08/22/2013, and is in good standing in this state.

Details for PBC L.L.C.

License Information

Name:	PBC L.L.C.
City, State, Zip, Country:	Las Vegas NV 89106 United States
Profession:	Pharmacy
License Type:	Pharmacy - Class D
License Number:	13508842-1708
Obtained By:	Application
License Status:	Active
Original Issue Date:	08/16/2023
Expiration Date:	09/30/2027
Agency and Disciplinary Action*:	NO DISCIPLINARY ACTIONS WITHIN THE TIME FRAME ESTABLISHED IN UTAH CODE 63G-4-106 AND 107**
Docket and Citation Number(s):	N/A
E-Prescriber:	

Doing Business As:

SPECIALTY CARE RX LV

This information is accurate as far as is contained in the Division's official records. It does not reflect whether an entity required to maintain a current registration with the Division of Corporations is current in that registration. You can verify such status at https://secure.utah.gov/bes/bes. Additionally, this verification does not show a complete license history or interruptions of licensure. Original issue dates listed as 01/01/1910 and 01/01/1911 were unknown at the time the Division implemented its first electronic licensing database.

*NOTE: The disciplinary documents linked to this website include final orders issued by DOPL, with the exception of citations. Click here for citations.

Give Feedback

Specialty Care Rx
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200 E. Katella Ave, Suite A
Orange, CA 92867
T (714) 941-6177
www.myscrx.com

January 7, 2026

Dear Nevada Board of Pharmacy:

Please find below the list of the LLC members/officers for the enclosed ownership information.

BPJ LLC

Top 4 Members

1. Brenda Brown-30%
2. Jeffrey Griffith-10%
3. Bhav Patel-21% (CasaFusion LLC)
4. Yatin Patel-9% (CasaFusion LLC)

Other Members

1. Grace Duarte-10%
2. Brandon Walend-10%
3. Gilbert Ursulo-10%

Please let us know if you have any questions or need further information.

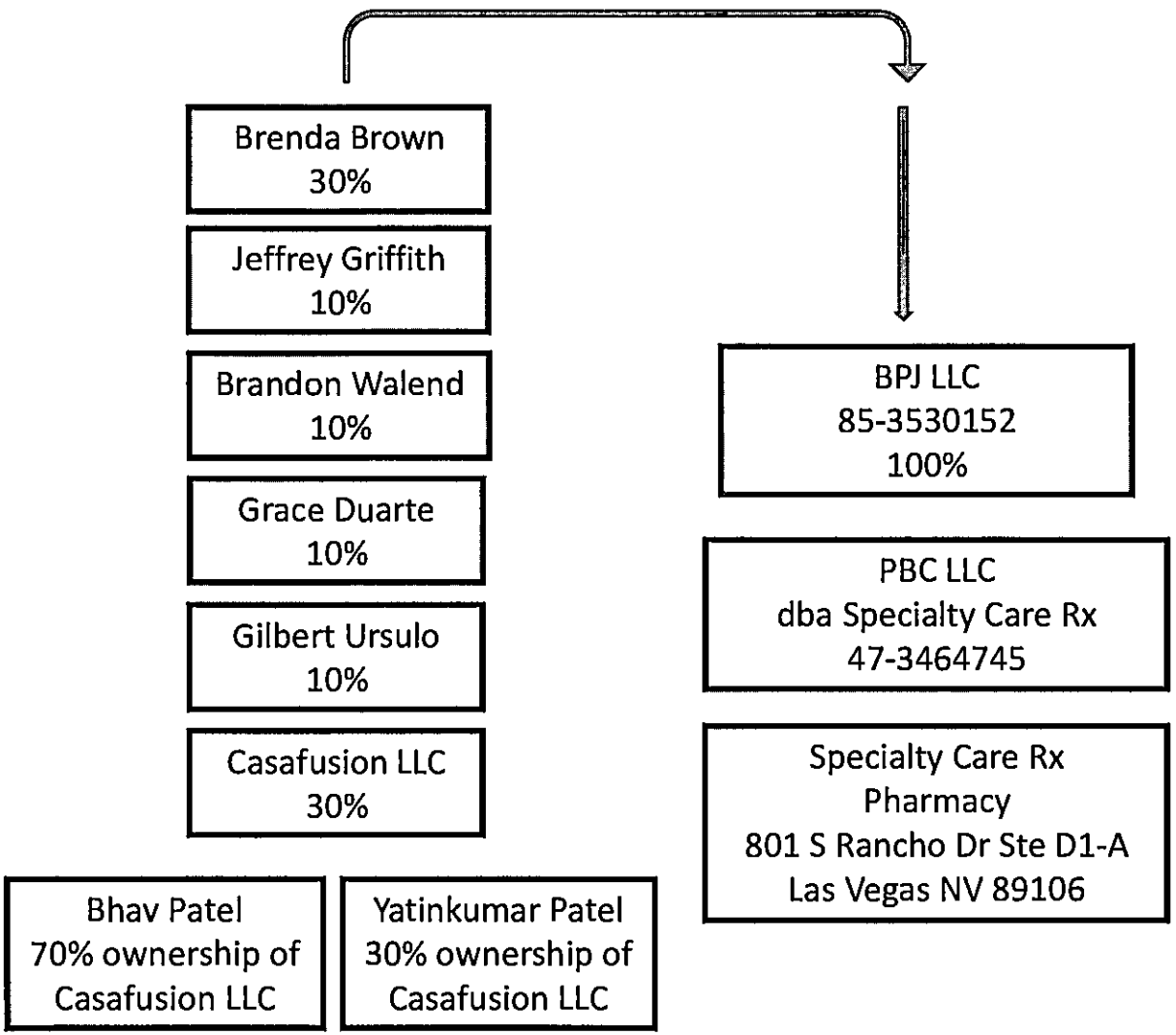
Thank you,

Specialty Care Rx
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Specialty Care Infusion Center
Care for life

Chat with me on Teams

Blanca Monterroza
Director of Contracts and Regulatory Affairs, CPhT/PRS
Specialty Care Rx
(949) 506-1300 Ext.270
(310) 909-9786
(866) 511-4654
bmonterroza@myscrx.com

We keep our patients at the center of everything we do!


Brenda Brown
30%
Jeffrey Griffith
10%
Brandon Walend
10%
Grace Duarte
10%
Gilbert Ursulo
10%
Casafusion LLC
30%
Bhav Patel
70% ownership of
Casafusion LLC
Yatinkumar Patel
30% ownership of
Casafusion LLC
BPJ LLC
85-3530152
100%
PBC LLC
dba Specialty Care Rx
47-3464745
Specialty Care Rx
Pharmacy
801 S Rancho Dr Ste D1-A
Las Vegas NV 89106

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PBC LLC DBA Specialty Care Rx

Pharmacy/Wholesaler License # (if applicable) PH03749

Physical Address 801 S Rancho Dr Ste D1A

City Las Vegas State NV Zip 89105

Mailing Address (if different from physical address) 200 E Katella Ave Ste C

City Orange State CA Zip 92867

Telephone 702-790-4404 Website www.myscrx.com

Licensing Company Email infovegas@myscrx.com

Section 2: Personal Information

First Kharen Middle Yap Last Lopez

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Stanto Tomas		06/89 - 03/93	
Address	**City**	**State**	**Zip**
Espana, Manila, Philippines			
Diploma/Degree obtained, if any			
BS Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
St. Francis School		06/85 -03/89	
Address	**City**	**State**	**Zip**
General Trias, Cavite, Philipiines			
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
02/08 - present				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
PBC, LLC dba Specialty Care RX			07/22 -present
Business Address	**City**	**State**	**Zip**
801 S Rancho Dr Ste D1-A	Las Vegas	NV	89106
Phone	**Title**		**Number of Employed Hours**
702-790-4404	Pharmacist in charge		6,240 hours

Description of Duties

In Charge of the daily operation of pharmacy. Ordering medication. Dispensing of medications to patients, making sure we are compliant with the Federal and State laws and ACHC. Calling MD offices for refills, RX and clarifications.

Business Name			From - To (MM/YY – MM/YY)
PMKM, LLC dba Quality Home Infusion			05/18 - 07/22
Business Address	**City**	**State**	**Zip**
801 S. Rancho Dr. Ste E-7	Las Vegas	NV	89106
Phone	**Title**		**Number of Employed Hours**
702-478-5133	Pharmacist in charge		8,320 hours

Description of Duties

In Charge of the daily operation of pharmacy. Ordering medication. Dispensing of medications to patients, making sure we are compliant with the Federal and State laws and ACHC. Calling MD offices for refills, RX and clarifications.

Business Name			From - To (MM/YY – MM/YY)
PMKM, LLC dba Quality Home Infusion			01/17 - 05/18
Business Address	**City**	**State**	**Zip**
801 S. Rancho Dr. Ste E-7	Las Vegas	NV	89106
Phone	**Title**		**Number of Employed Hours**
702-478-5133	Pharmacist		2,080 hours

Description of Duties

Calling MD office for refills, RX and clarifcations. Dispensing of medications to patients. ordering medication.

Business Name			From - To (MM/YY – MM/YY)
CNS Scrips Pharmacy			01/14 -01/17
Business Address	**City**	**State**	**Zip**
3370 Pinks Place Ste F	Las Vegas	NV	89106
Phone	**Title**		**Number of Employed Hours**
702-731-4800	Pharmacist in charge		

Description of Duties

In Charge of the daily operation of pharmacy. Ordering medication. Dispensing of medications to patients, making sure we are compliant with the Federal and State laws. Calling MD offices for refills, RX and clarifications.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Kharen Yap Lopez, **certify that as the designated representative for**

PBC, LLC dba Specialty Care RX,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KYL I am at least 21 years of age;
3. KYL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KYL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KYL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KYL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KYL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

KHAREN YAP LOPEZ
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/5/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kharen Lopez
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 1/5/2026

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Kharen Lopez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date 1/5/2026

Subscribed and Sworn to before me this 5 day of Jan 2026

Howard Rogers III
Notary Public Signature

HOWARD ROGERS III
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 11-3859-1
My Appt. Expires December 1, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PBC LLC DBA Specialty Care Rx

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH03749

Physical Address 801 S Rancho Dr Ste D1A

City Las Vegas State NV Zip 89106

Mailing Address (if different from physical address) 200 E Katella Ave Ste C

City Orange State CA Zip 92867

Telephone 702-790-4404 Website www.myscrx.com

Licensing Company Email infovegas@myscrx.com

Section 2: Personal Information

First YATINKUMAR Middle AMRUTLAL Last PATEL

Alias(es, nicknames, name changes, etc.) [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
WESTERN UNIVERSITY OF HEALTH SCIENCE		08/2006- 12/2008	
Address	**City**	**State**	**Zip**
309 E. Second St.	Pomona	CA	91766
Diploma/Degree obtained, if any			
Pharm.D.			

School Name		From - To (MM/YY – MM/YY)	
University of New south Wales		Jan/2004- Dec/2004	
Address	**City**	**State**	**Zip**
UNSW, Level 3, Mathews Building F23, Gate 11, Botany Street,	Kensington, Sydney	NSW	2033
Diploma/Degree obtained, if any			
Msc. in Biopharmaceuticals			

School Name		From - To (MM/YY – MM/YY)	
Hemchandracharya North Gujarat University		08/1999-04/2003	
Address	**City**	**State**	**Zip**
V45M+RP2, chamunda society	Patan	Gujarat	384265
Diploma/Degree obtained, if any			
Bachelor in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Saurabh High School		08/1997-04/1999	
Address	**City**	**State**	**Zip**
Near Bhavsar Hostel, New Vadaj,	Ahmedabad	Gujarat	380013
Diploma/Degree obtained, if any			
High School Graduate			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
05/2013- Current				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Specialty Care RX			02-2025- current	
Business Address	**City**		**State**	**Zip**
21450 Golden Spring Drive, Suite 110	Diamond Bar		CA	91789
Phone	**Title**			
818-848-8112	Pharmacist-in-charge			

Description of Duties

responsible for pharmacist and pharmacist-in-charge role. Responsible to overall pharmacy compliance for all regulatory agencies such as Board of Pharmacy, CMS, ACHC, FDA, DEA.

Business Name			From - To (MM/YY – MM/YY)	
JBGG LLC			04/24-Current	
Business Address	**City**		**State**	**Zip**
801 S Rancho Drive, Suite D1-B	Las Vegas		NV	89106
Phone	**Title**			
702-825-4900	Member			

Description of Duties

Assist in consulting operation whenever called upon by board

Business Name			From - To (MM/YY – MM/YY)	
RPh Partners, Inc			03/25-Current	
Business Address	**City**		**State**	**Zip**
4295 Jurupa St, Ste 102	Ontario		CA	91761
Phone	**Title**			
909-443-7294	shareholder			

Description of Duties

Assist in Consulting operations whenever called upon by board

Business Name			From - To (MM/YY – MM/YY)	
Casafusion LLC			08/24- Current	
Business Address	**City**		**State**	**Zip**
8 Rock Bluff Dr	Pomona		CA	91766
Phone	**Title**			
323-215-5965	Shareholder			

Description of Duties

Owner- Regular management and operation of business

Business Name			From - To (MM/YY – MM/YY)	
I4H pharmacy			12/2023-12/2024	
Business Address	**City**		**State**	**Zip**
11705 Slate Ave STE 100	Riverside		CA	92505
Phone	**Title**			
951-499-4911	Clinical Pharmacist			

Description of Duties

Responsible for Pharmacist duties for managing patients in home infusion setting as well as ambulatory infusion suites. Manage pharmacy operations, including inventory control, record-keeping, and compliance.

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Prime Therapeutics			03/2023-12/2023	
Business Address		City	State	Zip
2900 Ames Crossing Road, Suite 200		Eagan	MN	55121
Phone	Title			
800-858-0723	Prior Authorization Pharmacist			

Description of Duties

Positions in this function performed various duties related to the prior authorization of prescription orders and specialty medical utilization management.

Business Name			From - To (MM/YY – MM/YY)	
OptumRx and Optum Infusion Services			05/2018- 07/2022	
Business Address		City	State	Zip
4900 Rivergrade Rd		Irwindale	CA	91706
Phone	Title			
866-827-0972	Pharmacist-in-charge, Prior Authorization Pharmacist			

Description of Duties

Provided clinical and pharmacist oversight for factor and non-factor therapies, including prophylaxis, on-demand treatment, and preoperative management. Responsible as Pharmacist-in-charge

Business Name			From - To (MM/YY – MM/YY)	
A & J Family Pharmacy, Inc			06/2015- Current	
Business Address		City	State	Zip
8 Rock Bluff Rd		Pomona	Ca	91766
Phone	Title			
323-215-5965	Shareholder			

Description of Duties

Responsible for business operation and other related matters

Business Name			From - To (MM/YY – MM/YY)	
Coram Healthcare			10/2017-05/2018	
Business Address		City	State	Zip
4355 E Lowell St		Ontario	CA	91761
Phone	Title			
909-605-0010	Pharmacist			

Description of Duties

Pharmacist responsibilities for Branch service patient with acute and chronic therapy

Business Name			From - To (MM/YY – MM/YY)	
Modern Health Pharmacy			11/2011-09/2017	
Business Address		City	State	Zip
110 E Huntington Dr		Monrovia	CA	91016
Phone	Title			
626-932-1600	Infusion Services Manager/ IV pharmacist			

Description of Duties

Operational responsibilities for Infusion services for skilled nursing patients such as: overseeing staff scheduling, record keeping, competency tracking and assigning competencies, personal observation of compounding staff

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Yatinkumar Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/24/2025

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Yatinkumar Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/24/2025

Date

Subscribed and Sworn to before me this 24th day of December, 2025

Notary Public Signature

RITA PATEL
COMM. #2392359
Notary Public - California
LOS ANGELES COUNTY
My Comm. Exp. Feb. 8, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: PBC LLC DBA Specialty Care Rx

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH03749

Physical Address: 801 S Rancho Dr Ste D1A

City: Las Vegas State: NV Zip: 89106

Mailing Address (if different from physical address): 200 E Katella Ave Ste C

City: Orange State: CA Zip: 92867

Telephone: 702-790-4404 Website: www.myscrx.com

Licensing Company Email: infovegas@myscrx.com

Section 2: Personal Information

First: Brenda Middle: Aurora Last: Brown

Alias(es, nicknames, name changes, etc.): Brenda A Martinez

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
FIDM			09/1994- 06/ 1996
Address	**City**	**State**	**Zip**
919 S Grand Ave	Los Angeles	CA	90015
Diploma/Degree obtained, if any			
Fashion Merch. Mktg			

School Name			From - To (MM/YY – MM/YY)
John F. Kennedy HS			09/1991- 06/1994
Address	**City**	**State**	**Zip**
11254 Gothic Ave	Granada Hills	CA	91344
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2025- Present	[redacted]			
04/2024- 04/2025				
04/2017- 04/2024				
04/2014- 04/2017				
04/2012- 04/2014				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
PGBB LLC DBA Specialty Care Rx			01/2014- Present
Business Address	**City**	**State**	**Zip**
200 E Katella Ave	Orange	CA	92867
Phone	**Title**		
714-941-6177	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
RPH			07/2015- Present
Business Address	**City**	**State**	**Zip**
4295 E Jurupa St 102	Ontario	CA	91761
Phone	**Title**		
909-687-7064	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
SanFer Inc			01/2000- 04/2018
Business Address	**City**	**State**	**Zip**
15257 Parthenia St	North Hills	CA	91343
Phone	**Title**		
818-893-9971	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
IVIGRX LLC DBA Specialty Care Rx			01/2024- Present
Business Address	**City**	**State**	**Zip**
21450 Golden Springs Dr Suite 110	Diamond Bar	CA	91789
Phone	**Title**		
818-848-8112	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
PBC LLC DBA Specialty Care Rx			01/2017- Present
Business Address	**City**	**State**	**Zip**
801 S Rancho Dr Ste D1A	Las Vegas	NV	89106
Phone	**Title**		
702-790-4404	Officer		
Description of Duties			
Management			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Specialty Care Rx LLC			01/2021- Present
Business Address	**City**	**State**	**Zip**
150 Collins St	Memphis	TN	38112
Phone	**Title**		
901-560-3580	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
PBJ Partners LLC DBA Specialty Care Rx			01/2023- Present
Business Address	**City**	**State**	**Zip**
5736 Citrus Blvd Ste 103	New Orleans	LA	70123
Phone	**Title**		
504-340-5221	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
Excel Rx Consulting LLC DBA Specialty Care Rx			01/2021- Present
Business Address	**City**	**State**	**Zip**
6200 Chase Oaks Blvd Ste 102A	Plano	CA	75023
Phone	**Title**		
469-257-4200	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
JGBB LLC DBA Specialty Care Infusion Center			01/2018- Present
Business Address	**City**	**State**	**Zip**
801 S Rancho Dr Ste D1B	Las Vegas	NV	89106
Phone	**Title**		
702-825-4900	Officer		
Description of Duties			
Management			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brenda Brown

Print Name (First, Last)

B.A. B.

Original Signature (electronic, copies or stamps not accepted)

12/23/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Collin

I, Brenda A. Brown., being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

B.A.B.

Original Signature

12/23/2025.

Date

Subscribed and Sworn to before me this 23 day of December 2025

Notary Public Signature

BRYAN CULP BAKER
Notary Public, State of Texas
Comm. Expires 02-22-2026
Notary ID 133604919

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PBC LLC DBA Specialty Care Rx

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH03749

Physical Address 801 S Rancho Dr Ste D1A

City Las Vegas State NV Zip 89106

Mailing Address (if different from physical address) 200 E Katella Ave Ste C

City Orange State CA Zip 92867

Telephone 702-790-4404 Website www.myscrx.com

Licensing Company Email infovegas@myscrx.com

Section 2: Personal Information

First Bhav Middle Girish Last Patel

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
University of California, Los Angeles			09/16-06/21
Address	**City**	**State**	**Zip**
580 Portola Plaza	Los Angeles	CA	90095
Diploma/Degree obtained, if any			
BS, MS			

School Name			From - To (MM/YY – MM/YY)
La Salle High School			09/12-06/16
Address	**City**	**State**	**Zip**
3880 E Sierra Madre Blvd	Pasadena	CA	91107
Diploma/Degree obtained, if any			
GED			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
07/23-Current				
From - To (MM/YY – MM/YY)				
07/22-07/23				
From - To (MM/YY – MM/YY)				
09/21-07/22				
From - To (MM/YY – MM/YY)				
06/19-09/21				
From - To (MM/YY – MM/YY)				
09/17-06/19				
From - To (MM/YY – MM/YY)				
01/03-09/17				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Casafusion LLC			08/24-Current
Business Address	**City**	**State**	**Zip**
8 Rock Bluff Drive	Pomona	CA	91766
Phone	**Title**		
323-399-5958	Shareholder		
Description of Duties			
Owner - regular management duties			

Business Name			From - To (MM/YY – MM/YY)
IVIGRx LLC			09/24-Current
Business Address	**City**	**State**	**Zip**
21450 Golden Springs Drive, Suite 110	Diamond Bar	CA	91789
Phone	**Title**		
818-848-8112	Advisor		
Description of Duties			
Help with running the pharmacy branch from a finance/ops perspective.			

Business Name			From - To (MM/YY – MM/YY)
KB Real Estate Enterprise			05/24-Current
Business Address	**City**	**State**	**Zip**
330 Mount Olive Drive	Bradbury	CA	91008
Phone	**Title**		
323-399-5958	Owner		
Description of Duties			
Manage a real estate rental company for Single Family Homes			

Business Name			From - To (MM/YY – MM/YY)
BA Hospitality Consulting			11/23-Current
Business Address	**City**	**State**	**Zip**
330 Mount Olive Drive	Bradbury	CA	91008
Phone	**Title**		
847-208-0878	Shareholder		
Description of Duties			
Assist hotel owners with managing & running their business (silent partner).			

Business Name			From - To (MM/YY – MM/YY)
Shilo Inn Mammoth Lakes			01/23-Current
Business Address	**City**	**State**	**Zip**
2963 Main St	Mammoth Lakes	CA	93546
Phone	**Title**		
760-965-0544	Minority Shareholder		
Description of Duties			
Minority shareholder in Hotel property, assisting in renovations.			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Healing Soul LLC			10/22-Current
Business Address	**City**	**State**	**Zip**
40550 Del Luz Murrieta Rd	Fallbrook	CA	92028
Phone	**Title**		
323-399-5958	Shareholder		
Description of Duties			
Minority Shareholder for vineyard operations. Consult on farming operations.			

Business Name			From - To (MM/YY – MM/YY)
JGBB LLC			04/24-Current
Business Address	**City**	**State**	**Zip**
801 S Rancho Drive Suite D1-B	Las Vegas	NV	89106
Phone	**Title**		
702-825-4900	Member		
Description of Duties			
Assist in consulting operations whenever called upon by board.			

Business Name			From - To (MM/YY – MM/YY)
RPH Inc			3/25-Current
Business Address	**City**	**State**	**Zip**
4295 JURUPA ST STE 102	Ontario	CA	91761
Phone	**Title**		
909-443-7294	Shareholder		
Description of Duties			
Assist in consulting operations whenever called upon by leadership.			

Business Name			From - To (MM/YY – MM/YY)
Northrop Grumman			09/21-09/24
Business Address	**City**	**State**	**Zip**
1 Space Park	Redondo Beach	CA	90278
Phone	**Title**		
	FTL Systems Engineer		
Description of Duties			
Program/Project Manager on Aerospace Projects			

Business Name			From - To (MM/YY – MM/YY)
Falcon Exodynamics			11/20-06/21
Business Address	**City**	**State**	**Zip**
1730 E. Holly Ave.	El Segundo	CA	90245
Phone	**Title**		
	Mechanical Engineer		
Description of Duties			
Research & Development engineer for satellites.			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Quartus Engineering			06/19 - 09/19
Business Address	**City**	**State**	**Zip**
9689 Towne Centre Dr	San Diego	CA	92121
Phone	**Title**		
	Analysis Intern		
Description of Duties			
Engineering intern at consulting firm.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bhav, Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/24/25

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Bhav Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/24/25

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

See Attached

(Seal)

JURAT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 24th day of Dec,

2025 by Bhav Patel,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

RITA PATEL
COMM. #2392359
Notary Public - California
LOS ANGELES COUNTY
My Comm. Exp. Feb. 8, 2026

Signature _____ (Seal)

OPTIONAL INFORMATION

DESCRIPTION OF THE ATTACHED DOCUMENT

_____
(Title or description of attached document)

_____
(Title or description of attached document continued)

Number of Pages _____ Document Date _____

_____
Additional Information

INSTRUCTIONS

The wording of all Jurats completed in California after January 1, 2015 must be in the form as set forth within this Jurat. There are no exceptions. If a Jurat to be completed does not follow this form, the notary must correct the verbiage by using a jurat stamp containing the correct wording or attaching a separate jurat form such as this one with does contain the proper wording. In addition, the notary must require an oath or affirmation from the document signer regarding the truthfulness of the contents of the document. The document must be signed AFTER the oath or affirmation. If the document was previously signed, it must be re-signed in front of the notary public during the jurat process.

- State and county information must be the state and county where the document signer(s) personally appeared before the notary public.
- Date of notarization must be the date the signer(s) personally appeared which must also be the same date the jurat process is completed.
- Print the name(s) of the document signer(s) who personally appear at the time of notarization.
- Signature of the notary public must match the signature on file with the office of the county clerk.
- The notary seal impression must be clear and photographically reproducible. Impression must not cover text or lines. If seal impression smudges, re-seal if a sufficient area permits, otherwise complete a different jurat form.
  - Additional information is not required but could help to ensure this jurat is not misused or attached to a different document.
  - Indicate title or type of attached document, number of pages and date.
- Securely attach this document to the signed document with a staple.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PBC LLC DBA Specialty Care Rx

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH03749

Physical Address 801 S Rancho Dr Ste D1A

City Las Vegas State NV Zip 89106

Mailing Address (if different from physical address) 200 E Katella Ave Ste C

City Orange State CA Zip 92867

Telephone 702-790-4404 Website www.myscrx.com

Licensing Company Email infovegas@myscrx.com

Section 2: Personal Information

First Jeffrey Middle Scott Last Griffith

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern California		9/1989 - 12-1991	
Address	City	State	Zip
	Los Angels	CA	
Diploma/Degree obtained, if any			
BA Communications, Business, Spanish			

School Name		From - To (MM/YY – MM/YY)	
Pasadena City College		9-1987-6-1989	
Address	City	State	Zip
	Pasadena	CA	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Glendale CC		9-1986-6-1987	
Address	City	State	Zip
	Gendale	CA	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Glendale HS		9-1984 - 6/1986	
Address	City	State	Zip
Diploma/Degree obtained, if any			
Graduate			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/25 - Present	[redacted]			
12/17-7/25				
09/01 - 12/17				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
BMR Partners / Specialty Care RX			10/16 - Present
Business Address	**City**	**State**	**Zip**
200 E. Katella Ave , Suite C	Orange	CA	92867
Phone	**Title**		
Description of Duties			
SR. Leadership, Partner, Chief Business Development Officer			

Business Name			From - To (MM/YY – MM/YY)
Baxter / Baxalta / Shire			1/00-10/16
Business Address	**City**	**State**	**Zip**
	Round Lake	IL	60015
Phone	**Title**		
Description of Duties			
Sales Manager			

Business Name			From - To (MM/YY – MM/YY)
JHHG Enterprise			1/23-12/25
Business Address	**City**	**State**	**Zip**
4701 Borden Ct	Carlsbad	CA	92010
Phone	**Title**		
Description of Duties			
Consultant			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey Griffith

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/05/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Jeffrey Griffith, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-05

Date

Subscribed and Sworn to before me this 6 day of JANUARY, 2026

Notary Public Signature

Aubrey Caramanica
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 99-9921-01
My Appt. Expires February 6, 2027

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PGBB LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH03634

Physical Address 200 E. KATELLA AVE SUITE A

City ORANGE State CA Zip 92867

Mailing Address (if different from physical address) SAME AS ABOVE

City _____ State _____ Zip _____

Telephone 714-941-6177 Website WWW.MYSCRX.COM

Licensing Company Email OCINFO@MYSCRX.COM

Section 2: Personal Information

First GRACE Middle G Last DUARTE

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
10/24 - Present				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Specialty Care Rx			From - To (MM/YY – MM/YY): 05/17 Present	
Business Address: 200 E. Katella Ave	City: Orange	State: Ca	Zip: 92867	
Phone: 714 941-6177	Title: VP of Business Development			
Description of Duties: Sales and managing people.				

Business Name: Brothers Health Care			From - To (MM/YY – MM/YY): 2014 - 5/2017	
Business Address: 2175 Sampson Ave	City: Corona	State: Ca	Zip: 92879	
Phone: 951 808-5434	Title: Account manager.			
Description of Duties: Sales.				

Business Name:		From - To (MM/YY – MM/YY):	
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name:		From - To (MM/YY – MM/YY):	
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name:		From - To (MM/YY – MM/YY):	
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Grace Galvan Duarte
Print Name (First, Last)

Grace G Duarte
Original Signature (electronic, copies or stamps not accepted)

03/11/2026
Date

Please have this section completed in the presence of a Notary Public.

State of _____ ss. County of _____

I, _____ being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Grace G Duarte
Original Signature

03/11/2026
Date

Subscribed and Sworn to before me this _____ day of _____

SEE ATTACHED
Notary Public Signature

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Riverside

Subscribed and sworn to (or affirmed) before me on this 11th day of March, 20 26, by Grace Galvan Duarte

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

I. SERRATO
COMM. # 2478112
NOTARY PUBLIC - CALIFORNIA
RIVERSIDE COUNTY
COMM. EXPIRES JAN. 1, 2028

(Seal)

Signature

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PGBB LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH03634

Physical Address 200 E. KATELLA AVE SUITE A

City ORANGE State CA Zip 92867

Mailing Address (if different from physical address) SAME AS ABOVE

City _____ State _____ Zip _____

Telephone 714-941-6177 Website WWW.MYSCRX.COM

Licensing Company Email OCINFO@MYSCRX.COM

Section 2: Personal Information

First BRANDON Middle D Last WALEND

Alias(es, nicknames, name changes, etc.) _____

[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
San Gorgonio High			09/88 -06/91
Address	**City**	**State**	**Zip**
2299 Pacific St	San Bernardino	CA	92404
Diploma/Degree obtained, If any			
Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, If any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2024 -present	[redacted]			
04/2018-04/2024				
02/2012-5/2018				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
IVIGRX LLC	12/13/2024-CURRENT

Business Address	City	State	Zip
21450 GOLDEN SPRINGS DR SUITE 110	DIAMOND BAR	CA	91789

Phone	Title
818-848-8112	MEMBER

Description of Duties

MEMBER OF LLC

Business Name	From - To (MM/YY – MM/YY)
PGBB LLC	4/2012-CURRENT

Business Address	City	State	Zip
200 E. KATELLA AVE. SUITE A ORANGE, CA 92867			

Phone	Title
714-941-617	MEMBER

Description of Duties

MEMBER OF LLC

Business Name	From - To (MM/YY – MM/YY)
PBJ PARTNERS LLC	08/2023-CURRENT

Business Address	City	State	Zip
5736 Citrus Blvd Suite 103	NEW ORLEANS	LA	70123

Phone	Title
504-340-5221	MEMBER

Description of Duties

MEMBER OF LLC

Business Name	From - To (MM/YY – MM/YY)
PBC LLC	JAN 2017-CURRENT

Business Address	City	State	Zip
801 S. RANCHO DR. STE D1-A	LAS VEGAS	NV	89106

Phone	Title
702-790-4404	MEMBER

Description of Duties

MEMBER OF LLC

Business Name	From - To (MM/YY – MM/YY)
SPECIALTY CARE RX LLC	04/21-CURRENT

Business Address	City	State	Zip
150 COLLINS ST	MEMPHIS	TN	38112

Phone	Title
901-560-3580	MEMBER

Description of Duties

MEMBER OF LLC

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
EXCEL RX CONSULTING LLC			04/21-CURRENT	
Business Address		**City**	**State**	**Zip**
6200 CHASE OAKS BLVD SUITE 102A		PLANO	TX	75023
Phone	**Title**			
469-257-4200	MEMBER			
Description of Duties				
MEMBER OF LLC				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brandon Walend

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3-9-2026

Date

Please have this section completed in the presence of a Notary Public.

State of CA, ss. County of San Bernardino

I, Brandon Walend, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3-9-2026

Date

Subscribed and Sworn to before me this 9th day of March.

Notary Public Signature

Please see attached Notary Certificate

(Seal)

CALIFORNIA JURAT **GOVERNMENT CODE § 8202**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

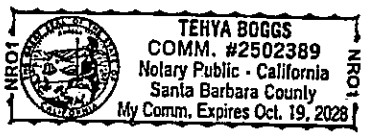
County of San Bernardino

Subscribed and sworn to (or affirmed) before me on this 9th (Date) day of March (Month), 2026 (Year), by

(1) Brandon D. Waterd

(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.



Signature _____
Signature of Notary Public

Place Notary Seal and/or Stamp Above

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Personal History Application

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

©2019 National Notary Association

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PGBB LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH03634

Physical Address 200 E. KATELLA AVE SUITE A

City ORANGE State CA Zip 92867

Mailing Address (if different from physical address) SAME AS ABOVE

City _____ State _____ Zip _____

Telephone 714-941-6177 Website WWW.MYSCRX.COM

Licensing Company Email OCINFO@MYSCRX.COM

Section 2: Personal Information

First GILBERT Middle J Last URSULO

Alias(es, nicknames, name changes, etc.) [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Bonita High School		9/1990 - 6/1994	
Address	**City**	**State**	**Zip**
3102 D Street	LaVerne	CA	91750
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Santiago Canyon College		9/1999-6/2002	
Address	**City**	**State**	**Zip**
8045 E. Chapman Ave	Orange	CA	92869
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2/2025 - present	[redacted]			
12/2012-2/2025				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7. Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
IVIGRx, LLC	12/13/2024-Current

Business Address	City	State	Zip
21450 Golden Springs Dr, Suite 110	Diamond Bar	CA	91789

Phone	Title
818-848-8112	Member

Description of Duties

Member of LLC

Business Name	From - To (MM/YY – MM/YY)
PGBB, LLC	4/2012-Current

Business Address	City	State	Zip
200 E. Katella Ave Suite A	Orange	CA	92867

Phone	Title
714-941-6177	Member

Description of Duties

Member of LLC

Business Name	From - To (MM/YY – MM/YY)
PBJ Partners, LLC	8/2023-Current

Business Address	City	State	Zip
5736 Citrus Blvd, Suite 103	New Orleans	LA	70123

Phone	Title
504-340-5221	Member

Description of Duties

Member of LLC

Business Name	From - To (MM/YY – MM/YY)
PBC, LLC	1/2017-Current

Business Address	City	State	Zip
801 S. Rancho Dr, Suite D1-A	Las Vegas	NV	89106

Phone	Title
702-790-4404	Member

Description of Duties

Member of LLC

Business Name	From - To (MM/YY – MM/YY)
Specialty Care Rx, LLC	4/2021-Current

Business Address	City	State	Zip
150 Collins St	Memphis	TN	38112

Phone	Title
901-560-3580	Member

Description of Duties

Member of LLC

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)
Excel Rx Cunsulting, LLC		4/2021-Current
Business Address	**City**	**State** / **Zip**
6200 Chase Oaks Blvd, Suite 102A	Plano	TX / 75023
Phone	**Title**	
469-257-4200	Member	
Description of Duties		
Member of LLC		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State** / **Zip**
Phone	**Title**	
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State** / **Zip**
Phone	**Title**	
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State** / **Zip**
Phone	**Title**	
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State** / **Zip**
Phone	**Title**	
Description of Duties		

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gilbert Ursulo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/11/2026

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of ORANGE

I, Gilbert Ursulo, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

03/11/2026

Date

Subscribed and Sworn to before me this 11 day of MARCH 2026

Notary Public Signature

MOHAMAD T. YOUNES
COMM. # 2443016
NOTARY PUBLIC-CALIFORNIA
ORANGE COUNTY
MY COMM. EXP. APRIL 1, 2027
(Seal)

A NOTARY PUBLIC OR OTHER OFFICER COMPLETING THIS CERTIFICATE VERIFIES ONLY THE IDENTITY OF THE INDIVIDUAL WHO SIGNED THE DOCUMENT TO WHICH THIS CERTIFICATE IS ATTACHED, AND NOT THE TRUTHFULNESS, ACCURACY, OR VALIDITY OF THAT DOCUMENT.

9

9A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 10078	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Compounding Pharmacy	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: [redacted] ☒ Non-sterile Compounding ☒ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Med Solutions Compounding Pharmacy

Physical Address: 1365 Westgate Center Drive Ste F-2

City: Winston Salem State: NC Zip: 27103

Mailing Address (if different from physical address): Same as Physical Address

City: _____ State: _____ Zip: _____

Telephone: 336 765-4406 Toll Free # (NAC 639.708, NRS 639.23286): 855-895-4495

Fax: 336-765-4489 Contact Email: Info@mscpharmacy.com

Website: mscpharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): _____

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): _____

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: [redacted]	NV Pharmacist Registration #: [redacted]
Name: Kyle Lindsey	NV Pharmacist Registration #: 24906
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address: N/A

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Hytham Mouna

Business Name: Med Solutions Compounding Pharmacy

Business Address: 1365 Westgate Center Drive Ste F-2

City: Winston Salem State: NC Zip: 27103

Telephone: 336-765-4406 Email: Info@mscpharmacy.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist Manager (title) for Med Solutions Compounding Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Hytham Mouna

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

06/18/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hytham Mouna

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

06/18/2025

Date

Board Use Only	Date Received: 12/23/25	Amount: $500-ck 5360189027 2

NORTH CAROLINA
Department of the Secretary of State

CERTIFICATE OF EXISTENCE

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify that

MEDSOLUTIONS COMPOUNDING PHARMACY, INC.

is a corporation duly incorporated under the laws of the State of North Carolina, having been incorporated on the 28th day of May, 2008, with its period of duration being Perpetual.

I FURTHER certify that, as of the date set forth hereunder, the said corporation's articles of incorporation are not suspended for failure to comply with the Revenue Act of the State of North Carolina; that the said corporation is not administratively dissolved for failure to comply with the provisions of the North Carolina Business Corporation Act; that its most recent annual report required by N.C.G.S. 55-16-22 has been delivered to the Secretary of State; and that the said corporation has not filed articles of dissolution as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 28th day of May, 2025.

Elaine F. Marshall

Secretary of State

Scan to verify online.

Certification# 124088156-1 Reference# 23032169-ACH Page: 1 of 1
Verify this certificate online at https://www.sosnc.gov/verification

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Med Solutions Compounding Pharmacy

Pharmacy/Wholesaler License # (if applicable): 10078

Physical Address: 1365 Westgate Center Drive Suite F-2

City: Winston Salem State: NC Zip: 27103

Mailing Address (if different from physical address): Same as Physical

City: State: Zip:

Telephone: 336-765-4406 Website: mscpharmacy.com

Licensing Company Email: Info@mscpharmacy.com

Section 2: Personal Information

First: Hytham Middle: C Last: Mouna

Alias(es, nicknames, name changes, etc.)

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University Of South Carolina		08/1983	05/1988
Address	**City**	**State**	**Zip**
1244 Blossom Street Suite 106	Columbia	SC	29208
Diploma/Degree obtained, if any			
Pharmacist			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2003- Prensent	[redacted]			
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above:

Business Name			From - To (MM/YY – MM/YY)
Med Solutions Compounding Pharmacy			07/2013- Present
Business Address	**City**	**State**	**Zip**
1365 Westgate Center Drive Suite F-2	Winston Salem	NC	27103
Phone	**Title**	**Number of Employed Hours**	
336-765-4406	Pharmacist Manager & CEO	40 hrs weekly	
Description of Duties			
As a manager my duties include supervising pharmacy staff, ensuring compliance, overseeing medications dispensing, training and mentoring. As a CEO setting the business vision and strategy, marketing and business development etc.			

Business Name			From - To (MM/YY – MM/YY)
Wake Forest University Baptist Medical Center			06/1988- 07/2022
Business Address	**City**	**State**	**Zip**
1 Medical Center Blvd	Winston Salem	NC	27157
Phone	**Title**	**Number of Employed Hours**	
336- 716-2011	Compounding Pharmacist	40hrs weekly	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Hytham Mouna, **certify that as the designated representative for**

Med Solutions Compounding Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. HM I am at least 21 years of age;
3. HM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. HM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. HM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. HM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. HM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Hytham Mouna

Print Name (First, Last)

Original signature (electronic, copies or stamps not accepted)

06/18/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hytham Mouna

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/18/2026

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Forsyth

I, Hytham Mouna, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/23/25

Date

Subscribed and Sworn to before me this 23rd day of June 2025

Notary Public Signature

ROBIN RAEBEL
Notary Public
Forsyth Co., North Carolina
My Commission Expires March 1, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Med Solutions Compounding Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): 10078

Physical Address: 1365 Westgate Center Drive Suite F-1

City: Winston Salem State: NC Zip: 27103

Mailing Address (if different from physical address): Same as Physical Address

City: State: Zip:

Telephone: Website:

Licensing Company Email: Info@mscpharmacy.com

Section 2: Personal Information

First: Hytham Middle: C Last: Mouna

Alias(es, nicknames, name changes, etc.):

[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University Of South Carolina			08/1983-05/1988	
Address		City	State	Zip
1244 Blossom Street Suite 106		Columbia	SC	29208
Diploma/Degree obtained, if any				
Pharmacist				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2003 - Present	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
Med Solutions Compounding Pharmacy		07/2013- Present	
Business Address	**City**	**State**	**Zip**
1365 Westgate Center Drive Suite F-2	Winston Salem	NC	27103
Phone	**Title**		
336-765-4406	Pharmacist Manager & CEO		

Description of Duties

As a manager my duties include supervising pharmacy staff, ensuring compliance, overseeing medications dispensing, training and mentoring, As a CEO setting business and strategy, marketing and business development etc

Business Name		From - To (MM/YY – MM/YY)	
Wake Forest University Baptist Medical Center		06/1988-07/2022	
Business Address	**City**	**State**	**Zip**
1 Medical Center Blvd	Winston Salem	NC	27157
Phone	**Title**		
336- 716-2011	Compounding -Pharmacist		

Description of Duties

I was involved in several drug studies with an IV protocol from 1988-2005. I worked mainly weekend shifts.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hytham Mouna

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/18/25

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Forsyth

I, Hytham Mouna, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/23/25

Date

Subscribed and Sworn to before me this 23rd day of June, 2025

Notary Public Signature

ROBIN RAEBEL
Notary Public
Forsyth Co., North Carolina
My Commission Expires March 1, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Med Solutions Compounding Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 1365 Westgate Center Drive Suite F-2

City: Winston Salem State: NC Zip: 27103

Mailing Address (if different from physical address): Same as Physical Address

City: _____ State: _____ Zip: _____

Telephone: 336--765-4406 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 336-765-4489 Contact Email: Info@mscpharmacy.com

Website: mscpharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Hytham Mouna

Supervising/Managing Pharmacist NV Pharmacist Registration #: _____

Name of Designated Person(s) as defined by revised USP-797 guidelines: Hytham Mouna

Email of Designated Person(s): lightningboxer@yahoo.com

Telephone of Designated Person(s): 336-406-6753

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

   ■ Category 1 ■ Category 2 ☐ Category 3

   If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 06/05/2025

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? _____

10. Will you be performing sterile hazardous drug compounding? Yes ■ No

    If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Myres Cocktail
Vancomycin 25 mg eye drops
Vancomycin 10 mg/mL (1 mg/ 10.1 mL) Injection
Amikacin 4 mg/ mL (400 mg 10.1 mL) PF Injection
Immune Bag
Ceftazidime 2 mg/0.1 mL Inj
Dexamethasone 400 mcg/0.1 mL Inj
Voriconazole 100 mcg/0.1 ml Inj
Clindamycin 1 mg/0.1 mL inj
Intralipid Bag

12. What laboratory performs your sterility or endotoxin testing?

Name: Eagle Analytical

Address: 11111 S Wilcrest Drive S1000

City: Houston State: TX Zip: 77099

Telephone: 800-745-8916

13. What is your procedure for visual inspection of compounded sterile products?

Inspecting particulate matter against white/black background using magnifying glass.

14. How often do you perform glove fingertip and medial fill testing?

Every three months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Each person must have a good understanding of SOP which includes the following:
o Principles of microbial contamination and aseptic technique
o Cleaning and disinfection procedures
o Garbing and hand hygiene
o Measuring and mixing
o Documentation of compounding process
o Engineering controls (PECs, SECs)

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

All cleaning steps should be documented along with date, the name of personnel performing the cleaning and the name of chemical used to clean , lot# and expiration date for each product
The daily cleaning procedure for the isolators hoods is as follows using 2 steps
After garbing according to USP797 cleaning can start
1)start with sterile TB 3300 (3 min contact) 2) sterile alcohol
The cleaning movement is perpendicular to the air flow using one shed free sterile paper disposable towel per one side
The weekly cleaning for the hoods using 4 steps with sterile shed free disposable towels
1)start with sterile TB 3300 disinfectant cleaner used for(3 minute contact) 2) sterile alcohol
3) Sterile Peridox (Sporicidal 7 min contact) 4) Sterile Alcohol
The cleaning movement is perpendicular to the air flow using one shed free sterile paper disposable towel per one side
Monthly cleaning for the clean room including ceiling, walls, surface, Isolators hoods, floors, trash collection using the following steps
Monthly cleaning for the clean room including ceiling, walls, surface, Isolators hoods, floors, trash collection using the following steps using the same 4 steps in the weekly cleaning

17. Who performs the sterile compounding process at your facility?

Only trained Technician and Pharmacist

18. Who is responsible and accountable for the sterile compounding process at your facility?

Pharmacist and Technician

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

We use Styrofoam coolers enclosed in cardboard boxes and packed with large ice blocks to ship refrigerated items. All shipments are sent via overnight delivery, and we closely track them to ensure they arrive on time. Our delivery system has been tested using temperature monitors that log hourly temperature readings until the package is delivered.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	■ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	■ Yes	No
9. If yes, list the name of the device: N/A		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

N/A

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

N/A

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:
NA

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?
NA

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?
NA

5. What is the frequency for completing surface sampling? NA		
6. What is the frequency for using sporicidal agents? NA		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

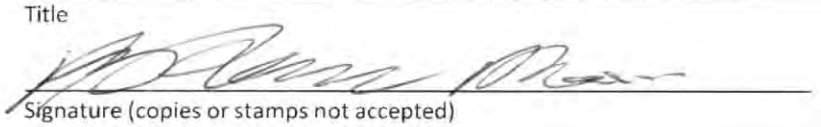
I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hytham Mouna RPh.

Name of Person who Completed the Form

Pharmacy Manager / CEO

Title



Signature (copies or stamps not accepted)

06/18/2025

Date

Board Use Only	Date Received: 12/23/25 Date Approved: _____ Approved By: _____

Inspection Details

Name	Med Solutions Compounding Pharmacy	**Case #**		**Permit**	10078
		Person Providing Info	PM Hytham Mouna	**Inspection Date**	07/15/2024
Address	1365 Westgate Center Dr, F2 Winston-Salem, NC 27103			**Inspection User**	Edmondson , Kristy
		Person In Charge	Hytham Mouna	**Inspection District**	DISTRICT2
		Rx Volume/Date	60		
		Hours	M-T 9 AM to 5:30 PM, Friday 9 AM to 2 PM, Saturday		
# RPhs	3				
# Techs	4				
Follow-Up CAP	No	**Office**	No		
CAP Requested	No	**Commercial Use**	No		
CAP Documentation Received	No	**Ship to Other States**	Yes		
		States Shipped To	Maryland: 168303		
Additional Documents	Yes	**Commercial Use Documented Clinical Indication**	No		
Office Use	No				
Office Use Comments					

Non-Sterile Compounding

Non-Sterile	No
Does the pharmacy engage in Occasional Basic Non-Sterile Compounding?	Yes
Does facility engage in moderate or complex sterile compounding?	Yes
Does facility engage in Hazardous Drug Compounding?	Yes
Is there documented clinical indication for the approved medication?	

Sterile Compounding

Sterile Compounding	No
Does facility compound Immediate Use CSP?	No
Does facility compound Category 1 Sterile Compounding?	Yes
Does facility compound Category 2 Sterile Compounding?	Yes
Does facility compound Category 3 Sterile Compounding?	No
Does facility compound hazardous medications?	No
Does facility compound Allergenic Extracts?	No

Pharmacy Staffing

How many pharmacists are employed at the pharmacy: 3

How many technicians are employed at the pharmacy: 4

What is the P:T ratio at the time of inspection: 2:4

How often is there only one pharmacist on duty:

If ratio is above 1:2 at the time of inspection, how many certified technicians are on shift:
1

How many technicians are usually on shift at a time: 3

Are pharmacists asked to do any duties outside of the pharmacy :

What is the approved Pharmacist: Technician ratio? N/A

Pharmacy Volume

What is the average daily prescription volume of the pharmacy:
60

Does pharmacy conduct any point of care testing such as COVID:
No

Does pharmacy administer vaccines: No

What is the daily average of testing:

What is the daily average of vaccines:

What staff is responsible for administering test and what is testing procedure:

What staff members are administering vaccines and what type of vaccines:

Are administered vaccines reported to the appropriate vaccine registry:

How far behind is the pharmacy on filling and verifying prescriptions:
N

Please explain:

How long has this backlog persisted:

Comments

This pharmacy operated two (2) CAIs in a segregated compounding area. The SCA was certified, and the pharmacy required gowning and garbing before entry. The pharmacy shared the compounding area and CAIs with Carolina IV Solutions. Both pharmacies followed the same policies and procedures and conducted the same trainings. Carolina IV Solutions was owned and operated by RPh. Noma Mouna who was also an employee of Med Solutions Compounding Pharmacy.

General Pharmacy Regulations

	Answer	Question
1)	Satisfactory	NCGS 90-85.15A (a) - tech must register with the Board within 30 days after the date of completing the training program.
2)	Satisfactory	NCGS 90-85.15A (b) – Current registration of a pharmacy tech shall be readily available for inspection
3)	Satisfactory	NCGS 90-85.15A (c) - 2:1 ratio, if ratio above provide waiver documentation. Any technician above the 2:1 ratio must be certified.
4)	Unsatisfactory	NCGS 90-85.23- PM license, permit and current renewal shall be posted. Licenses and renewals of each RPh. are readily available for inspection.
		Comments: PM's reciprocity license was not posted at the time of inspection.
5)	Satisfactory	NCGS 90-85.25 (b) - PM shall report within 10 days any disaster, accident, theft.
6)	Satisfactory	NCGS 90-85.26 (a) - prescriptions preserved for 3 years. (b) - Documentation of alleged medication errors.
7)	Satisfactory	NCGS 90-85.29 (1) - prescription label shall contain a discard date that is earlier of 1 yr. from date dispensed or manuf's exp. date, whichever is earlier. (2) - not obscure exp. date and storage statement when product dispensed in manuf's original container.
8)	Satisfactory	NCGS 90-85.32 (a) - prescriptions marked PRN not refilled more than 1 yr. after issue date.
9)	Satisfactory	NCGS 90-85.47 - Quality Assurance Program
10)	Not Applicable	NCGS 90-93 (3)(d): Sch. V log book or record of disposition.
11)	Satisfactory	NCGS 90-106.1 (a) - documentation system of photo ID. Kept on premises or central location for 3 years.
12)	Not Applicable	NCGS 90-113.52 (b) - pseudoephedrine Products kept behind counter. (c) - record of every purchaser, amount of product in grams. (d) - records kept for two 2 years.
13)	Not Applicable	NCGS 90-113.54 - posting of sign prohibiting sale of more than 2 pkgs (3.6grams total) of pseudoeph. /day, no more than 3 pkgs (9grams total) within 30- day period.
14)	Satisfactory	NCGS 90-640 (b) - ID badge
15)	Satisfactory	21CFR 201.17- Misbranded drugs: Medications stored in pharmacy should be labeled with an expiration date and manufacturer lot number. Note: Return to stock prescription vial with the pharmacy's own label affixed will not be deemed misbranded
16)	Satisfactory	21 NCAC 46.106-134.1 (4)(b)- label lacks any requirement listed in the subsection. (px name, name/add. of pharmacy, disp. rph's name, rx #, fill date of rx, prescriber name, dir. for use, name & strength of drug.)
17)	Satisfactory	21 NCAC 46.1601 (a)(2)- posted Pharmacy hours. (4)(A-E)- reference library, hard copy or electronic. (5)- lavatory facilities w/ hot and cold running water; clean, orderly and sanitary. (b)(1)- records are readily retrievable. (b)(2)- toll free number on labels of dispensed medications. (e)- pharmacy permit is countersigned by rphmgr. as represented in the application.
18)	Satisfactory	21 NCAC 46.1802 (a) - refills limited to prescriber's orders.
19)	Satisfactory	21 NCAC 46.1803 - All records pertaining to the filling and refilling of prescriptions shall be available to designated employees of the Board during normal business hours.
20)	Satisfactory	21 NCAC 46.1806 - proper documentation and handling of transferred rxs
21)	Satisfactory	21 NCAC 46.1818 - label shall list generic name of drug, even if unavailable to dispense or generic is not authorized.
22)	Satisfactory	21 NCAC 46.2302 (a)(1-5) - records of dispensing shall be kept for 3 years.
23)	Satisfactory	21 NCAC 46.2303 - records of prescription filling and refilling shall be kept for 3 yrs.
24)	Satisfactory	21 NCAC 46.2304 (1) - produce sight-readable documents. (3) - RPh. responsible for completeness and accuracy of entries, provides documentation that prescription information entered is correct. (5) - pharmacy has auxiliary recordkeeping system. (7) - current version of drug interactions software is utilized
25)	Satisfactory	21 NCAC 46.2305 - To maintain the confidentiality of patients' prescription orders, there must be adequate safeguards or security of the records.
26)	Satisfactory	21 NCAC 46.2502 (a) - PM shall assure that rx meds & cs meds are safe/secure within the pharmacy. (b) - PM

General Pharmacy Regulations		
	Answer	**Question**
		is present one-half the hrs. the pharmacy is open or 32 hrs. /wk., whichever is less. (d) - system of inventory recordkeeping and control to detect any shortage or discrepancies of cs meds. (e) - control of all keys to pharmacy. (j) - written disaster plan. (k) - separate from the dispensing stock all drugs more than 6 months out of date.
27)	Satisfactory	21 NCAC 46.2504 (a) - effective communication of information to the patient(s). (b) - offer to counsel for all new and transfer prescriptions. (g) - Documentation of refusals.
28)	Satisfactory	21 NCAC 46.3001 (a) - policy/procedure for all out dated, improperly labeled, adulterated damaged or unwanted drugs or drug containers are destroyed or disposed.
29)	Satisfactory	21 NCAC 46.3301 (b) - Current registration of a pharmacy tech shall be readily available for inspection.
30)	Satisfactory	21CFR 1301.75 (b) - controlled substances listed in II, III, IV, and V shall be stored in a substantially constructed cabinet, or disbursed throughout the non-controlled substances
	Comments: Locked safe.	
31)	Satisfactory	21CFR 1304.04 (2)(h)(1) - inventories and records of Sch. I & II substances maintained separate from all other records (2)(h)(2)- paper prescriptions for Sch. II substances maintained in separate file.
32)	Satisfactory	21CFR 1304.11 (a) - complete/accurate inventory of all cs meds and maintained at the registered location. (c) - Biennial Inventory.
	Comments: Last biennial inventory completed on 7/1/24.	
33)	Not Applicable	21CFR 1305.05 (a) - power of attorney on file at registered location.
	Comments: PM is DEA registrant. The facility rarely orders C2s currently.	
34)	Not Applicable	21CFR 1305.12 (b) - purchaser shall record 1 item on each numbered line. (c) - name/address of supplier on form. Only 1 supplier on any form. (d)- DEA Form 222 properly signed and dated.
35)	Not Applicable	21CFR 1305.13 (e) - purchaser must record the number of commercial or bulk containers furnished on each item and dates on which the containers are received.
36)	Satisfactory	21CFR 1305.22 Procedure for filling electronic orders. (g) - purchaser receives shipment, purchaser must create a record of the quantity of each item received and date received. Record must be electronically linked to the original order and archived.
37)	Satisfactory	21CFR 1305.27 Preservation of electronic orders. (a) purchaser must, for each order filled, retain the original signed order and all linked records for that order for 2 years. Purchaser must also retain all copies of each unaccepted or defective order and each linked statement. (b) supplier must retain each original order filled and the linked records . (Note: 2yrs for Federal Law; 3yrs for NC Law) (c) If electronic order records are maintained on a central server, records must be readily retrievable at the registered location. (Note: 2yrs for Federal Law; 3yrs for NC Law)
38)	Satisfactory	21CFR 1306.05 (a) - all cs prescriptions shall bear full name and address of the patient along with date, drug, strength, dosage form, quantity, dirs. for use, and name, address and registration number of practitioner. (d) - computer generated prescription that is printed or faxed must be manually signed
39)	Satisfactory	21CFR 1306.08 (3)(b) - pharmacy may fill electronically transmitted prescription for a cs med provided the pharmacy complies with all requirements. A Sch. II order signed by the prac- titioner.
40)	Satisfactory	21CFR 1306.14 (a) - prescription vials labeled for Sch. II display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.
41)	Satisfactory	21CFR 1306.21 (a) - order for Sch. III, IV, or V that is a facsimile is signed by practitioner.
42)	Satisfactory	21CFR 1306.22 (b) - cs refills entered on a medication record or electronic record must be uniformly maintained and readily retrievable.
43)	Satisfactory	21CFR 1306.24 (a) - prescription vials labeled for Sch. III, IV, or V display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.
44)	Not Applicable	21CFR 1306.26 (b) - not more than 8oz. of any cs containing opium, nor more than 4oz. of any other cs; not more than 48 dosage units of any such cs containing opium, nor more than 24 dosage units of any other such cs to the same purchaser in any 48-hr. period. (c) - purchaser at least 18 yoa (d) - furnish suitable ID (e) - maintain log containing name and address of purchaser, name and qty. of cs, date of purchase, name or initials of RPh. who dispensed the substance.
45)	Satisfactory	21CFR 1311.10 Eligibility to obtain a CSOS digital certificate. (a) - person who signed the most recent DEA registration application or renewal application and a person authorized to sign a registration application (b)

General Pharmacy Regulations		
	Answer	**Question**
		person granted power of attorney by a DEA registrant to sign orders for one or more schedules of controlled substances.
46)	Satisfactory	21CFR 1311.30 Requirements for storing and using a private key for digitally signing orders. (a) - Only the certificate holder may access or use his or her digital certificate and private key. (b) - The certificate holder must provide FIPSapproved secure storage for the private key, as discussed by FIPS 140-2, 180-2, 186-2, and accompanying change notices and annexes, as incorporated by reference in §1311.08. (c) - A certificate holder must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key.
47)	Satisfactory	21CFR 1311.35 Number of CSOS digital certificates needed. A purchaser of Schedule I and II controlled substances must obtain a separate CSOS certificate for each registered location for which the purchaser will order these controlled substances.
48)	Satisfactory	21CFR 1311.60 Recordkeeping. (a) - supplier and purchaser must maintain records of CSOS electronic orders and any linked records for 2 years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records. (Note: 2yrs for Federal Law; 3yrs for NC Law) (b) - Electronic records must be easily readable or easily rendered into a format that a person can read. Must be made available to the Administration upon request. (c) - CSOS certificate holders must maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate.

Section A: OCCASIONAL BASIC NON-STERILE COMPOUNDING:		
	Answer	**Question**
1)	Satisfactory	Occasional Basic Non-Sterile Compounding means combining one or more conventionally manufactured products pursuant to an individual prescription on an occasional basis. This includes but is not limited to: Magic Mouthwash, GI Cocktail, creams or ointments using only conventionally manufactured products. Documentation includes the following:
2)	Satisfactory	a) Official name, strength, and dosage of preparation.
3)	Satisfactory	b) Name and quantities of all components.
4)	Satisfactory	c) Sources, lot numbers, and expiration dates of components.
5)	Satisfactory	d) Name of the person who compounded and the person who verified the preparation.
6)	Satisfactory	e) Date preparation.
7)	Satisfactory	f) Assigned BUD.
8)	Satisfactory	g) Description of final preparation.
9)	Satisfactory	h) Description of Compounding Steps

Section B: PERSONNEL TRAINING AND EVALUATION:		
	Answer	**Question**
1)	Satisfactory	Facility has a written SOP for knowledge and competency of core skills.
2)	Satisfactory	Personnel are able to demonstrate knowledge of principles and competency of skills for performing non-sterile manipulations that include:
3)	Satisfactory	a) Hand hygiene
4)	Satisfactory	b) Garbing
5)	Satisfactory	c) Cleaning and sanitizing
6)	Satisfactory	d) Handling and transporting components and CNSPs
7)	Satisfactory	e) Measuring and mixing
8)	Satisfactory	f) Proper use of equipment and devices used to compound CNSPs
9)	Satisfactory	g) Documentation of the compounding process (e.g., master formulation and compounding records)
10)	Satisfactory	Steps in the training procedure must include:
11)	Satisfactory	a) Read and understand USP<795>, all referenced standards, and other relevant literature.
12)	Satisfactory	b) Understand and interpret Safety Data Sheets (SDSs) and Certificates of Analysis (COAs).

Section B: PERSONNEL TRAINING AND EVALUATION:

	Answer	Question
13)	Satisfactory	c) Read and understand facility compounding procedures related to staff duties.
14)	Satisfactory	All personnel who conduct compounding activities or have direct oversight must be trained in the facility's SOPs.
15)	Satisfactory	Initial and annual training documentation present for compounding personnel observed and verified by Designated Person(s) or Assigned Trainer(s).
16)	Satisfactory	Proficiency and competency demonstrated every twelve (12) months. Any deficiencies identified must be addressed, corrective actions applied, and documented.

Section B HD: USP <800> TRAINING PROGRAM

	Answer	Question
1)	Satisfactory	USP<800>: Facility has a written HD Training Program which includes:
2)	Satisfactory	a) Review of facility's HD list and their assessment of risks.
3)	Satisfactory	b) Review of facility's SOPs related to HDs. SOPs must be reviewed every twelve (12) months and must be documented in accordance with this chapter, OSHA standard (1910.120) and other applicable laws and regulations.
4)	Satisfactory	c) Proper receiving, handling, and storage of HDs.
5)	Satisfactory	d) Proper Use of PPE.
6)	Satisfactory	e) Proper use of equipment and devices (e.g. engineering controls).
7)	Satisfactory	f) Response to HD exposure – known or suspected.
8)	Satisfactory	g) Spill Management.
9)	Satisfactory	h) Proper disposal of HDs and trace-contaminated materials.
10)	Satisfactory	Initial and annual training documentation present for all personnel who handle HDs observed and verified by Designated Person or Assigned Trainer.
11)	Satisfactory	Proficiency and competency demonstrated every twelve (12) months.
12)	Satisfactory	Personnel of reproductive capability must confirm in writing that they understand the risk of handling HDs.
13)	Satisfactory	Qualified Personnel must be available for spill management at all times while HDs are handled.

Section C: PERSONAL HYGIENE AND GARBING:

	Answer	Question
1)	Satisfactory	Prior to entering a compounding area, staff:
2)	Satisfactory	a) Removes personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests).
3)	Satisfactory	b) Removes all hand, wrist, and other exposed jewelry including piercings.
4)	Satisfactory	c) Not wear earbuds or headphones.
5)	Satisfactory	Garbing requirements and order of donning and doffing must be documented in facility SOPs.
6)	Satisfactory	Hand Hygiene: wash hands and forearms up to the elbows, for at least 30 seconds, using soap and water.
7)	Satisfactory	Reusable garb (e.g. goggles) should be cleaned and sanitized with 70% IPA before each use.

Section C HD: USP <800>: Personal Protective Equipment:

	Answer	Question
1)	Satisfactory	Facility has written SOPs for PPE use based on risk of exposure and activities performed that include:
2)	Satisfactory	a) Receipt
3)	Satisfactory	b) Storage
4)	Satisfactory	c) Transport
5)	Satisfactory	d) Compounding (sterile and nonsterile)
6)	Satisfactory	e) Deactivation/decontamination, cleaning, and disinfecting
7)	Satisfactory	f) Spill control

Section C HD: USP <800> Personal Protective Equipment:		
	Answer	**Question**
8)	Satisfactory	g) Waste disposal
9)	Satisfactory	h) Contaminated clothing must not go home under any circumstances
10)	Satisfactory	Two pairs of powder free chemotherapy gloves (ASTM D6978 or successor) must be used when compounding.
11)	Satisfactory	Changed every thirty (30) minutes, according to manufacturer recommendation, torn, punctured, or suspected contamination.
12)	Satisfactory	Hands must be washed with soap and water after doffing gloves.
13)	Satisfactory	Coated disposable gowns that are impermeable to liquids.
14)	Satisfactory	a) Open in back.
15)	Satisfactory	b) Long sleeved with cuffs.
16)	Satisfactory	c) Changed per manufacturer's information or every two (2) to three (3) hours.
17)	Satisfactory	Head, hair and shoe covers that:
18)	Satisfactory	a) Protect against HDs.
19)	Satisfactory	b) Second pair of shoe covers donned before entering C-SEC and doffed before exiting C-SEC.
20)	Satisfactory	Goggles:
21)	Satisfactory	a) Worn when risk for spill or splashes outside of a C-PEC.
22)	Satisfactory	b) Best practice – goggles with face shield.
23)	Satisfactory	Respiratory protection:
24)	Satisfactory	a) Fit-tested NIOSH certified N-95 respirator – sufficient but offers not protection from gases and vapors or direct splash.
25)	Satisfactory	b) Evidence of fit testing for workers of N95 mask or other respirator by an occupational health practitioner.
26)	Satisfactory	c) Full face-piece chemical cartridge respirator or Powered Air-Purifying Respirator (PAPR) should be worn when there is a risk of respiratory exposure to HD.
27)	Satisfactory	Gloves and sleeve covers in C-PEC – removed and discarded in container or sealed bag before exiting C-PEC.
28)	Satisfactory	All waste disposed of accordance with local, state and federal regulation.

Section D: BUILDING AND FACILITIES:		
	Answer	**Question**
1)	Satisfactory	Area is specifically designated for non-sterile compounding & method of designation is identified in facility SOP.
2)	Satisfactory	Compounding space is well lighted.
3)	Satisfactory	Clean, orderly, sanitary, in good repair. It allows for orderly placement of equipment and minimizes cross-contamination.
4)	Satisfactory	Temperatures monitored daily and documented on temperature log. Documentation from electronic recording device must be retrievable.
5)	Satisfactory	Temperature monitoring equipment is calibrated or verified per manufacturer recommendation (or every 12 months if not specified).
6)	Satisfactory	Compounding components, equipment, and containers are stored off the floor to prevent contamination and promote cleaning.
7)	Satisfactory	Sink with hot and cold water is easily accessible.
8)	Satisfactory	Sink is emptied of all items not related to compounding & cleaned when visibly soiled.
9)	Satisfactory	Plumbing system free of defects that could contribute to the contamination of any CNSP.

Section D HD: USP <800> FACILITIES & ENGINEERING CONTROLS:		
	Answer	**Question**
10)	Satisfactory	HD Handling areas located away from breakrooms, refreshment areas for personnel, patients, or visitors.
11)	Satisfactory	Designated areas for: receipts & unpacking of HD in neutral or negative pressure relative to surrounding areas.

Section D HD: USP <800> FACILITIES & ENGINEERING CONTROLS:		
	Answer	**Question**
12)	Satisfactory	All HD API's and HDs requiring manipulation other than counting/repackaging of final dosage forms or reconstitution according to the manufacturer's directions in the FDA approved labeled stored in externally vented, negative pressure with 12ACPH (Non-antineoplastic, reproductive risk only, may be stored with other inventory if facility policy & Assessment of Risk allows).
13)	Satisfactory	HDs stored off the floor in a manner that prevents spillage or container breakage in negative pressure with 12 ACPH. (e.g low to the floor; use of resealable plastic bag if appropriate for small container, etc).
14)	Satisfactory	C-SEC where compounding activities occur and storage area for HDs is externally vented, physically separated, has minimum 12 ACPH, and negative pressure 0.01-0.03 in water column relative to adjacent areas.
15)	Satisfactory	Facility has signs and spill kits readily available to identify and contain spills.

Section E: CLEANING AND SANITIZING:		
	Answer	**Question**
1)	Satisfactory	Work surfaces and floors are cleaned and sanitized at the beginning of each shift on days compounding occurs, after spills, and when contamination is known or suspected.
2)	Satisfactory	Walls are visible soiled, after spills, and when contamination known or suspected.
3)	Satisfactory	Ceilings cleaned and sanitized when visibly soiled or contaminated.
4)	Satisfactory	Storage areas cleaned and sanitized quarterly.
5)	Satisfactory	Cleaning and sanitizing agents must be selected and used with consideration of compatibilities, effectiveness, and to minimize the potential to leave residues. If performed as separated steps, cleaning occurs prior to sanitizing.

Section E HD: USP <800> DEACTIVATING, DECONTAMINATING, CLEANING, DISINFECTING:		
	Answer	**Question**
1)	Satisfactory	Reusable equipment and areas are deactivated, decontaminated, and cleaned according to facility's written procedures.
2)	Satisfactory	Procedures include agents used, dilutions (if applicable), frequency, and documentation requirements.
3)	Satisfactory	Agents used are compatible with facility surfaces and appropriate for the documented task(s) (List Agents used).
5)	Satisfactory	C-PEC Deactivation, decontamination, and cleaning occurs daily and is documented.
5)	Satisfactory	Underside of C-PEC work tray is deactivated and decontaminated, cleaned at least monthly and is documented.

Section F: EQUIPMENT AND COMPONENTS:		
	Answer	**Question**
Equipment:		
1)	Satisfactory	Equipment and supplies are suitable for the specific compounding process. Must not be reactive, additive, sorptive, or alter quality of non-sterile preparations. Storage prevents risk of contamination
2)	Satisfactory	Equipment and devices used in compounding or testing compounded preparations are inspected before use and verified for accuracy per manufacturer recommendation or every 12 months, whichever is more frequent
3)	Satisfactory	Equipment is cleaned after each preparation to prevent cross-contamination
4)	Satisfactory	Weighing, measuring, and manipulating components that could generate airborne particles is assessed to determine if the activity requires closed system processing device (e.g. CVE, BSC, or single-use containment glove bag). Must be documented.
5)	Satisfactory	CVE or BSC is certified at least every 12 months
6)	Satisfactory	CVE is cleaned and sanitized at the beginning and end of each shift, between compounds with different components, after spills, and when contamination is suspected.
7)	Satisfactory	Equipment and devices are cleaned and sanitized before use, and between compounds using different components.
Components:		
8)	Satisfactory	Compounding personnel follow SOP that addresses the selection, receipt, evaluation, handling, storage, and documentation of all CNSP components, including ingredients, containers, and closures.
9)	Satisfactory	CNSP components meet the following criteria:

Section F: EQUIPMENT AND COMPONENTS:

	Answer	Question
10)	Satisfactory	a) An active ingredient in an FDA approved drug
11)	Satisfactory	b) Comply with an applicable USP-NF monograph if one exists:
12)	Satisfactory	c) Have a COA that includes specifications and testing results.
13)	Satisfactory	d) Obtained from a registered FDA facility or selected from a acceptable reliable source.
14)	Satisfactory	Certificates of Analysis (COA) are examined at the time of receipt of the API. Information from the COA is noted and used as appropriate in the compounding process to ensure quality compounds.
15)	Satisfactory	The receipt date, quantity received, supplier name, lot number, expiration date, and any in-house or third-party testing performed must be documented for all components.
16)	Satisfactory	Components are examined for deterioration and other aspects of unacceptable quality when received and re-inspected before use.
17)	Satisfactory	Unacceptable components are clearly labeled and segregated for disposal.
18)	Satisfactory	Date of receipt is marked or added on each API that lacks expiration date. An conservative expiration date that does not exceed 3 years is noted on API packaging.
19)	Satisfactory	Components stored under appropriate conditions according to manufacture requirements.
20)	Satisfactory	Facility maintains SDS and updates chemical hazard & disposal information every 12 months.
21)	Satisfactory	Waste is disposed in accordance with applicable laws & regulations (e.g. USP 800, EPA, OSHA, etc).

Section F HD: USP <800> EQUIPMENT AND COMPONENTS

	Answer	Question
1)	Satisfactory	USP <800>: C-PEC used for compounding HD CNSP is externally vented to the outside or has a redundant HEPA filter in series. The C-PEC is placed within the C-SEC under negative pressure.

Section G: MASTER FORMULATION AND COMPOUNDING RECORD:

	Answer	Question
Master Formulation Record:		
1)	Satisfactory	Master Formulation Record created for each unique formulation CNSP.
2)	Satisfactory	The Master formulation record includes name, strength, activity, and dosage form of CNSP.
3)	Satisfactory	Identities and amounts of all components.
4)	Satisfactory	Container Closure system
5)	Satisfactory	Complete instructions for preparing the CNSP, including:
6)	Satisfactory	Equipment
7)	Satisfactory	Supplies
8)	Satisfactory	Description of compounding steps
9)	Satisfactory	Physical description for expected appearance of final CNSP.
10)	Satisfactory	Assigned BUD and storage requirements with referenced sources.
11)	Satisfactory	Calculation to determine and verify quantities and/or concentration of components.
12)	Satisfactory	Labeling requirements
13)	Satisfactory	QC procedures and expected results (pH testing, visual inspection)
14)	Satisfactory	Other information needed to describe the compounding process (ie: adjusting pH and temperature, adjustment for assay, loss on drying of or waters of hydration of the API.)
15)	Satisfactory	Source for stability-indicating study or USP monograph that allows extension of BUDs beyond <795> defaults. Make sure they are performing all required tests in the USP Compounded Preparation Monograph. (e.g. pH).
16)	Satisfactory	Any changes or alterations to the MFR must be approved and documented according to facility's SOP.
Compounding Record:		
17)	Satisfactory	Compounding Record includes name, strength, activity, and dosage form of CNSP.

Section G: MASTER FORMULATION AND COMPOUNDING RECORD:

	Answer	Question
18)	Satisfactory	Date and time of preparation of the CNSP.
19)	Satisfactory	Assigned identification number (Rx number, Lot number, order number, etc).
20)	Satisfactory	Identity of personnel involved in compounding and verifying the CNSP.
21)	Satisfactory	Name, vendor or manufacturer, lot number, and expiration date of each component.
22)	Satisfactory	Weigh or measurement of each component.
23)	Satisfactory	Total quantity compounded.
24)	Satisfactory	Assigned BUD and storage requirements.
25)	Satisfactory	Physical description of appearance for final CNSP.
26)	Satisfactory	QC results (pH testing and visual inspection).
27)	Satisfactory	Master Formulation Reference.

Section H: RELEASE INSPECTION:

	Answer	Question
1)	Satisfactory	1. CNSP visually inspected to determine physical appearance meet expectations.
2)	Satisfactory	2. Checks, inspections, and test conducted in accordance to the Master Formulation Record.
3)	Satisfactory	3. Checks, inspections, and test documented in Compounding Record.
4)	Satisfactory	4. Pre-Release inspection includes visual inspection of container closure integrity (ie: check of leakage, cracks, or improper packaging).
5)	Satisfactory	5. Inspection confirm the CSNP and its label match Compounding Record and prescription order.

Section I: LABELING:

	Answer	Question
1)	Satisfactory	Labeling for each CNSP contains at minimum:
2)	Satisfactory	a) Identification number (ie: prescription number, lot number, barcode).
3)	Satisfactory	b) Active components, amounts, activities, or concentrations (no abbreviations).
4)	Satisfactory	c) Dosage form.
5)	Satisfactory	d) Amount or volume in each container.
6)	Satisfactory	e) Storage condition if other than controlled room temperature.
7)	Satisfactory	f) Beyond Use Date.
8)	Satisfactory	g) Route of administration.
9)	Satisfactory	h) Indication that the preparation is compounded.
10)	Satisfactory	i) Any special handling instructions.
11)	Satisfactory	j) Any warning statements if applicable.
12)	Satisfactory	k) Name, address, and contact information of the compounding facility if the CNSP is to be sent outside of a healthcare facility.
13)	Satisfactory	l) Compounded medications for Veterinary application labeled to indicate "Veterinary Use".
14)	Satisfactory	Labeling procedures followed as described in facility SOP to prevent mix-ups and errors.
15)	Satisfactory	Label verified to ensure it conforms to prescription/medication order, MFR, and compounding record.

Section I HD: USP <800>

	Answer	Question
1)	Satisfactory	HD handling precautions must be clearly labeled at all times during transport.
2)	Satisfactory	Personnel ensure that the labeling process for compounded preparation do not introduce contamination into the non-HD areas.

Section J: ESTABLISHING BEYOND USE DATING:

	Answer	Question
Parameters for Establishing a BUD:		
1)	Satisfactory	The chemical and physical stability properties of the API and any added substance in the preparation (e.g. if the API and added substance in the preparation are known to degrade over time and/or under certain storage conditions, which would reduce strength and/or produce harmful impurities).
2)	Satisfactory	The compatibility of the container closure system with the finished preparation (e.g. leachables, interactions, adsorption, and storage conditions.
3)	Satisfactory	Degradation of the container closure system, which can lead to reduction in integrity of the CNSP.
4)	Satisfactory	The potential for microbial proliferation in the CNSP.
BUD limits in absence of a USP-NF Compound monograph or specific stability information or BUDs that are known to be shorter due to instability:		
5)	Satisfactory	Non-preserved aqueous (water activity greater than 0.60) dosage form BUD is 14 days refrigerated.
6)	Satisfactory	Preserved aqueous dosage form BUD is 35 days at controlled room temperature or refrigerated.
7)	Satisfactory	Nonaqueous dosage form (water activity less than 0.6) BUD is 90 days at controlled room temperature or refrigerated.
8)	Satisfactory	Solid dosage forms BUD is 180 days at controlled room temperature or refrigerated.
Shorter Beyond Use Dates:		
9)	Satisfactory	If the API or any other components in the CNSP have an expiration date that is earlier than the BUD that could be assigned in the absence of a USP-NF compounded preparation monograph or CNSP- specific stability information., the expiration date supersedes the BUD and must be the assigned shortest date.
10)	Satisfactory	If the CNSP includes components from conventionally manufactured products, the BUD of the CNSP must not exceed the shortest remaining expiration date of any of those products.
11)	Satisfactory	If the CNSP includes components from other compounded preparations, the BUD of the final CNSP must not exceed the shortest remaining BUD of any of those compounded preparations.
12)	Satisfactory	If the formulation is known to require a shorter BUD.
Extended Beyond Use Dates:		
13)	Satisfactory	If there is a USP-NF compounded preparation monograph for the CNSP, the BUD must not exceed the BUD specified in the monograph.
14)	Satisfactory	The BUD for aqueous dosage forms and nonaqueous dosage forms may be extended up to a maximum of 180 days if there is a stability study (Stability indicating assay USP <1163> Potency over time not acceptable).
15)	Satisfactory	Aqueous formulations that are extended must be tested for antimicrobial effectiveness (USP<51>).
16)	Satisfactory	When using peered reviewed source compounding process must follow all aspects documented in source to include exact ingredients and container closures and tests performed.

Section K: QUALITY ASSURANCE AND QUALITY CONTROL

	Answer	Question
1)	Satisfactory	Facility has written SOP Quality Assurance and Quality Control Program for non-sterile compounding procedures. The Program must be able to identity the following:
2)	Satisfactory	a) That procedures were followed
3)	Satisfactory	b) Prevention and Detection of Errors and other quality problems.
4)	Satisfactory	c) Evaluation of Complaints and Adverse Events with documentation.
5)	Satisfactory	d) Appropriate Investigations and Corrective Actions
6)	Satisfactory	Facility has a designated person(s) responsible for QA and QC program for non-sterile compounding.
7)	Satisfactory	Designated QA and QC person has documented training for non-sterile compounding.
8)	Satisfactory	QA and QC program reviewed annually and documented.

Section L. CNSP PACKAGING AND TRANSPORTING

	Answer	Question
1)	Satisfactory	SOP for packaging CNSPs.
2)	Satisfactory	Materials used for packaging maintain physical and chemical integrity and stability of the CNSPs.

Section L. CNSP PACKAGING AND TRANSPORTING

	Answer	Question
3)	Satisfactory	Materials used for packaging protect the CNSPs from damage, leakage, contamination, and degradation.

Section L HD: USP <800>

	Answer	Question
1)	Satisfactory	Packaging materials must protect the healthcare worker from exposure.
2)	Satisfactory	Facility does not use pneumatic tubes to transport HDs.

Section M: COMPLAINT HANDLING AND ADVERSE EVENT REPORTING:

	Answer	Question
1)	Satisfactory	Facility has an SOP for Complaint handling and adverse Event reporting.
1)	Satisfactory	The compounding record permits traceability, and the facility can initiate recall.
2)	Satisfactory	Facility has a designated person who is responsible for reviewing complaints to determine if the complaint indicates a potential quality problem with CNSP.
3)	Satisfactory	Facility does an investigation into the complaint if a quality problem is identified.
4)	Satisfactory	Facility has a readily retrievable record-keeping system of all complaints with CNSPs that include
5)	Satisfactory	a) name of patient,
6)	Satisfactory	b) prescription number,
7)	Satisfactory	c) name and strength of CNSP,
8)	Satisfactory	d) date of complaint,
9)	Satisfactory	e) nature of complaint,
10)	Satisfactory	f) results of the investigation and follow up.

Section B: PERSONNEL TRAINING AND EVALUATION:

	Answer	Question
Demonstrate Knowledge and Competency of Core Skills		
1)	Satisfactory	Facility has a written SOP for knowledge and competency of core skills. Personnel are able to demonstrate knowledge of principles and competency of skills for performing sterile manipulations that include:
2)	Satisfactory	a) Hand hygiene
3)	Satisfactory	b) Garbing
4)	Satisfactory	c) Cleaning and disinfection
5)	Satisfactory	d) Calculations, measuring, and mixing
6)	Satisfactory	e) Aseptic technique
7)	Satisfactory	f) Achieving and/or maintaining sterility and apyrogenicity
8)	Satisfactory	g) Use of equipment
9)	Satisfactory	h) Documentation of the compounding process (e.g., master formulation and compounding records)
10)	Satisfactory	i) Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area
11)	Satisfactory	j) Proper use of primary engineering controls (PECs)
12)	Satisfactory	k) Principles of movement of materials and personnel within the compounding area
13)	Satisfactory	Documentation present for initial training and competency assessment of skills for compounding personnel or personnel who have direct oversight.
14)	Satisfactory	Documentation present for training and competency completed every 12 months.
15)	Satisfactory	Documentation present for training and competency for any other personnel accessing the compounding area (e.g cleaning staff/companies).
Garbing and Hand Hygiene Competency		
16)	Satisfactory	Facility has SOP for Garbing and Hand Hygiene Competency which includes procedures, documentation,

Section B: PERSONNEL TRAINING AND EVALUATION:		
	Answer	**Question**
		incubation, and interpreting results.
17)	Satisfactory	Garbing and Hand Hygiene Competency (Gloved Fingertip Testing) observed and documented for compounding personnel or personnel who have direct oversight initially in the classified area or Segregated Compounding Area (SCA).
18)	Satisfactory	Hand Hygiene, Garbing, and Gloved Fingertip Testing is completed three (3) separate times in succession.
19)	Satisfactory	All failures of Gloved Fingertip Testing documented along with corrective action taken that includes retesting the entire process.
20)	Satisfactory	Documentation must include:
21)	Satisfactory	a) Name of the person evaluated.
22)	Satisfactory	b) Evaluation date/time.
23)	Satisfactory	c) Manufacturer, lot, and expiration numbers of media and components used.
24)	Satisfactory	d) Incubation temperature intervals (30-35 degrees C for first 48 hours 20-25 degrees C for no less than 5 days) .
25)	Satisfactory	e) Dates of incubation.
26)	Satisfactory	f) Results.
27)	Satisfactory	g) Name of observer and the person who reads/documents the results.
28)	Satisfactory	All failures of Gloved Fingertip Testing documented along with corrective action taken that includes retesting the entire process.
29)	Satisfactory	Garbing and Gloved Fingertip observations and testing are completed every six (6) months in the classified areas or SCA.
Aseptic Manipulation Competency Testing		
31)	Satisfactory	Facility has SOP for Aseptic Manipulation Competency Testing which includes procedures, documentation, incubation, and interpreting results.
32)	Satisfactory	Aseptic Manipulation Competency which included observation, media fill testing, gloved fingertip testing, and surface sampling performed initially for compounding personnel or personnel who have direct oversight.
33)	Satisfactory	Testing simulates the most challenging compounding procedures.
34)	Satisfactory	Documentation includes:
35)	Satisfactory	a) Name of the person evaluated.
36)	Satisfactory	b) Evaluation date/time.
37)	Satisfactory	c) Manufacturer, lot, and expiration numbers of media and components used.
38)	Satisfactory	d) Incubation temperature intervals (20-25 degrees C for 7 days then 30-35 degrees C for 7 days).
39)	Satisfactory	e) Dates of incubation.
40)	Satisfactory	f) Results.
41)	Satisfactory	g) Name of observer and the person who reads/documents the results.
42)	Satisfactory	All failures of the Aseptic Manipulation Competency Testing documented along with corrective action taken that includes retesting the entire process.
43)	Satisfactory	Certificate of Analysis is present for commercial growth media.
44)	Satisfactory	In-house media demonstrates growth promotion in accordance with USP<71>.
45)	Satisfactory	Aseptic Manipulation Competency is completed every 6 months.

Section C: PERSONAL HYGIENE AND GARBING:		
	Answer	**Question**
1)	Satisfactory	Facility has written SOP on personal hygiene and garbing procedure logically based on location of hand hygiene sink (e.g. outside of ante room, dirty side of ante room, clean side of ante room).
2)	Satisfactory	Prior to entering a compounding area, staff:
3)	Satisfactory	a. Removes personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests).
4)	Satisfactory	b. Removes all cosmetics because they shed flakes and particles.

Section C: PERSONAL HYGIENE AND GARBING:

	Answer	Question
5)	Satisfactory	c. Removes all hand, wrist, and other exposed jewelry including piercings. Cover any jewelry that cannot be removed.
6)	Satisfactory	d. Not wear earbuds or headphones.
7)	Satisfactory	e. Not bring electronic devices that are not necessary for compounding or other required tasks into the compounding area.
8)	Satisfactory	f. Keep nails clean and neatly trimmed to minimize particle shedding and avoid glove punctures. Nail products (e.g. polish, artificial nails, and extenders) must not be worn.
9)	Satisfactory	g. Wipe eyeglasses, if worn
10)	Satisfactory	h. Documentation by designated person for any permissible excursion that do not compromise the quality of the classified environment.
11)	Satisfactory	Hand Hygiene:
12)	Satisfactory	a. Wash hands and forearms up to the elbows, for at least 30 seconds, using soap containers that cannot be refilled.
13)	Satisfactory	b. Use of nail picks.
14)	Satisfactory	c. No scrub brush used in hand hygiene.
15)	Satisfactory	d. Dry hands and elbows using low-lint towels or wipes (no hand dryers).
16)	Satisfactory	e. Hands sanitized with alcohol based hand rub.
17)	Satisfactory	Facility SOPs for hand hygiene/garbing address cleanroom suite sink placement
18)	Satisfactory	Facility has SOP for garbing order and garbing materials.
19)	Satisfactory	Garbing materials if Category 1 or 2 include
20)	Satisfactory	a. Face mask and Beard cover, if applicable.
21)	Satisfactory	b. Low-lint garb such as gowns/coveralls, disposable covers for shoes, head, and facial hair.
26)	Satisfactory	Gloves must be powder free and sterile, donned inside SCA or Classified area.
27)	Satisfactory	a. Sterile 70% IPA applied regularly throughout the compounding process.
28)	Satisfactory	RABS (CACI and CAI) – Disposable gloves worn inside gloves attached to RABS sleeves, and sterile gloves donned over gloves attached to RABS.
29)	Satisfactory	RABS sleeves changed per manufacturers' recommendations/SOPs.

Section D: FACILITIES AND ENGINEERING CONTROLS:

	Answer	Question
Segregated Compounding Area (SCA)		
1)	Satisfactory	The SCA and all surfaces in the SCA are clean, uncluttered, and dedicated to compounding.
2)	Satisfactory	Surfaces are smooth, impervious, free from cracks and crevices, easily cleanable, and resistant to damage from cleaning and disinfecting agents.
3)	Satisfactory	SCA is located away from unsealed windows and doors that connect to the outside and away from high-traffic flow areas. Must not be near restrooms, warehouses, or food preparation areas.
4)	Satisfactory	SCA has a visible perimeter.
5)	Satisfactory	SCA is clear of free-standing humidifiers/dehumidifiers or air conditioners .
6)	Satisfactory	Sink located more than 1 meter from PEC .
Cleanroom Suite (Buffer and Ante Rooms)		
7)	Not Applicable	ISO-classified Anterooms and buffer rooms are separated from unclassified areas by fixed walls, doors, etc.
8)	Not Applicable	Buffer room maintains at least ISO 7 air quality.
9)	Not Applicable	Anteroom providing access to a positive pressure ISO 7 buffer room maintains at least ISO 8.
10)	Not Applicable	Anteroom providing access to a negative pressure ISO 7 buffer room maintains at least ISO 7.
11)	Not Applicable	Primary Engineering Control (PEC) is located within ISO 7 positive pressure, provides unidirectional HEPA-filtered airflow, and maintains ISO 5 or better air quality during dynamic operating conditions.

Section D: FACILITIES AND ENGINEERING CONTROLS:		
	Answer	**Question**
12)	Not Applicable	Sterile compounding facilities are well-light and comfortable (USP<166>)
13)	Not Applicable	Temperature and Humidity are monitored and documented in each room of the cleanroom suite each day compounding is performed (should maintain 20 degrees C or cooler and relative humidity below 60% to provide comfortable conditions for personnel who are garbed).
14)	Not Applicable	Electronic documentation of Temperature and Humidity must be retrievable.
15)	Not Applicable	Temperature and Humidity readings reviewed per facility SOPs.
16)	Not Applicable	ISO-classified areas are clear of free-standing humidifiers/dehumidifiers or air conditioners
17)	Not Applicable	Air supplied to the cleanroom suite is introduced by HEPA filters located in the ceilings of ante and buffer rooms.
18)	Not Applicable	Air returns are located low on wall.
19)	Not Applicable	a. Visual smoke study demonstrates no stagnant airflow if returns are not located low on walls.
20)	Not Applicable	b. Visual smoke study and environmental monitoring is repeated when equipment placement is changed, HVAC alterations are made, or HEPA filters are changed .
21)	Not Applicable	All ISO classified rooms are equipped with pressure-differential monitoring, and electronic records are readily retrievable.
22)	Not Applicable	Room pressures are documented at least daily.
23)	Not Applicable	Room pressures are reviewed at least daily.
24)	Not Applicable	Minimum 0.02-inch water column positive pressure differential between buffer room and anteroom.
25)	Not Applicable	Pressure differential between anteroom and unclassified area not less than 0.02-inch water column .
26)	Not Applicable	Anteroom has a line of demarcation that indicates a clean side for garbing.
27)	Not Applicable	Procedures are in place to minimize the influx of lower-quality air ISO-classified areas.
28)	Not Applicable	Both doors of pass-throughs are not opened at the same time.
29)	Not Applicable	No tacky mats in ISO-classified areas.
30)	Not Applicable	If compounding both sterile and nonsterile preparations (e.g weighing and mixing):
32)	Not Applicable	a. PECs must be placed in separate rooms unless ISO 7 can be continuously maintained.
33)	Not Applicable	b. If in the same room, respective PECs for sterile and nonsterile must be 1 meter apart and no particle-generating activities occur during sterile compounding.
34)	Not Applicable	Surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, worksurfaces, counters, and cabinets in classified areas are smooth, impervious, free from cracks and crevices, and non-shedding.
35)	Not Applicable	Anteroom does not contain a floor drain.
36)	Not Applicable	Buffer room does not include plumbed water sources (sinks, eye washes, showers or floor drains)
37)	Not Applicable	All surfaces are resistant to damage by cleaning agents, disinfectants, sporicidal agents, and tools used for cleaning.
38)	Not Applicable	Walls are constructed of or covered with durable material (e.g. epoxy painted walls, heavy-gauge polymers)
39)	Not Applicable	Junctures between ceilings and walls, and walls and floors are sealed to eliminate cracks and crevices.
40)	Not Applicable	Floors include coving to the sidewall or juncture between floor and wall is caulked
41)	Not Applicable	Ceiling panels caulked on all sides.
42)	Not Applicable	Dust-collecting overhangs, pipes, and/or ledges are minimized. All such areas are easily cleanable, and cleaning is documented.
Facilities Preparing CSPs from Nonsterile Ingredients/Components:		
43)	Satisfactory	Weighing and mixing before sterilization completed in ISO 8 or better environment (e.g. anteroom or buffer room) and in a single-use containment glove bag, containment ventilated enclosure (CVE), BSC, or CACI.
44)	Satisfactory	CVE, BSC, CACI used for weighing and mixing must be certified at least every six months.
45)	Satisfactory	Secondary engineering control used for weighing and mixing is certified under dynamic conditions.
Placement and Movement of Materials.		
46)	Satisfactory	Classified area or SCA contain only furniture, equipment, and materials necessary for compounding which are

Section D: FACILITIES AND ENGINEERING CONTROLS:		
	Answer	**Question**
		low-shedding, promote easy cleaning & disinfecting, and do not impact environmental air quality
47)	Satisfactory	Equipment removed from the classified area or SCA is cleaned and wiped with SIPA (or appropriate disinfectant) before returning to the area. (Should not be removed except for calibration, servicing, or required maintenance activity).
48)	Satisfactory	No cartons, corrugated cardboard, or uncoated cardboard in classified areas or SCA
49)	Satisfactory	Carts or equipment in classified areas are non-porous with cleanable casters and wheels. Carts do not cross to the opposite side of the line of demarcation unless the entire cart is cleaned and disinfected.
50)	Satisfactory	Only equipment necessary for compounding is located in the PEC. Placement is verified by a dynamic airflow smoke pattern test initially and repeated if the equipment is moved.

Section E: CERTIFICATION AND RECERTIFICATION:		
	Answer	**Question**
1)	Satisfactory	PEC is certified initially and every six months under dynamic conditions.
2)	Satisfactory	Certification report contains Airflow Testing, HEPA Filter Integrity Testing, Total Particle Count Testing, and Dynamic Airflow Smoke Pattern Test
3)	Satisfactory	Certification report contains Airflow Testing, HEPA Filter Integrity Testing, Total Particle Count Testing, Dynamic Airflow Smoke Pattern Test, and when applicable, manufacturer specifications.
4)	Satisfactory	All ISO Classified rooms and PECs are certified initially, at least every six months, and when changes occur (e.g. redesign, construction, relocation and/or replacement of PECs and any changes affecting airflow or air quality).
5)	Satisfactory	Airflow testing is performed and documented under dynamic operating conditions.
6)	Unsatisfactory	ISO 7 rooms maintain 30 ACPH or more during dynamic operating conditions.
		Comments: [illegible]
7)	Not Applicable	Minimum of 15 ACPH are supplied by HVAC via ceiling HEPA filters.
8)	Satisfactory	PEC used to meet minimum ACPH is not turned off except for maintenance (rooms & PEC must be recertified following maintenance).
9)	Not Applicable	Total ACPH, ACPH contributed from PEC, and ACPH from HVAC are documented in the certification report
10)	Not Applicable	ISO 8 rooms maintain 20 ACPH or more during dynamic operating conditions.
11)	Satisfactory	HEPA filter integrity testing is performed after installation and as part of recertification.
12)	Satisfactory	Total Particle Count Testing is performed under dynamic conditions using calibrated equipment.
13)	Not Applicable	ISO 8 less than or equal to 3,520,000
14)	Unsatisfactory	ISO 7 less than or equal to 352,000
		Comments: See #6.
15)	Satisfactory	ISO 5 less than or equal to 3,520
16)	Satisfactory	All sampling sites and procedures are documented in facility SOPs
17)	Satisfactory	Dynamic airflow smoke pattern tests performed in each PEC and demonstrated unidirectional airflow and sweeping action over & away from preparations (Video documentation required).
18)	Satisfactory	Number of personnel in PECs and SECs during total particle counts & dynamic smoke pattern tests are documented.
19)	Satisfactory	Certification and recertifications are reviewed by the designated person(s).
20)	Satisfactory	Corrective Action Plan is documented in response for out-of-range results. Corrective Actions are reviewed for effectiveness and documented.

Section F: MICROBIAL AIR AND SURFACE MONITORING:		
	Answer	**Question**

Section F: MICROBIAL AIR AND SURFACE MONITORING:		
	Answer	**Question**
1)	Satisfactory	Facility has developed and implemented written SOPs for microbiological air and surface monitoring
2)	Satisfactory	A diagram of sampling locations is included in SOP
3)	Satisfactory	Procedures for collecting samples included in SOP
4)	Satisfactory	Size of samples (e.g. surface area, volume of air) is defined in SOP
5)	Satisfactory	Time of day of sampling is included in SOP
6)	Satisfactory	CFUs are documented
7)	Satisfactory	Action limits are documented
8)	Satisfactory	The facility documents all microbiological air and surface monitoring test results
9)	Satisfactory	Results are reviewed along with personnel data to assess state of control and identify potential risks for contamination
10)	Satisfactory	Corrective action taken is documented in response to out-of-range results.
11)	Satisfactory	Corrective actions are reviewed for effectiveness when completed and documented.
12)	Satisfactory	Impaction samplers are serviced and calibrated as recommended by the manufacturer.
13)	Satisfactory	Facility has access to C of A for media used during sampling.
14)	Satisfactory	Facility personnel who perform sampling are trained and demonstrate competency in air and surface sampling .
Monitoring Air Quality for Viable Airborne Particles:		
15)	Satisfactory	Volumetric active air sampling is performed at least every six months in all classified areas (ISO 5 PEC, ISO 7 and 8 rooms) during dynamic operating conditions.
	[redacted]	
17)	Satisfactory	Volume of air sampled is 1 cubic meter (1000 L) for each sample location.
18)	Satisfactory	Action levels for Viable Airborne Particles Sampling:
19)	Satisfactory	a. greater than 1 CFU for ISO 5 PECs;
20)	Not Applicable	b. greater than 10 CFU for ISO 7 rooms;
21)	Not Applicable	c. greater than 100 CFU for ISO 8 rooms
22)	Satisfactory	CFUs exceeding action levels are identified to the genus level (USP <1113>) and corrective actions documented.
23)	Satisfactory	Results are reviewed and documented as described in facility SOPs.
24)	No	Does Facility Perform its own Viable Air Samples?
Monitoring Surfaces for Viable Particles.		
34)	Unsatisfactory	Surface sampling is performed at least monthly for all classified areas (ISO 5 PECs, ISO 7 and 8 rooms) and pass-throughs.
	[redacted]	
39)	Satisfactory	All sampling sites and procedures are described in facility SOPs.
40)	Satisfactory	Action Levels for Surface Sampling:
41)	Satisfactory	a. greater than 3 CFU for ISO 5 PECs;
42)	Not Applicable	b. greater than 5 CFU for ISO 7 rooms;
43)	Not Applicable	c. greater than 50 CFU for ISO 8 rooms.
44)	Satisfactory	CFU exceeding action levels are identified to the genus level (USP <1113>) and corrective action is documented.
45)	Satisfactory	Results are reviewed and documented as described in facility SOPs
46)	No	Does perform its own Viable Surface Sampling?

NORTH CAROLINA BOARD OF PHARMACY

Facility: Med Solutions Compounding Pharmacy
Address: 1365 Westgate Center Dr, F2
Winston-Salem, NC 27103
Permit Type: Pharmacy
Permit #: 10078
Re-Issue Date: 11/05/2025
Expiration Date: 12/31/2026
Pharmacy Manager: Hytham Mouna (#10340)

NC Law requires notification of address change within 30 days.

PLEASE NOTIFY BOARD OF NAME AND/OR ADDRESS CHANGE

REFER TO YOUR LICENSE NUMBER IN ANY COMMUNICATION

Permit #: 10078

NORTH CAROLINA BOARD OF PHARMACY

2026 Pharmacy

This is to certify that

Med Solutions Compounding Pharmacy

doing business as

Med Solutions Compounding Pharmacy

1365 Westgate Center Dr, F2 Winston-Salem, NC 27103 Forsyth

Has been renewed for the year ending December 31st 2026, as required by law and is issued to the pharmacist-manager pursuant to the representations made in application therefore. The issuance of this renewal permit is not complete and the permit is not valid until countersigned in the space indicated below by the pharmacist-manager as represented in the application. THIS PERMIT CERTIFICATE MUST BE CONSPICUOUSLY DISPLAYED IN THE PHARMACY TO WHICH IT APPLIES. Pharmacy permits are not transferable and may be revoked for the causes specified in the Law and the Rules and Regulations of the Board.

Hytham Mouna (#10340)

11/05/2025
Re-Issued

PRESIDENT

EXECUTIVE DIRECTOR

Jack W. Campbell, IV
Executive Director

Barbara Ellen Vick
Associate Executive Director

Mailing Address:
6015 Farrington Rd., Suite 201
Chapel Hill, NC 27517
919-246-1050 FAX: 919-246-1056
www.ncbop.org

Clinton R. Pinyan
Brooks, Pierce, McLendon,
Humphrey & Leonard, LLP
Legal Counsel

NORTH CAROLINA

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5/28/2025

RE: PHARMACY PERMIT VERIFICATION

This is to certify that the following was permitted in the state of North Carolina as a pharmacy:

Med Solutions Compounding Pharmacy

Permit Number: 10078

Issue Date: 05/05/2008

Expires: 12/31/2025

Registration Status: Active

Our files show no disciplinary action against this permit.

NORTH CAROLINA BOARD OF PHARMACY

Jack W. Campbell
Executive Director

Revised 05/2025

Located at I-40 & 54
6015 Farrington Road, Suite 201
Chapel Hill, NC 27517-8154

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10A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☑ Nevada ☐ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☑ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Elizbiz Limited Liability Company

Physical Address: [redacted]

City: Henderson State: NV Zip: [redacted]

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: [redacted] Website: Elizbiz.com

Name of Designated Representative (DR): Elizabeth Gichanga

Licensing Company Email: gichangae@elizbiz.com DR Email: gichangae@gmail.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☑ Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: government agencies, schools		☑ Others: government contracts

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
				N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11-5-25

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: NA

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: NA

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: NA

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: NA

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: NA

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: Elizabeth Gichanga

Business Name: Elizbiz Limited Liability Company

Business Address: [redacted]

City: Henderson State: NV Zip: [redacted]

Telephone: [redacted] Email: gichangae@gmail.com

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** NA	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** NA	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Elizbiz Limited Liability Company

Facility Name

Elizabeth Gichanga

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11-5-25

Date

Board Use Only	Date Received: 11/20/25	Amount: $1000.00

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Elizbiz Limited Liability Company** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 02/06/2023, and in good standing in this State.

I further certify that the above DOMESTIC LIMITED-LIABILITY COMPANY (86) has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 10/13/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202510136174661
You may verify this certificate online at https://www.nvsilverflume.gov/home

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Elizbiz Limited Liability Company

Nevada Business Identification # NV20232691504
Expiration Date: 02/28/2026

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/22/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202501225373315
You may verify this certificate online at https://www.nvsilverflume.gov/home

CNA

HEALTHCARE PROVIDERS SERVICE ORGANIZATION PURCHASING GROUP
Certificate of Insurance
OCCURRENCE PROFESSIONAL LIABILITY POLICY FORM

nso

Print Date: 01/07/25

The application for the Policy and any and all supplementary information, materials, and statements submitted therewith shall be maintained on file by us or our Program Administrator and will be deemed attached to and incorporated into the Policy as if physically attached.

PRODUCER	BRANCH	PREFIX	POLICY NUMBER
018098	970	HPG	0738208306

Policy Period:

From: 04/14/25 to 04/14/26 at 12:01 AM Standard Time

Named Insured

Elizbiz Limited Liability Company
[redacted]
Henderson, NV[redacted]

Program Administered by:

Nurses Service Organization
1100 Virginia Drive, Suite 250
Fort Washington, PA 19034-3278
215-509-5437
www.nso.com

Medical Specialty	Code
Nursing Firm Excludes Cosmetic Procedures	80964

Insurance is provided by:

American Casualty Company of Reading, Pennsylvania
151 N. Franklin Street, Chicago, IL 60606

Professional Liability

Professional Liability	$1,000,000	each claim	$3,000,000	aggregate

Your professional liability limits shown above include the following:
- Good Samaritan Liability
- Malplacement Liability
- Personal Injury Liability
- Sexual Misconduct included in the PL Limit shown above subject to $25,000 aggregate sublimit

Coverage Extensions

License Protection	$25,000	per proceeding	$25,000	aggregate
Defendant Expense Benefit	$1,000	per day limit	$25,000	aggregate
Deposition Representation	$10,000	per deposition	$10,000	aggregate
Assault *Includes Workplace Violence Counseling*	$25,000	per incident	$25,000	aggregate
Medical Payments	$25,000	per person	$100,000	aggregate
First Aid	$10,000	per incident	$10,000	aggregate
Damage to Property of Others	$10,000	per incident	$10,000	aggregate
Enterprise Privacy Protection - Claims Made Retroactive Date: 04/14/23 - Defense inside limits	$25,000	per incident	$25,000	aggregate
Media Expense	$25,000	per incident	$25,000	aggregate

General Liability

General Liability	$1,000,000 each claim / $3,000,000 aggregate
Fire and Water Legal Liability	Included in the GL limit above subject to $250,000 aggregate sublimit
Personal Liability	Excluded

Total: $1,016.00

Policy Forms & Endorsements (Please see attached list of policy forms and endorsements)

Chairman of the Board

Secretary

Keep this document in a safe place. It and proof of payment are your proof of coverage. There is no coverage in force unless the premium is paid in full. In order to activate your coverage, please remit premium in full by the effective date of this Certificate of Insurance.

Coverage Change Date:
CNA93692 (11-2018)

Endorsement Date:

Master Policy : 188711433

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9147059-002002-0122

POLICY FORMS & ENDORSEMENTS

The following are the policy forms and endorsements that apply to your current professional liability insurance policy.

COMMON POLICY FORMS & ENDORSEMENTS

FORM #	DESCRIPTION
G-121500-D (04-08)	Common Policy Conditions
G-121501-C (07-01)	Occurrence Policy Form
CNA82011 (04-15)	Related Claims Endorsement
G-145184-A (06-03)	Policyholder Notice - OFAC Compliance Notice
G-147292-A (03-04)	Policyholder Notice - Silica, Mold & Asbestos Disclosure
CNA81753 (03-15)	Coverage & Cap on Losses from Certified Acts Terrorism
CNA81758 (01-21)	Notice - Offer of Terrorism Coverage & Disclosure of Premium
GSL13424 (05-09)	Services to Animals
GSL13425 (05-09)	Business Owner Coverage Extension Endorsement
GSL15564 (10-09)	Sexual Misconduct Sublimits of Liability Professional Liability & Sexual Misconduct Exclusion
GSL15565 (03-10)	Healthcare Providers Professional Liability Assault Coverage
GSL17101 (02-10)	Exclusion of Specified Activities Reuse of Parenteral Devices and Supplies
CNA80052 (09-14)	Distribution or Recording of Material or Information in Violation of Law Exclusion Endorsement
CNA94164 (11-18)	Amendment Definition of Claim Endorsement
G-123816-C27 (12-01)	Nevada Amendatory Change
G-123846-C27 (07-01)	Nevada Cancellation and Non-Renewal
CNA79516 (07-14)	Enterprise Privacy Protection
CNA79575 (07-14)	Exclusion of Cosmetic Procedures
CNA89026 (05-17)	Media Expense Coverage
CNA96096 (06-19)	Amended Definition of You and Yours
G-121504-C (07-01)	General Liability Form

Healthcare Providers Service Organization is a registered trade name of Affinity Insurance Services, Inc.; (TX 13695); (AR 100106022); in CA, MN, AIS Affinity Insurance Agency, Inc. (CA 0795465); in OK, AIS Affinity Insurance Services, Inc.; in CA, Aon Affinity Insurance Services, Inc., (CA 0G94493), Aon Direct Insurance Administrators and Berkely Insurance Agency and in NY , AIS Affinity Insurance Agency.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. PB12409400386

Application/License No. _____

ELIZBIZ LIMITED LIABILITY COMPANY (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is [redacted] HENDERSON, NV [redacted] (Address of Applicant/Principal), as PRINCIPAL, and PHILADELPHIA INDEMNITY INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of PENNSYLVANIA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is ONE BALA PLAZA SUITE 100 BALA CYNWYD, PA 19004-0950 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on NOVEMBER 7, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 10TH day of NOVEMBER, 2025.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

ELIZABETH GICHANGA

SURETY

Surety Company's Representative

ERIC FAUERBACH, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness George Kwelpama

Witness Kavitha Phuntsok

SIGNED and SEALED in the presence of:

Witness Taylor Branum

Witness Jason O'Leary

Countersigned by:

Not Needed
Nevada Resident Agent

Posted February 20, 2020

Bond # PB12409400386

PHILADELPHIA INDEMNITY INSURANCE COMPANY
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint **Eric Fauerbach of Surety Bonds Direct, LLC** its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed **$50,000,000.**

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November 2016.

RESOLVED: That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

FURTHER RESOLVED: That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF OCTOBER 2024.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of October, 2024 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**; that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Notary Public: Vanessa McKenzie

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Delaware County
My commission expires November 3, 2028
Commission number 1366394
Member, Pennsylvania Association of Notaries

residing at: Linwood, PA

My commission expires: November 3, 2028

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day October 2024 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 10th day of November, 2025.

Edward Sayago, Corporate Secretary
PHILADELPHIA INDEMNITY INSURANCE COMPANY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Elizbiz LLC MDEG License # (if applicable) _____

Physical Address [redacted]

City Henderson State NV Zip [redacted]

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone [redacted] Website Elizibiz.com

Licensing Company Email gichangae@elizbiz.com

Section 2: Personal Information

First Elizabeth Middle Wanjiru Last Gichanga

Alias(es, nicknames, name changes, etc.) Shearry

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Henderson State NV Zip [redacted]

Telephone [redacted] Email gichangae@gmail.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Touro University		08/19 - 08/20	
Address	**City**	**State**	**Zip**
874 American Pacific Dr	Henderson	NV	89014
Diploma/Degree obtained, if any			
BSN			

School Name		From - To (MM/YY – MM/YY)	
Highline Community College		05/04 - 05/05	
Address	**City**	**State**	**Zip**
2400 S 240th St	Des Moines	WA	98198
Diploma/Degree obtained, if any			
Associates Degree in Nursing			

School Name		From - To (MM/YY – MM/YY)	
Renton Technical college		01/01 - 12/01	
Address	**City**	**State**	**Zip**
3000 NE 4th St	Renton	WA	98056
Diploma/Degree obtained, if any			
Licensed Practical Nurse Certification			

School Name		From - To (MM/YY – MM/YY)	
Daystar University		04/93 - 04/97	
Address	**City**	**State**	**Zip**
	Athi River	Kenya	
Diploma/Degree obtained, if any			
Bachelors Degree - Business Administration and Management			

School Name		From - To (MM/YY – MM/YY	
Kyeni Girls High School		01/88 - 12/91	
Address	**City**	**State**	**Zip**
	Embu	Kenya	
Diploma/Degree obtained, if any			
High School Certificate of Completion			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]	City	State	[redacted]
01/17- 10/25		Henderson	NV	
From - To (MM/YY – MM/YY)		City	State	
8/16 - 01/17		Henderson	NV	
From - To (MM/YY – MM/YY)		City	State	
01/13 - 08/16		Federal Way	WA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Roots Home health Company			02/23- 10/25	
Business Address		**City**	**State**	**Zip**
2012 San Juan Blvd, Farmington		Farmington	NM	87401
Phone	**Title**		**Number of Employed Hours**	
(505) 258-4471	Registered Nurse		1500+	
Description of Duties				
Provide skilled nursing care to patients in their home as prescribed by the physician. Duties include assessing patient, administering and managing medications, wound care, coordinate patient care with other providers.				

Business Name			From - To (MM/YY – MM/YY)	
Giving Home Health Care			10/20-10/25	
Business Address		**City**	**State**	**Zip**
10190 Covington Cross Dr 2nd Floor		Las Vegas	NV	89144
Phone	**Title**		**Number of Employed Hours**	
702-474-4000	Registered Nurse		1500+	
Description of Duties				
Provide skilled nursing care to patients in their home as prescribed by the physician. Duties include assessing patient, administering medications, tracheostomy care, feeding tube management.				

Business Name			From - To (MM/YY – MM/YY)	
Elizbiz LLC			02/23 - 10/25	
Business Address		**City**	**State**	**Zip**
6436 Extreme Shear Ave # 103		Henderson	NV	89011
Phone	**Title**		**Number of Employed Hours**	
253-670-4203	Owner		1500+	
Description of Duties				
Provide skilled nursing care to patients in their home as prescribed by the physician. Duties include assessing patient, administering and managing medications, wound care, coordinate patient care with other providers.				

Business Name			From - To (MM/YY – MM/YY)	
Henderson Hospital			03/17 - 09/20	
Business Address		**City**	**State**	**Zip**
1050 W. Galleria Drive		Henderson	NV	89011
Phone	**Title**		**Number of Employed Hours**	
702-963-7000	Registered Nurse		1500+	
Description of Duties				
Performed and documented patient assessments, reported any change in condition and notified the physician. Administered medications and treatments as prescribed.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
N/A				
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.	✓	

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
9/02/2020	3/24/2021	NV	Henderson	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
202009037		Nevada State Board of Nursing		
Reason/Charge				
Allegations stated that I may have violated nursing statutes and/or regulations.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Nevada State Board of Nursing / Elizabeth Gichanga				
Name of Business/Industry/Entity				
Henderson Hospital				

Provide explanation below:

The Henderson Hospital in Henderson, Nevada, submitted a complaint against me to the Nevada State Board of Nursing. The complaint was regarding my nursing practice related to an incident where a patient was found unresponsive while I was working at the hospital on September 2nd 2020. The allegations stated that I may have violated statutes and/or regulations including but not limited to unprofessional conduct, and/or failing to observe/report, customary stands of practice, and /or causing harm to a patient. Following the investigation, the board said that there was a potential for possible action against my license in Nevada if it was determined that there had been a violation of the Nurse Practice Act. My attorney responded to the Board and after investigation I entered into an agreement for reprimand and continuing education with the board . I completed the continuing education as agreed and in April 2021 received a letter from the board stating that I had complied with the agreement. My license remained active and I was able to continue practicing as a Registered Nurse.

Original Signature (electronic, copies or stamps not accepted)

11-6-2025
Date

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.	✔	

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
10/27/2021	April 1st 2022	California	San Diego	USA
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
4002021006387		BOARD OF RN DEPT. OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
Reason/Charge				
None renewal of CA license and discipline of license in another state				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Board of Registered Nursing CA / Elizabeth Gichanga				
Name of Business/Industry/Entity				

Provide explanation below:

In April 1st 2022, RN license No. 831862 was revoked by California Board of Registered Nursing for the following reasons:
1. None renewal of expired California license.
2. Nevada registered license being disciplined by the Nevada Board of Nursing in March 24, 2021.

Original Signature (electronic, copies or stamps not accepted)

11-5-25
Date

I, Elizabeth Gichanga, **certify that as the MDEG Administrator for**

Elizbiz Limited Liability Company,

that I (initial that you have read and meet the following requirements):

1. EG Have a high school diploma or its equivalent;
2. EG Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. EG Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. EG Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Elizabeth Gichanga
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-5-25
Date

Board Use Only	Date Received: 11/7/2025

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Y

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Elizbiz Limited Liability Company

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 6436 Extreme Shear Ave. #103

City Henderson State NV Zip 89011

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 253-670-4203 Website Elizbiz.com

Licensing Company Email gichangae@elizbiz.com

Section 2: Personal Information

First Elizabeth Middle Wanjiru Last Gichanga

Alias(es, nicknames, name changes, etc.) Shearry

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 6436 Extreme Shear Ave. #103

City Henderson State NV Zip 89011

Telephone 253-670-4203 Email gichangae@gmail.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Touro University		08/19 - 08/20	
Address	**City**	**State**	**Zip**
874 American Pacific Dr	Henderson	NV	89014
Diploma/Degree obtained, if any			
BSN			

School Name		From - To (MM/YY – MM/YY)	
Highline Community College		05/04 - 05/05	
Address	**City**	**State**	**Zip**
2400 S 240th St	Des Moines	WA	98198
Diploma/Degree obtained, if any			
Associates Degree in Nursing			

School Name		From - To (MM/YY – MM/YY)	
Renton Technical College		01/01 - 12/01	
Address	**City**	**State**	**Zip**
3000 NE 4th St	Renton	WA	98056
Diploma/Degree obtained, if any			
Licensed Practical Nurse Certification			

School Name		From - To (MM/YY – MM/YY)	
Daystar University		04/93 - 04/97	
Address	**City**	**State**	**Zip**
	Athi River	Kenya	
Diploma/Degree obtained, if any			
Bachelors Degree - Business Administration and Management			

School Name		From - To (MM/YY – MM/YY)	
Kyeni Girls High School		01/88 - 12/91	
Address	**City**	**State**	**Zip**
	Embu	Kenya	
Diploma/Degree obtained, if any			
High School Certification of Competion			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/17 - 10/25	[redacted]	Henderson	NV	
08/16 - 01/17		Henderson	NV	
01/13 - 08/16		Federal Way	WA	

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Roots Home Health Care			12/23 - 10/25	
Business Address		**City**	**State**	**Zip**
2012 San Juan Blvd.		Farmington	NM	87401
Phone	**Title**		**Number of Employed Hours**	
505-258-4471	Registered Nurse			
Description of Duties				
Provide skilled nursing care services to patients in their home as prescribed by the physician. Duties include administering and managing medications, wound care, coordinate patient care with other providers.				

Business Name			From - To (MM/YY – MM/YY)	
Elizbiz LLC			02/23 - 10/25	
Business Address		**City**	**State**	**Zip**
6436 Extreme Shear Ave. #103		Henderson	NV	89011
Phone	**Title**		**Number of Employed Hours**	
253-670-4203	Owner/ Managing Officer			
Description of Duties				
Contract with established home healthcare agencies to provide skilled nursing care services to patients in their home as prescribed by the physician.				

Business Name			From - To (MM/YY – MM/YY)	
Giving Home Health Care			10/20 - 10/25	
Business Address		**City**	**State**	**Zip**
10190 Covington Cross Dr. 2nd Floor		Las Vegas	NV	89144
Phone	**Title**		**Number of Employed Hours**	
702-474-4000	Registered Nurse		3000+	
Description of Duties				
Provide skilled nursing care services to patients in their home as prescribed by the physician. Duties include administering and managing medications, wound care, coordinate patient care with other providers.				

Business Name			From - To (MM/YY – MM/YY)	
Community Home Health Care			10/20 - 11/21	
Business Address		**City**	**State**	**Zip**
2880 E Flamingo Rd		Las Vegas	NV	89121
Phone	**Title**		**Number of Employed Hours**	
702-333-1356	Registered Nurse		1000+	
Description of Duties				
Provide skilled nursing care services to patients in their home as prescribed by the physician. Duties included administering and managing medications, wound care, managing iv sites and infusions.				

Business Name			From - To (MM/YY – MM/YY)	
Henderson Hospital			03/17 - 09/20	
Business Address		**City**	**State**	**Zip**
1050 W. Galleria drive		Henderson	NV	89011
Phone	**Title**		**Number of Employed Hours**	
702-963-7000	Registered Nurse		3000+	
Description of Duties				
Duties included assessment and documentation of patient condition, coordinating patient care with other departments. Administering medication and treatments to patients as ordered by physician.				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4,5,6 **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
09/02/2020	03/24/2021	NV	Henderson	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
202009037		Nevada State Board of Nursing		
Reason/Charge				
Allegations stated that I may have violated nursing statutes and / or regulations.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
NV State Board of Nursing / Elizabeth Gichanga				
Name of Business/Industry/Entity				
Henderson Hospital				

Provide explanation below:

The Henderson Hospital in Henderson, Nevada, submitted a complaint against me to the Nevada State Board of Nursing. The complaint was regarding my nursing practice related to an incident where a patient was found unresponsive while I was working at the hospital on September 2nd 2020. The allegations stated that I may have violated statutes and/or regulations including but not limited to unprofessional conduct, and/or failing to observe/report, customary stands of practice, and /or causing harm to a patient. Following the investigation, the board said that there was a potential for possible action against my license in Nevada if it was determined that there had been a violation of the Nurse Practice Act. My attorney responded to the Board and after investigation I entered into an agreement for reprimand and continuing education with the board . I completed the continuing education as agreed and in April 2021 received a letter from the board stating that I had complied with the agreement. My license remained active and I was able to continue practicing as a Registered Nurse.

Re: Designated Representative Experience Narrative – Elizabeth Gichanga, RN

I am a Registered Nurse with over 25 years of healthcare experience, including 20 years in hospital medical-surgical care and 5 years in home health. Throughout my career, I have worked extensively with medical supplies and durable medical equipment (DME) essential to patient safety and infection control.
I have used and overseen PPE (gloves, masks, gowns, face shields), mobility aids (wheelchairs, walkers, canes), daily living aids (shower chairs, commodes), and diagnostic kits (blood pressure monitors, glucose meters, COVID-19 tests). I have also managed first aid supplies, oxygen equipment, IV kits, and sharps containers, ensuring proper storage, labeling, and compliance with healthcare regulations.
My hands-on experience with these products has given me a strong understanding of quality assurance, regulatory compliance, and safe handling practices. I am fully qualified to serve as the Designated Representative for Elizbiz LLC, ensuring the compliant distribution of reliable medical and safety supplies.
Sincerely,
Elizabeth Gichanga, RN,Owner & Designated Representative Applicant - Elizbiz LLC

Original Signature (electronic, copies or stamps not accepted)

11-6-2025
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

4.5.6 **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
10/27/2021	04/01/2022	CA	San Diego	USA

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
4002021006387	Board of Nursing California

Reason/Charge
None renewal of CA license and discipline of license in another state

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Board of Nursing CA / Elizabeth Gichanga	

Name of Business/Industry/Entity

Provide explanation below:

On April 2022, my RN license No.831862 was revoked by the California Board of Registered Nursing for the following reasons:

1. Non-renewal of California license
2. Nevada registered license being disciplined by the Nevada Board of Nursing on March 24, 2021.

Original Signature (electronic, copies or stamps not accepted)

11-6-25
Date

MCBRIDE HALL
ATTORNEYS AT LAW

May 3, 2021

VIA E-MAIL

Washington State Department of Health
Board of Nursing
nursing@doh.wa.gov

Re: *Nevada Board of Nursing v. Elizabeth Gichanga, RN*
Our File No.: 544-6600-01

To Whom It May Concern:

I represent Elizabeth Gichanga, RN. Attached for your records, please find a copy of the Settlement Agreement between Elizabeth Gichanga, RN and the Nevada State Board of Nursing in relation to a Complaint submitted by Henderson Hospital. Ms. Gichanga has already fully complied with the terms of the Agreement.

Should you have any questions or concerns in this regard, please do not hesitate to contact me.

Sincerely,
McBRIDE HALL

/s/ Heather S. Hall

HEATHER S. HALL, ESQ.

HSH/cpc
Enclosure
cc: Elizabeth Gichanga, RN

8329 West Sunset Road, Suite 260
Las Vegas, Nevada 89113
T: 702-792-5855 | F: 702-796-5855
www.mcbridehall.com

Nevada State Board of
NURSING

April 23, 2021

Elizabeth Gichanga
[redacted]
Henderson, Nevada [redacted]

Dear Ms. Gichanga:

This office has received documentation of your successful completion of Documentation: A Critical Aspect of Client Care, Righting a Wrong- Ethics & Professionalism in Nursing and Nevada Nurse Practice Act courses to meet the educational requirements of your Agreement for Reprimand and Continuing Education. Completion of these courses places you in compliance with that Agreement.

Congratulations and thank you for your cooperation in this matter. If you have any questions, please do not hesitate to contact me in writing, or by telephone at 888-590-6726, ext. 77726.

Sincerely,
NEVADA STATE BOARD OF NURSING

Elaine Ralph, RN

Elaine Ralph, BSN, RN, FN-CSp
Investigator

cc: Heather Hall, Esq.

5011 Meadowood Mall Way, Suite 300, Reno, NV 89502-6547 (fax) 775-687-7707
4220 S. Maryland Parkway, Suite B300, Las Vegas, NV 89102-4392 (fax) 702-486-5803
www.nevadanursingboard.org - 888-590-6726 - nursingboard@nsbn.state.nv.us

ORIGINAL

BEFORE THE NEVADA STATE BOARD OF NURSING

IN THE MATTER OF ELIZABETH GICHANGA LICENSED PROFESSIONAL NURSE NEVADA LICENSE NO. RN87793 RESPONDENT	AGREEMENT FOR REPRIMAND AND CONTINUING EDUCATION CASE NO. 202009037

This Agreement is hereby entered into between ELIZABETH GICHANGA, (RESPONDENT) and the NEVADA STATE BOARD OF NURSING, (BOARD).

It is hereby stipulated and agreed, by and between the parties to the above-entitled matter, that the following statements are true:

1. Respondent is aware of, understands, and has been advised of the effect of this Agreement, which Respondent herein has carefully read and fully acknowledges. No coercion has been exerted on the Respondent. Respondent acknowledges her right to an attorney at her own expense. The Respondent has had the benefit at all times of obtaining advice from competent counsel of her choice.

2. Respondent understands the nature of the allegations under investigation by the Nevada State Board of Nursing. Respondent freely admits that on September 2, 2020, while licensed and working as a Registered Nurse at a hospital in Henderson, Nevada she failed to document a nursing assessment and glucose monitoring results on a patient assigned to her care. The Respondent further admits she failed to ensure the patient was connected to telemetry monitoring as ordered by the physician. Respondent acknowledges this conduct constitutes a violation of the Nevada Revised Statutes 632.347 (1)(g) unprofessional conduct, and Nevada Administrative Code 632.890 (20) inaccurate recording, falsifying, or otherwise altering or destroying records and (25) failing to observe the conditions, signs and symptoms of a patient, to record the information or to report significant changes to the appropriate persons. Respondent

further acknowledges that such acts and admissions subject her to disciplinary action by the Board.

3. Respondent is aware of the Respondent's rights, including the right to a hearing on any charges and allegations, the right to an attorney at her own expense, the right to examine witnesses who would testify against her, the right to present evidence in her favor and call witnesses on her behalf, or to testify herself, the right to contest the charges and allegations, the right to reconsideration, appeal or any other type of formal judicial review of this matter, and any other rights which may be accorded to her pursuant to the Nevada Administrative Procedures Act and the provisions of Chapter 632 of the Nevada Revised Statutes and the Nevada Administrative Code. Respondent agrees to waive the foregoing rights upon acceptance of this Agreement by the Board.

4. Respondent understands that the Board is free to accept or reject this Agreement, and if rejected by the Board, a disciplinary proceeding may be commenced.

5. Should the Agreement be rejected by the Board, it is agreed that presentation to and consideration by the Board of such proposed Agreement, shall not disqualify the Board, or any of its members, from further participation, consideration, adjudication or resolution of these proceedings, and that no Board member shall be disqualified or challenged for bias therefore.

6. This Agreement shall only become effective when both parties have duly executed it and unless so executed, this Agreement will not be construed as an admission.

7. This Agreement shall not be construed as excluding or reducing any criminal or civil penalties or sanction or other remedies that may be applicable under federal, state or local laws.

8. This Agreement shall cover any nursing license and/or certificate issued by the State of Nevada.

9. Based upon the foregoing stipulations and recitals, it is hereby agreed that the Board may issue the following decision and order:

DECISION AND ORDER

Based on the foregoing, and good cause appearing therefore, it is hereby ordered that:

1. Respondent be publicly reprimanded.

2. As a condition of licensure Respondent, within the first ninety (90) days of this Agreement, shall take, and successfully complete the following courses:

   a. Documentation: A Critical Aspect of Client Care; and

   b. Righting a Wrong, Ethics and Professionalism in Nursing; and

   c. The Nevada Nurse Practice Act web based course.

The courses must be pre-approved by the Executive Director, or the Director of Nursing Practice. Documentation of successful course completion must be submitted to the Board within ninety (90) days of the execution of this Agreement or the license is automatically suspended without further proceedings until all requirements are completed.

This Agreement will become part of the Respondent's permanent record, will become public information, will be published with the list of disciplinary actions the Board has taken, and may be reported to any national repository which records disciplinary action taken against licensees or holders of certificates; or any agency or another state which regulates the practice of nursing.

///

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///

The Agreement may be used in any subsequent hearings by the Board. In the event other misconduct is reported to the Board, this Agreement may be used as evidence against the Respondent to establish a pattern of behavior and for the purpose of proving additional acts of misconduct.

Dated this 3rd day of March, 2021

RESPONDENT
ELIZABETH GICHANGA

Dated this 3rd day of March, 2021

HEATHER HALL, ESQ.

Accepted and approved this 24 day of March, 2021

NEVADA STATE BOARD OF NURSING

By:

Susan S. VanBeuge, DNP, APRN, FNP-BC, FAANP
Board President

BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **ELIZABETH WANJIRU GICHANGA** [redacted] **Henderson, NV** [redacted] **Registered Nurse License No. 831862** Respondent.	Case No. 4002021006387 **DEFAULT DECISION AND ORDER** [Gov. Code, §11520]

FINDINGS OF FACT

1. On or about October 27, 2021, Complainant Loretta Melby, R.N., M.S.N., in her official capacity as the Executive Officer of the Board of Registered Nursing (Board), Department of Consumer Affairs, filed Accusation No. 4002021006387 against Elizabeth Wanjiru Gichanga (Respondent) before the Board. (Accusation attached as Exhibit A.)

2. On or about October 31, 2012, the Board issued Registered Nurse License No. 831862 to Respondent. The Registered Nurse License expired on December 31, 2017, and has not been renewed.

3. On or about November 1, 2021, Respondent was served by Certified and First Class Mail copies of the Accusation No. 4002021006387, Statement to Respondent, Notice of Defense, Request for Discovery, and Discovery Statutes (Government Code sections 11507.5, 11507.6,

and 11507.7) at Respondent's address of record which, pursuant to California Code of Regulations, title 16, section 1409.1, is required to be reported and maintained with the Board. Respondent's address of record was and is [redacted], Henderson, NV [redacted]

4. Service of the Accusation was effective as a matter of law under the provisions of Government Code section 11505, subdivision (c) and/or Business and Professions Code section 124.

5. Government Code section 11506, subdivision (c) states, in pertinent part:

> The respondent shall be entitled to a hearing on the merits if the respondent files a notice of defense . . . and the notice shall be deemed a specific denial of all parts of the accusation . . . not expressly admitted. Failure to file a notice of defense . . . shall constitute a waiver of respondent's right to a hearing, but the agency in its discretion may nevertheless grant a hearing.

6. The Board takes official notice of its records and the fact that Respondent failed to file a Notice of Defense within 15 days after service upon her of the Accusation, and therefore waived her right to a hearing on the merits of Accusation No. 4002021006387.

7. California Government Code section 11520, subdivision (a) states, in pertinent part:

> (a) If the respondent either fails to file a notice of defense . . . or to appear at the hearing, the agency may take action based upon the respondent's express admissions or upon other evidence and affidavits may be used as evidence without any notice to respondent . . . .

8. Pursuant to its authority under Government Code section 11520, the Board finds Respondent is in default. The Board will take action without further hearing and, based on the relevant evidence contained in the Default Decision Investigatory Evidence Packet in this matter, as well as taking official notice of all the investigatory reports, exhibits and statements contained therein on file at the Board's offices regarding the allegations contained in Accusation No. 4002021006387, finds that the charges and allegations in Accusation No. 4002021006387, are separately and severally, found to be true and correct by clear and convincing evidence.

DETERMINATION OF ISSUES

1. Based on the foregoing findings of fact, Respondent Elizabeth Wanjiru Gichanga has subjected her Registered Nurse License No. 831862 to discipline.

2. The agency has jurisdiction to adjudicate this case by default.

3. The Board is authorized to revoke Respondent's Registered Nurse License based upon the following violations alleged in the Accusation which are supported by the evidence contained in the Default Decision Investigatory Evidence Packet in this case:

a. Respondent has subjected her registered nurse license to disciplinary action under Code section 2761, subdivision (a)(4), in that her Nevada registered license was disciplined by the Nevada Board of Nursing.

ORDER

IT IS SO ORDERED that Registered Nurse License No. 831862, issued to Respondent Elizabeth Wanjiru Gichanga, is revoked.

Pursuant to Government Code section 11520, subdivision (c), Respondent may serve a written motion requesting that the Decision be vacated and stating the grounds relied on within seven (7) days after service of the Decision on Respondent. The agency in its discretion may vacate the Decision and grant a hearing on a showing of good cause, as defined in the statute.

This Decision shall become effective on April 1, 2022.

It is so ORDERED March 2, 2022

Sharon Johnson

FOR THE BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS

83166702.DOCX
DOJ Matter ID:SD2021801670

Attachment:
Exhibit A: Accusation

Exhibit A

Accusation

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
ERIN M. SUNSERI
Deputy Attorney General
State Bar No. 207031
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9419
Facsimile: (619) 645-2061
Attorneys for Complainant

BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:	Case No. 4002021006387
ELIZABETH WANJIRU GICHANGA [redacted] **Henderson, NV** [redacted]	**ACCUSATION**
Registered Nurse License No. 831862	
Respondent.	

PARTIES

1. Loretta Melby, R.N., M.S.N. (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Registered Nursing (Board), Department of Consumer Affairs.

2. On or about October 31, 2012, the Board issued Registered Nurse License No. 831862 to Elizabeth Wanjiru Gichanga (Respondent). The Registered Nurse License expired on December 31, 2017, and has not been renewed.

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JURISDICTION

3. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Section 2750 of the Code provides, in pertinent part, that the Board may discipline any licensee, including a licensee holding a temporary or an inactive license, for any reason provided in Article 3 (commencing with section 2750) of the Nursing Practice Act.

5. Section 2764 of the Code provides, in pertinent part, that the expiration of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary proceeding against the licensee or to render a decision imposing discipline on the license.

STATUTORY PROVISIONS

6. Section 2761 of the Code states:

> The board may take disciplinary action against a certified or licensed nurse or deny an application for a certificate or license for any of the following:
>
> (a) Unprofessional conduct, which includes, but is not limited to, the following:
>
> ...
>
> (4) Denial of licensure, revocation, suspension, restriction, or any other disciplinary action against a health care professional license or certificate by another state or territory of the United States, by any other government agency, or by another California health care professional licensing board. A certified copy of the decision or judgment shall be conclusive evidence of that action.
>
> ....

COST RECOVERY

7. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licensee found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licensee to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

///

CAUSE FOR DISCIPLINE

(Disciplinary Action Against Licentiate by the Nevada Board of Nursing)

8. Respondent has subjected her registered nurse license to disciplinary action under Code section 2761, subdivision (a)(4), in that her Nevada registered license was disciplined by the Nevada Board of Nursing (Nevada Board). Effective March 24, 2021, in a disciplinary matter entitled, "*In the Matter of Elizabeth Gichanga Licensed Professional Nurse Nevada License No. RN87793*," Respondent entered into an Agreement for Reprimand and Continuing Education with the Nevada Board. The Nevada Board issued an Order that Respondent be publicly reprimanded, and that as a condition of licensure, Respondent take and successfully complete the following courses: Documentation: A Critical Aspect of Client Care; Righting a Wrong, Ethics and Professionalism in Nursing; and the Nevada Nurse Practice Act web based course, with submission of successful completion of these course due within 90 days of the execution of the Agreement or the license would to be automatically suspended without further proceedings until all requirements were completed.

9. The circumstances that led to the Nevada Board's discipline, as stated in the formal charges adopted by the Nevada Board, and pursuant to Respondent's admissions, are that on September 2, 2020, while licensed and working as a Registered Nurse at a hospital in Henderson, Nevada, Respondent failed to document a nursing assessment and glucose monitoring results on a patient assigned to her care, and failed to ensure the patient was connected to telemetry monitoring as ordered by the physician. The Nevada Board concluded that Respondent's actions constituted grounds for disciplinary action under Nevada Revised Statues 632.347 (1)(g) (unprofessional conduct), and Nevada Administrative Code sections 632.890 (20) (inaccurate recording, falsifying or otherwise altering or destroying records), and (25) (failing to observe the conditions, signs, and symptoms of a patient, to record the information or to report significant changes to the appropriate persons).

///

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///

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Registered Nursing issue a decision:

1. Revoking or suspending Registered Nurse License Number 831862 issued to Elizabeth Wanjiru Gichanga;

2. Ordering Elizabeth Wanjiru Gichanga to pay the Board of Registered Nursing the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

3. Taking such other and further action as deemed necessary and proper.

DATED: October 27, 2021

for LORETTA MELBY, R.N., M.S.N.
Executive Officer
Board of Registered Nursing
Department of Consumer Affairs
State of California
Complainant

SD2021801670
83007713.docx

I, Elizabeth Gichanga, **certify that as the designated representative for**

Elizbiz Limited Liability Company,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. EG I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. EG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. EG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. EG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. EG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Elizabeth Gichanga

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-4-25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Elizabeth Gichanga

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-4-25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Elizabeth Gichanga, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11-4-25

Date

Subscribed and Sworn to before me this 4 day of NOV. 2025

Notary Public Signature

MONICA NICOLE MAESTAS
Notary Public, State of Nevada
Appointment No. 24-2402-01
My Appt. Expires Sep 9, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Elizbiz Limited liability Company

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: [redacted]

City: Henderson State: NV Zip: [redacted]

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: [redacted] Website: Elizbiz.com

Licensing Company Email: gichangae@elizbiz.com

Section 2: Personal Information

First: Elizabeth Middle: Wanjiru Last: Gichanga

Alias(es, nicknames, name changes, etc.): Sheamy

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Henderson State: NV Zip: [redacted]

Telephone: [redacted] Email: gichangae@gmail.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Touro University			08/19 - 08/20	
Address		City	State	Zip
874 American Pacific Dr		Henderson	NV	89014
Diploma/Degree obtained, if any				
BSN				
School Name			From - To (MM/YY – MM/YY)	
Highline Community College			05/04-05/05	
Address		City	State	Zip
2400 S 240th St		Des Moines	WA	98198
Diploma/Degree obtained, if any				
Associates Degree in Nursing				
School Name			From - To (MM/YY – MM/YY)	
Renton Technical College			01/01 - 12/01	
Address		City	State	Zip
3000 NE 4th St		Renton	WA	98056
Diploma/Degree obtained, if any				
Licensed Pratical Nurse Certification				
School Name			From - To (MM/YY – MM/YY)	
Daystar University			04/93 - 04/97	
Address		City	State	Zip
		Athi River	Kenya	
Diploma/Degree obtained, if any				
Bachelors Degree - Business Administration and Management				
School Name			From - To (MM/YY – MM/YY	
Kyeni Girls High School			01/88 - 12/91	
Address		City	State	Zip
		Embu	Kenya	
Diploma/Degree obtained, if any				
High School Certificate of Completion				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/17 - 10/25	[redacted]	Henderson	NV	[redacted]
08/16 - 01/17		Henderson	NV	
01/13 - 08/16		Federal Way	WA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Roots Home Health			12/23 - 10/25
Business Address	**City**	**State**	**Zip**
2012 San Juan Blvd	Farmington	NM	87401
Phone	**Title**		
(505) 258-4471	Registered Nurse		

Description of Duties

Provide skilled nursing care to patients in their home as prescribed by the physician. Duties include assessing patient, administering and managing medications, wound care, coordinate patient care with other providers.

Business Name			From - To (MM/YY – MM/YY)
Elizbiz LLC			02/23 - 10/25
Business Address	**City**	**State**	**Zip**
6436 Extreme Shear ave Unit 103	Henderson	NV	89011
Phone	**Title**		
253-670-4203	Owner		

Description of Duties

Provide skilled nursing care to patients in their home as prescribed by the physician. Duties include assessing patient, administering and managing medications, wound care, coordinate patient care with other providers.

Business Name			From - To (MM/YY – MM/YY)
Giving Home Health Company			10/20 - 10/25
Business Address	**City**	**State**	**Zip**
10190 Covington Cross Dr 2nd Floor	Las Vegas	NV	89144
Phone	**Title**		
(702) 474-4000	Registered Nurse		

Description of Duties

Provide skilled nursing care to patients in their home as prescribed by the physician. Duties include assessing patient, administering medications, tracheostomy care, feeding tube management.

Business Name			From - To (MM/YY – MM/YY)
Community Home health			10/20 - 11/21
Business Address	**City**	**State**	**Zip**
2880 E Flamingo Rd	Las Vegas	NV	89121
Phone	**Title**		
(702) 333-1356	Registered Nurse		

Description of Duties

Provide skilled nursing care to patients in their home as prescribed by the physician. Duties include assessing patient, administering medications, drawing blood, wound care, managing iv sites and giving appropriate iv infusions.

Business Name			From - To (MM/YY – MM/YY)
Henderson Hospital			03/17 - 09/20
Business Address	**City**	**State**	**Zip**
1050 W. Galleria Drive	Henderson	NV	89011
Phone	**Title**		
702-963-7000	Registered Nurse		

Description of Duties

Performed and documented patient assessments, reported any change in condition and notified the physician. Administered medications and treatments as prescribed.

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Horizon Home Health			09/16 - 03/17
Business Address	**City**	**State**	**Zip**
1210 SOUTH VALLEY VIEW, STE 114	Las Vegas	NV	89107
Phone	**Title**		
(702) 259-4966	Registered Nurse		
Description of Duties			
Provide skilled nursing care to patients in their home as prescribed by the physician. Duties include assessing patient, administering medications, drawing blood, wound care, managing iv sites and giving appropriate iv infusions.			

Business Name			From - To (MM/YY – MM/YY)
St Joseph Medical Center			08/05 - 08/16
Business Address	**City**	**State**	**Zip**
1717 South J Street	Tacoma	WA	98405
Phone	**Title**		
253-426-4101	Registered Nurse		
Description of Duties			
Performed and documented patient assessments, reported any change in condition and notified the physician. Administered medications and treatments as prescribed.			

Business Name			From - To (MM/YY – MM/YY)
St Francis Hospital			05/01 - 08/05
Business Address	**City**	**State**	**Zip**
34515 9th Avenue South	Federal Way	WA	98003
Phone	**Title**		
253-944-8100	Licensed Practical Nurse		
Description of Duties			
Administered medications and treatments as delegated by my supervising Registered Nurse.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
	N/A		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
	N/A		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
9/02/2020	3/24/2021	NV	Henderson	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
202009037		Nevada State Board of Nursing		
Reason/Charge				
Allegations stated that I may have violated nursing statutes and/or regulations.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Nevada State Board of Nursing / Elizabeth Gichanga				
Name of Business/Industry/Entity				
Henderson Hospital				

Provide explanation below:

The Henderson Hospital in Henderson, Nevada, submitted a complaint against me to the Nevada State Board of Nursing. The complaint was regarding my nursing practice related to an incident where a patient was found unresponsive while I was working at the hospital on September 2nd 2020. The allegations stated that I may have violated statutes and/or regulations including but not limited to unprofessional conduct, and/or failing to observe/report, customary stands of practice, and /or causing harm to a patient. Following the investigation, the board said that there was a potential for possible action against my license in Nevada if it was determined that there had been a violation of the Nurse Practice Act. My attorney responded to the Board and after investigation I entered into an agreement for reprimand and continuing education with the board . I completed the continuing education as agreed and in April 2021 received a letter from the board stating that I had complied with the agreement. My license remained active and I was able to continue practicing as a Registered Nurse.

Original Signature (electronic, copies or stamps not accepted)

11-6-25
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
10/27/2021	04/01/2022	California	San Diego	USA
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
4002021006387		Board of Nursing California		
Reason/Charge				
None renewal of CA license and discipline of license in another state				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Board of Registered Nursing CA / Elizabeth Gichanga				
Name of Business/Industry/Entity				

Provide explanation below:

On April 1st, 2022, RN license No. 831862 was revoked by California Board of Registered Nursing for the following reasons:
1. Non-renewal of California license.
2. Nevada registered license being disciplined by the Nevada Board of Nursing on March 24, 2021.

Original Signature (electronic, copies or stamps not accepted)

11-6-2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Elizabeth Gichanga

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-1-25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Elizabeth Wanjiru Gichanga, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11-1-25

Date

Subscribed and Sworn to before me this 1st day of November 2025.

Notary Public Signature

MARCOS MATA
Notary Public, State of Nevada
Appointment No. 13-10381-1
My Appt. Expires Sep 24, 2027

(Seal)

ORIGINAL

BEFORE THE NEVADA STATE BOARD OF NURSING

IN THE MATTER OF ELIZABETH GICHANGA LICENSED PROFESSIONAL NURSE NEVADA LICENSE NO. RN87793 RESPONDENT	AGREEMENT FOR REPRIMAND AND CONTINUING EDUCATION CASE NO. 202009037

This Agreement is hereby entered into between ELIZABETH GICHANGA, (RESPONDENT) and the NEVADA STATE BOARD OF NURSING, (BOARD).

It is hereby stipulated and agreed, by and between the parties to the above-entitled matter, that the following statements are true:

1. Respondent is aware of, understands, and has been advised of the effect of this Agreement, which Respondent herein has carefully read and fully acknowledges. No coercion has been exerted on the Respondent. Respondent acknowledges her right to an attorney at her own expense. The Respondent has had the benefit at all times of obtaining advice from competent counsel of her choice.

2. Respondent understands the nature of the allegations under investigation by the Nevada State Board of Nursing. Respondent freely admits that on September 2, 2020, while licensed and working as a Registered Nurse at a hospital in Henderson, Nevada she failed to document a nursing assessment and glucose monitoring results on a patient assigned to her care. The Respondent further admits she failed to ensure the patient was connected to telemetry monitoring as ordered by the physician. Respondent acknowledges this conduct constitutes a violation of the Nevada Revised Statutes 632.347 (1)(g) unprofessional conduct, and Nevada Administrative Code 632.890 (20) inaccurate recording, falsifying, or otherwise altering or destroying records and (25) failing to observe the conditions, signs and symptoms of a patient, to record the information or to report significant changes to the appropriate persons. Respondent

further acknowledges that such acts and admissions subject her to disciplinary action by the Board.

3. Respondent is aware of the Respondent's rights, including the right to a hearing on any charges and allegations, the right to an attorney at her own expense, the right to examine witnesses who would testify against her, the right to present evidence in her favor and call witnesses on her behalf, or to testify herself, the right to contest the charges and allegations, the right to reconsideration, appeal or any other type of formal judicial review of this matter, and any other rights which may be accorded to her pursuant to the Nevada Administrative Procedures Act and the provisions of Chapter 632 of the Nevada Revised Statutes and the Nevada Administrative Code. Respondent agrees to waive the foregoing rights upon acceptance of this Agreement by the Board.

4. Respondent understands that the Board is free to accept or reject this Agreement, and if rejected by the Board, a disciplinary proceeding may be commenced.

5. Should the Agreement be rejected by the Board, it is agreed that presentation to and consideration by the Board of such proposed Agreement, shall not disqualify the Board, or any of its members, from further participation, consideration, adjudication or resolution of these proceedings, and that no Board member shall be disqualified or challenged for bias therefore.

6. This Agreement shall only become effective when both parties have duly executed it and unless so executed, this Agreement will not be construed as an admission.

7. This Agreement shall not be construed as excluding or reducing any criminal or civil penalties or sanction or other remedies that may be applicable under federal, state or local laws.

8. This Agreement shall cover any nursing license and/or certificate issued by the State of Nevada.

9. Based upon the foregoing stipulations and recitals, it is hereby agreed that the Board may issue the following decision and order:

DECISION AND ORDER

Based on the foregoing, and good cause appearing therefore, it is hereby ordered that:

1. Respondent be publicly reprimanded.

2. As a condition of licensure Respondent, within the first ninety (90) days of this Agreement, shall take, and successfully complete the following courses:

   a. Documentation: A Critical Aspect of Client Care; and

   b. Righting a Wrong, Ethics and Professionalism in Nursing; and

   c. The Nevada Nurse Practice Act web based course.

The courses must be pre-approved by the Executive Director, or the Director of Nursing Practice. Documentation of successful course completion must be submitted to the Board within ninety (90) days of the execution of this Agreement or the license is automatically suspended without further proceedings until all requirements are completed.

This Agreement will become part of the Respondent's permanent record, will become public information, will be published with the list of disciplinary actions the Board has taken, and may be reported to any national repository which records disciplinary action taken against licensees or holders of certificates; or any agency or another state which regulates the practice of nursing.

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The Agreement may be used in any subsequent hearings by the Board. In the event other misconduct is reported to the Board, this Agreement may be used as evidence against the Respondent to establish a pattern of behavior and for the purpose of proving additional acts of misconduct.

Dated this 3rd day of March, 2021

RESPONDENT
ELIZABETH GICHANGA

Dated this 3rd day of March, 2021

HEATHER HALL, ESQ.

Accepted and approved this 24 day of March, 2021

NEVADA STATE BOARD OF NURSING

By:

Susan S. VanBeuge, DNP, APRN, FNP-BC, FAANP
Board President

Nevada State Board of
NURSING

April 23, 2021

Elizabeth Gichanga
[redacted]
Henderson, Nevada [redacted]

Dear Ms. Gichanga:

This office has received documentation of your successful completion of Documentation: A Critical Aspect of Client Care, Righting a Wrong- Ethics & Professionalism in Nursing and Nevada Nurse Practice Act courses to meet the educational requirements of your Agreement for Reprimand and Continuing Education. Completion of these courses places you in compliance with that Agreement.

Congratulations and thank you for your cooperation in this matter. If you have any questions, please do not hesitate to contact me in writing, or by telephone at 888-590-6726, ext. 77726.

Sincerely,
NEVADA STATE BOARD OF NURSING

Elaine Ralph, RN

Elaine Ralph, BSN, RN, FN-CSp
Investigator

cc: Heather Hall, Esq.

5011 Meadowood Mall Way, Suite 300, Reno, NV 89502-6547 (fax) 775-687-7707
4220 S. Maryland Parkway, Suite B300, Las Vegas, NV 89102-4392 (fax) 702-486-5803
www.nevadanursingboard.org - 888-590-6726 - nursingboard@nsbn.state.nv.us

MCBRIDE HALL
ATTORNEYS AT LAW

May 3, 2021

VIA E-MAIL

Washington State Department of Health
Board of Nursing
nursing@doh.wa.gov

Re: *Nevada Board of Nursing v. Elizabeth Gichanga, RN*
Our File No.: 544-6600-01

To Whom It May Concern:

I represent Elizabeth Gichanga, RN. Attached for your records, please find a copy of the Settlement Agreement between Elizabeth Gichanga, RN and the Nevada State Board of Nursing in relation to a Complaint submitted by Henderson Hospital. Ms. Gichanga has already fully complied with the terms of the Agreement.

Should you have any questions or concerns in this regard, please do not hesitate to contact me.

Sincerely,
McBRIDE HALL

/s/ Heather S. Hall

HEATHER S. HALL, ESQ.

HSH/cpc
Enclosure
cc: Elizabeth Gichanga, RN

T: 702-792-5855 | F: 702-796-5855
www.mcbridehall.com
8329 West Sunset Road, Suite 260
Las Vegas, Nevada 89113

BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **ELIZABETH WANJIRU GICHANGA** [redacted] **Henderson, NV** [redacted] **Registered Nurse License No. 831862** Respondent.	Case No. 4002021006387 **DEFAULT DECISION AND ORDER** [Gov. Code, §11520]

FINDINGS OF FACT

1. On or about October 27, 2021, Complainant Loretta Melby, R.N., M.S.N., in her official capacity as the Executive Officer of the Board of Registered Nursing (Board), Department of Consumer Affairs, filed Accusation No. 4002021006387 against Elizabeth Wanjiru Gichanga (Respondent) before the Board. (Accusation attached as Exhibit A.)

2. On or about October 31, 2012, the Board issued Registered Nurse License No. 831862 to Respondent. The Registered Nurse License expired on December 31, 2017, and has not been renewed.

3. On or about November 1, 2021, Respondent was served by Certified and First Class Mail copies of the Accusation No. 4002021006387, Statement to Respondent, Notice of Defense, Request for Discovery, and Discovery Statutes (Government Code sections 11507.5, 11507.6,

and 11507.7) at Respondent's address of record which, pursuant to California Code of Regulations, title 16, section 1409.1, is required to be reported and maintained with the Board. Respondent's address of record was and is: [redacted] Henderson, NV [redacted]

4. Service of the Accusation was effective as a matter of law under the provisions of Government Code section 11505, subdivision (c) and/or Business and Professions Code section 124.

5. Government Code section 11506, subdivision (c) states, in pertinent part:

> The respondent shall be entitled to a hearing on the merits if the respondent files a notice of defense . . . and the notice shall be deemed a specific denial of all parts of the accusation . . . not expressly admitted. Failure to file a notice of defense . . . shall constitute a waiver of respondent's right to a hearing, but the agency in its discretion may nevertheless grant a hearing.

6. The Board takes official notice of its records and the fact that Respondent failed to file a Notice of Defense within 15 days after service upon her of the Accusation, and therefore waived her right to a hearing on the merits of Accusation No. 4002021006387.

7. California Government Code section 11520, subdivision (a) states, in pertinent part:

> (a) If the respondent either fails to file a notice of defense . . . or to appear at the hearing, the agency may take action based upon the respondent's express admissions or upon other evidence and affidavits may be used as evidence without any notice to respondent . . . .

8. Pursuant to its authority under Government Code section 11520, the Board finds Respondent is in default. The Board will take action without further hearing and, based on the relevant evidence contained in the Default Decision Investigatory Evidence Packet in this matter, as well as taking official notice of all the investigatory reports, exhibits and statements contained therein on file at the Board's offices regarding the allegations contained in Accusation No. 4002021006387, finds that the charges and allegations in Accusation No. 4002021006387, are separately and severally, found to be true and correct by clear and convincing evidence.

DETERMINATION OF ISSUES

1. Based on the foregoing findings of fact, Respondent Elizabeth Wanjiru Gichanga has subjected her Registered Nurse License No. 831862 to discipline.

2. The agency has jurisdiction to adjudicate this case by default.

3. The Board is authorized to revoke Respondent's Registered Nurse License based upon the following violations alleged in the Accusation which are supported by the evidence contained in the Default Decision Investigatory Evidence Packet in this case:

a. Respondent has subjected her registered nurse license to disciplinary action under Code section 2761, subdivision (a)(4), in that her Nevada registered license was disciplined by the Nevada Board of Nursing.

ORDER

IT IS SO ORDERED that Registered Nurse License No. 831862, issued to Respondent Elizabeth Wanjiru Gichanga, is revoked.

Pursuant to Government Code section 11520, subdivision (c), Respondent may serve a written motion requesting that the Decision be vacated and stating the grounds relied on within seven (7) days after service of the Decision on Respondent. The agency in its discretion may vacate the Decision and grant a hearing on a showing of good cause, as defined in the statute.

This Decision shall become effective on April 1, 2022.

It is so ORDERED March 2, 2022

FOR THE BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS

83166702.DOCX
DOJ Matter ID:SD2021801670

Attachment:
Exhibit A: Accusation

I hereby certify the foregoing to be a true copy of the documents on file in our office.
BOARD OF REGISTERED NURSING
Loretta Melby, RN, MSN
Acting Executive Officer

Exhibit A

Accusation

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
ERIN M. SUNSERI
Deputy Attorney General
State Bar No. 207031
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9419
Facsimile: (619) 645-2061
Attorneys for Complainant

BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **ELIZABETH WANJIRU GICHANGA** [redacted] **Henderson, NV** [redacted] **Registered Nurse License No. 831862** Respondent.	Case No. 4002021006387 **ACCUSATION**

PARTIES

1. Loretta Melby, R.N., M.S.N. (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Registered Nursing (Board), Department of Consumer Affairs.

2. On or about October 31, 2012, the Board issued Registered Nurse License No. 831862 to Elizabeth Wanjiru Gichanga (Respondent). The Registered Nurse License expired on December 31, 2017, and has not been renewed.

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JURISDICTION

3. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Section 2750 of the Code provides, in pertinent part, that the Board may discipline any licensee, including a licensee holding a temporary or an inactive license, for any reason provided in Article 3 (commencing with section 2750) of the Nursing Practice Act.

5. Section 2764 of the Code provides, in pertinent part, that the expiration of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary proceeding against the licensee or to render a decision imposing discipline on the license.

STATUTORY PROVISIONS

6. Section 2761 of the Code states:

> The board may take disciplinary action against a certified or licensed nurse or deny an application for a certificate or license for any of the following:
>
> (a) Unprofessional conduct, which includes, but is not limited to, the following:
>
> ...
>
> (4) Denial of licensure, revocation, suspension, restriction, or any other disciplinary action against a health care professional license or certificate by another state or territory of the United States, by any other government agency, or by another California health care professional licensing board. A certified copy of the decision or judgment shall be conclusive evidence of that action.
>
> ...

COST RECOVERY

7. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licensee found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licensee to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

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CAUSE FOR DISCIPLINE

(Disciplinary Action Against Licentiate by the Nevada Board of Nursing)

8. Respondent has subjected her registered nurse license to disciplinary action under Code section 2761, subdivision (a)(4), in that her Nevada registered license was disciplined by the Nevada Board of Nursing (Nevada Board). Effective March 24, 2021, in a disciplinary matter entitled, "*In the Matter of Elizabeth Gichanga Licensed Professional Nurse Nevada License No. RN87793*," Respondent entered into an Agreement for Reprimand and Continuing Education with the Nevada Board. The Nevada Board issued an Order that Respondent be publicly reprimanded, and that as a condition of licensure, Respondent take and successfully complete the following courses: Documentation: A Critical Aspect of Client Care; Righting a Wrong, Ethics and Professionalism in Nursing; and the Nevada Nurse Practice Act web based course, with submission of successful completion of these course due within 90 days of the execution of the Agreement or the license would to be automatically suspended without further proceedings until all requirements were completed.

9. The circumstances that led to the Nevada Board's discipline, as stated in the formal charges adopted by the Nevada Board, and pursuant to Respondent's admissions, are that on September 2, 2020, while licensed and working as a Registered Nurse at a hospital in Henderson, Nevada, Respondent failed to document a nursing assessment and glucose monitoring results on a patient assigned to her care, and failed to ensure the patient was connected to telemetry monitoring as ordered by the physician. The Nevada Board concluded that Respondent's actions constituted grounds for disciplinary action under Nevada Revised Statues 632.347 (1)(g) (unprofessional conduct), and Nevada Administrative Code sections 632.890 (20) (inaccurate recording, falsifying or otherwise altering or destroying records), and (25) (failing to observe the conditions, signs, and symptoms of a patient, to record the information or to report significant changes to the appropriate persons).

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Registered Nursing issue a decision:

1. Revoking or suspending Registered Nurse License Number 831862 issued to Elizabeth Wanjiru Gichanga;

2. Ordering Elizabeth Wanjiru Gichanga to pay the Board of Registered Nursing the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

3. Taking such other and further action as deemed necessary and proper.

DATED: October 27, 2021

for LORETTA MELBY, R.N., M.S.N.
Executive Officer
Board of Registered Nursing
Department of Consumer Affairs
State of California
Complainant

SD2021801670
83007713.docx

Elizbiz Limited Liability Company

List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.

1. Elizabeth W. Gichanga - Owner

11

11A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacist Application
Non-Refundable $250 fee

133256 Y

Section 1: Select how will you be obtaining your Nevada Pharmacist Registration

☐ Examination

☐ Score Transfer (Transfer your NAPLEX SCORE to Nevada within 89 days after taking your exam at https://nabp.pharmacy/ before completing this application.)

■ Reciprocation (Complete NABP's Electronic Licensure Transfer Program (e-LTP) application at https://nabp.pharmacy/ before completing this application.)

Are you submitting this application to RETAKE the NAPLEX and/or NVLE? ☐ Yes ■ No

Section 2: General Information

First: Mark Middle: Meinrad Last: Mullins

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Section 3: Employment Information

Pharmacy Name: CVS pharmacy NV Pharmacy License # (if applicable): _____

Address: 1001 E 120th Ave

City: Thornton State: CO Zip: 80233

Telephone: 303-280-6273 Email: _____

Section 4: College of Pharmacy Information

School Name: University of the Pacific

Address: 3601 Pacific Ave

City: Stockton State: CA Zip: 95211

Country/Territory/Province: United States of America

Graduation Date: 05/01/2004 Degree: ■ PharmD ☐ BS in Pharmacy ☐ Other

Section 5: ONLY COMPLETE this section if you are applying for a Nevada Pharmacist Registration by RECIPROCATION.

Original State of licensure/registration you are reciprocating from must be active and issued by exam (passing the NAPLEX and that state's MPJE or law examination).

State: CO License #: PHA.0019548 Date of Issuance: 08/01/2011 Expiry Date: 10/31/2025

Section 6: List all pharmacist license/registration you have/had in other states. Use another sheet if additional space is needed.								
State	License/ Registration #	Issued Date	Expiry Date	License/Registration Status (check applicable box)				
				Active	Inactive	Expired	Revoked	Surrendered
CA	RPH 56060	09/01/2004	08/31/2018					X

Section 7: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 8: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 9: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or administrative action whether completed or pending in <u>any</u> state?	✔	
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 9 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Administrative action from California board.
Surrendered license in March/2018, license expired on 08/31/2018.

http://www.pharmacy.ca.gov/enforcement/fy1718/ac176331

Original Signature (electronic, copies or stamps not accepted)

8-18-2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I attest to the knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. NRS 639.132

I understand that Nevada law requires a registered pharmacist who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Mark Mullins

Print Name

Mark Mullins

Original Signature, no copies or stamps accepted

8-18-25

Date

Board Use Only	Date Received: 8/21/25	Amount: $250 ck 568
	NAPLEX:	NVLE:

Lookup Detail View

Licensee Information

This serves as primary source verification of the license.*

**Primary source verification: License information provided by the Colorado Division of Professions and Occupations, established by 24-34-102 C.R.S.*

Name	City, State, Zip Code
Mark Meinrad Mullins	[redacted]

Credential Information

License Number	License Method	License Type	License Status	Original Issue Date	Effective Date	Expiration Date
PHA.0019548	License Transfer	Pharmacist	Active	08/01/2012	11/01/2023	10/31/2025

Board/Program Actions

Discipline
There is no Discipline or Board Actions on file for this credential.

Generated on: 8/25/2025 12:01:26 PM

BOARD OF PHARMACY

LICENSING DETAILS FOR: RPH 56060

NAME: MULLINS, MARK MEINRAD

LICENSE TYPE: REGISTERED PHARMACIST

LICENSE STATUS: CANCELLED

SECONDARY STATUS: VOLUNTARY SURRENDER

ADDRESS NOT DISCLOSED

ISSUANCE DATE

SEPTEMBER 1, 2004

EXPIRATION DATE

AUGUST 31, 2018

CURRENT DATE / TIME

AUGUST 25, 2025
10:59:30 AM

PUBLIC RECORDS

› DISCIPLINARY ACTIONS (1)

DISCLAIMER: DISCIPLINARY ACTIONS

DESCRIPTION: CURRENT WEB SITE INFORMATION ON BOARD OF PHARMACY DISCIPLINARY ACTIONS ONLY GOES AS FAR BACK AS *JANUARY 1998* FOLLOWING THE EFFECTIVE DATE OF THE DISCIPLINARY PENALTY.
DISCIPLINARY ACTIONS RENDERED BY THE BOARD AND PENALTIES IMPOSED BECOME OPERATIVE ON THE EFFECTIVE DATE OF THE ACTION EXCEPT IN SITUATIONS WHERE THE LICENSEE OBTAINS A COURT-ORDERED STAY THROUGH THE APPEAL PROCESS. THIS MAY OCCUR AFTER THE PUBLICATION OF THE INFORMATION ON THIS WEBSITE.

TO OBTAIN INFORMATION PRIOR TO JANUARY 1998 OR FOR INFORMATION ON SPECIFIC DISCIPLINE LISTED SUBMIT A WRITTEN REQUEST TO THE *STATE BOARD OF PHARMACY, 2720 GATEWAY OAKS DRIVE, SUITE 100, SACRAMENTO, CA 95833, ATTENTION PUBLIC RECORDS DESK.*

PUBLIC DISCLOSURES:

- **CASE NUMBER:** AC201700633100
- **EFFECTIVE DATE OF ACTION:** FEBRUARY 27, 2019
- **DESCRIPTION OF ACTION:** THROUGH A DISCIPLINARY ACTION OF THE BOARD, THE LICENSE IS REVOKED, THE REVOCATION IS STAYED, AND THE LICENSEE IS PLACED ON PROBATION FOR FIVE YEARS SUBJECT TO THE TERMS AND CONDITIONS IN THE DECISION.

PUBLIC DOCUMENTS

› DOCUMENTS (1)

CASE NUMBER: AC201700633100 **DOCUMENT:** LINK

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MARK MEINRAD MULLINS** [redacted] **Pharmacist License No. RPH 56060** Respondent.	Case No. 6331 OAH No. 2018060906

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on February 27, 2019.

It is so ORDERED on January 28, 2019.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

Victor Law, R.Ph.
Board President

XAVIER BECERRA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
CARRA L. RHAMY
Deputy Attorney General
State Bar No. 163269
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9607
Facsimile: (619) 645-2061
E-mail: Carra.Rhamy@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MARK MEINRAD MULLINS** [redacted] **Pharmacist License No. RPH 56060** Respondent.	Case No. 6331 OAH No. 2018060906 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Carra L. Rhamy, Deputy Attorney General.

2. Respondent Mark Meinrad Mullins (Respondent) is represented in this proceeding by attorney Tony J. Park, whose address is: 49 Discovery, Suite 240, Irvine, CA 92618-6713.

3. On or about September 1, 2004, the Board issued Pharmacist License No. RPH 56060 to Mark Meinrad Mullins (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 6331 and was set to expire on August 31, 2018. On or about March 14, 2018, the Office of Administrative Hearings issued an Amended Interim Suspension Order suspending Respondent's Pharmacist License pursuant to Business and Professions Code section 494. The license currently remains under suspension.

JURISDICTION

4. Accusation No. 6331 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on March 14, 2018. Respondent timely filed his Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 6331 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6331. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent admits the truth of each and every charge and allegation in Accusation No. 6331.

10. Respondent agrees that his Pharmacist License is subject to discipline and he agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

///

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 56060 issued to Respondent Mark Meinrad Mullins is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

1. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy- two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed,

probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. **Reporting of Employment and Notice to Employers**

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 6331 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, respondent shall report to the board in writing the name, physical address, and mailing address of each of his employer(s), and the name(s) and telephone number(s) of all of his direct supervisor(s), as well as any pharmacist(s)-in- charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior

employment. Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause (a) his direct supervisor, (b) his pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of his employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 6331, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, respondent shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 6331, and the terms and conditions imposed thereby.

If respondent works for or is employed by or through an employment service, respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board of the decision in case number 6331, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through an employment service, respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a Pharmacist, or any position for which a Pharmacist is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. **Notification of Change(s) in Name, Address(es), or Phone Number(s)**

Respondent shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address or phone number. Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

8. **Restrictions on Supervision and Oversight of Licensed Facilities**

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any entity licensed by the board, nor serve as a consultant. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

9. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $6,252.50. Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

There shall be no deviation from the schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

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10. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

11. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current Pharmacist License with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current Pharmacist License shall be considered a violation of probation.

If respondent's Pharmacist License expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

12. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may relinquish his license, including any indicia of licensure issued by the board, along with a request to surrender the license. The board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as

of the date the application for that license is submitted to the board, including any outstanding costs.

13. **Practice Requirement – Extension of Probation**

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a Pharmacist in California for a minimum of 32 hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, respondent must nonetheless comply with all terms and conditions of probation, unless respondent receives a waiver in writing from the board or its designee.

If respondent does not practice as a Pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a Pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

14. **Violation of Probation**

If respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and the board shall provide notice to respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a

violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

16. **Pharmacists Recovery Program (PRP)**

By no later than ten (10) days after the effective date of this decision, respondent shall have contacted the Pharmacists Recovery Program (PRP) for evaluation only. If deemed appropriate following the evaluation by PRP clinical staff, Respondent shall immediately enroll in the PRP; complete, sign, and return the treatment contract as well as any addendums required or suggested by the PRP; successfully complete registration for any drug or alcohol testing mandated by the treatment contract and/or by enrollment in the PRP; and begin compliance with the drug or alcohol testing protocol(s). Respondent shall successfully participate in the PRP and complete the treatment contract and any addendums required or suggested by the PRP. The costs for PRP participation shall be borne by the respondent.

If respondent is currently enrolled in the PRP, said participation is now mandatory and as of the effective date of this decision is no longer considered a self-referral under Business and Professions Code section 4362 (a)(2). Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

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Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation of probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to the PRP.

Any of the following shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation:

Failure to contact the PRP within ten (10) days of the effective date of the decision;

Failure to, if deemed appropriate after evaluation, immediately complete enrollment, and execute and return the treatment contract with the PRP, including any addendum(s), as directed by the PRP;

Failure to immediately complete registration for any drug or alcohol testing mandated by the treatment contract and/or by the PRP, and begin compliance with the testing protocol(s), as directed by the PRP;

Failure to comply with testing protocols regarding daily check-in and/or failure to complete a mandated test as directed by the PRP;

Any report from the PRP of material non-compliance with the terms and conditions of the treatment contract and/or any addendum(s); or

Termination by the PRP for non-compliance, failure to derive benefit, or as a public risk.

Respondent may not resume the practice of pharmacy until notified by the board in writing.

Probation shall be automatically extended until respondent successfully completes the PRP. The board will provide notice of any such suspension or extension of probation.

During any suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice as a Pharmacist nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have

access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During any suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a Pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances.

Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

17. **Drug and Alcohol Testing**

Respondent, at his own expense, shall participate in testing as directed by the board or its designee for the detection of alcohol, controlled substances, and dangerous drugs and/or dangerous devices. Testing protocols may include biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other testing protocols as directed by the board or its designee. All testing must be pursuant to an observed testing protocol, unless respondent is informed otherwise in writing by the board or its designee. Respondent may be required to participate in testing for the entire probation period and frequency of testing will be determined by the board or its designee.

By no later than thirty (30) days after the effective date of this decision, respondent shall have completed all of the following tasks: enrolled and registered with an approved drug and alcohol testing vendor; provided that vendor with any documentation, and any information necessary for payment by respondent; commenced testing protocols, including all required contacts with the testing vendor to determine testing date(s); and begun testing. At all times, respondent shall fully cooperate with the testing vendor, and with the board or its designee, with regard to enrollment, registration, and payment for, and compliance with, testing. Any failure to cooperate timely shall be considered a violation of probation.

Respondent may be required to test on any day, including weekends and holidays. Respondent is required to make daily contact with the testing vendor to determine if a test is required, and if a test is required must submit to testing on the same day.

Prior to any vacation or other period of absence from the area where the approved testing vendor provides services, respondent shall seek and receive approval from the board or its designee to use an alternate testing vendor to ensure testing can occur. Upon approval, respondent shall enroll and register with the approved alternate drug testing vendor, provide to that alternate vendor any documentation required by the vendor, including any necessary payment by respondent. During the period of absence of the area, respondent shall commence testing protocols with the alternate vendor, including required daily contacts with the testing vendor to determine if testing is required, and required testing. Any failure to timely seek or receive approval from the board or its designee, or to timely enroll and register with, timely commence testing protocols with, or timely undergo testing with, the alternate testing vendor, shall be considered a violation of probation.

Upon detection of an illicit drug, controlled substance or dangerous drug, the board or its designee may require respondent to timely provide documentation from a licensed practitioner authorized to prescribe the detected substance demonstrating that the substance was administered or ingested pursuant to a legitimate prescription issued as a necessary part of treatment. All such documentation shall be provided by respondent within ten (10) days of being requested.

Any of the following shall be considered a violation of probation and shall result in respondent being immediately suspended from practice as a Pharmacist until notified by the board in writing that he may resume practice: failure to timely complete all of the steps required for enrollment/registration with the drug testing vendor, including making arrangements for payment; failure to timely commence drug testing protocols; failure to contact the drug testing vendor as required to determine testing date(s); failure to test as required; failure to timely supply documentation demonstrating that a detected substance was taken pursuant to a legitimate prescription issued as a necessary part of treatment; and/or detection through testing of alcohol, or of an illicit drug, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment. In the event of a suspension ordered after detection through testing of alcohol, an illicit drug, or of a controlled substance or dangerous drug absent documentation that the detected substance was

taken pursuant to a legitimate prescription and a necessary treatment, the board or its designee shall inform respondent of the suspension and inform him to immediately leave work, and shall notify respondent's employer(s) and work site monitor(s) of the suspension.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party-logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a Pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices.

Failure to comply with any such suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

18. **Notification of Departure**

Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.

19. **Abstain from Drugs and Alcohol**

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, illicit drugs, dangerous drugs and/or dangerous devices, or their associated paraphernalia, except when possessed or used pursuant to a legitimate prescription issued as a

necessary part of treatment. Respondent shall ensure that he is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, dangerous drugs and/or dangerous devices or controlled substances, or their associated paraphernalia for which a legitimate prescription has not been issued as a necessary part of treatment, or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

20. **Prescription Coordination and Monitoring of Prescription Use**

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board, for its prior approval, the name and qualifications of a single physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice, who shall be aware of the respondent's history with the use of controlled substances, and who will coordinate and monitor any prescriptions for respondent for dangerous drugs and/or dangerous devices, controlled substances or mood-altering drugs. The approved practitioner shall be provided with a copy of the board's Accusation and decision. A record of this notification must be provided to the board or its designee upon request. Respondent shall sign a release authorizing the practitioner to communicate with the board or its designee about respondent's treatment(s). The coordinating physician, nurse practitioner, physician assistant, or psychiatrist shall report to the board on a quarterly basis for the duration of probation regarding respondent's compliance with this condition. If any substances considered addictive have been prescribed, the report shall identify a program for the time limited use of any such substances. The board or its designee may require that the single coordinating physician, nurse practitioner, physician assistant or psychiatrist be a specialist in addictive medicine, or consult a specialist in addictive medicine. Should respondent, for any reason, cease supervision by the approved practitioner, respondent shall notify the board or its designee immediately and, within thirty (30) days of ceasing supervision, submit the name of a replacement physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice to the board or its designee for its prior approval. Failure to timely submit the selected practitioner or replacement practitioner to the board or its designee for approval, or to ensure the required quarterly reporting thereby, shall be considered a violation of probation.

If at any time an approved practitioner determines that respondent is unable to practice safely or independently as a Pharmacist, the practitioner shall notify the board or its designee immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice as a Pharmacist until notified by the board or its designee that practice may be resumed.

During any suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances. Respondent shall not resume practice until notified by the board.

During any suspension, respondent shall not engage in any activity that requires the professional judgment and/or licensure as a Pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances.

Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

21. **Work Site Monitor**

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board or its designee, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board monthly or on another schedule as directed by the board or its designee. Should the designated work site monitor suspect at any time during

the probationary period that respondent has abused alcohol or drugs, he or she shall notify the board immediately.

In the event of suspected abuse, the monitor shall make at least oral notification within one (1) business day of the occurrence, and shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is no longer able to be monitored by the approved work site monitor, within ten (10) days respondent shall designate a new work site monitor for approval by the board or its designee. Failure to timely identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the board by the monitor, shall be considered a violation of probation.

Within thirty (30) days of being approved by the board or its designee, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;

2) Interview other staff in the office regarding respondent's behavior, if applicable; and

3) Review respondent's work attendance.

The written reports submitted to the board or its designee by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete the required consent forms and sign an agreement with the work site monitor and the board to allow the board to communicate with the work site monitor.

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22. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee that complies with Title 16 California Code of Regulations section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days of completion, respondent shall submit a copy of the certificate of completion to the board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully complete it before the end of the second year of probation, or to timely submit proof of completion to the board or its designee, shall be considered a violation of probation.

23. **No Ownership or Management of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 11-28-18

MARK MEINRAD MULLINS
Respondent

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I have read and fully discussed with Respondent Mark Meinrad Mullins the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 11/29/2018

TONY J. PARK
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated: 11/29/18

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General

CARRA L. RHAMY
Deputy Attorney General
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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MARK MEINRAD MULLINS** [redacted] **Pharmacist License No. RPH 56060** Respondent.	Case No. 6331 **ACCUSATION**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

2. On or about September 1, 2004, the Board issued Pharmacist License Number RPH 56060 to Mark Meinrad Mullins (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2018, unless renewed.

JURISDICTION

3. This Accusation is brought before the Board, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

4. Section 4300, subdivision (a) of the Code states "Every license issued may be suspended or revoked."

5. Section 4300.1 of the Code states:

> The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

6. Section 4301 of the Code states:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
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> . . . .
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> (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
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> (g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
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> (h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.
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> . . . .
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> (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
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> . . . .
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> (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

7. Section 4059 of the Code states:

(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

. . . .

8. Section 4060 of the Code states:

No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, or a physician assistant pursuant to Section 3502.1, or naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

9. Section 4113, subdivision (c) of the Code states: "The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

10. Health and Safety Code section 11170 states that no person shall prescribe, administer, or furnish a controlled substance for himself.

COST RECOVERY

11. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUGS

12. Tramadol is a Schedule IV controlled substance pursuant to Code of Federal Regulations, title 21, section 1308.14(b)(3), and a dangerous drug pursuant to Business and Professions Code section 4022

13. Zolpidem is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d), and a dangerous drug pursuant to Business and Professions Code section 4022

FACTUAL ALLEGATIONS

14. Respondent was employed as the PIC at Rite Aid Pharmacy store 5728 located in Murrieta, California. In September 2017, a Rite Aid Pharmacy District Manager was notified by Rite Aid Pharmacy Headquarters that there were discrepancies concerning tramadol drug counts in reports generated from Rite Aid Pharmacy store 5728. Based on that information, on October 4, 2017, the Pharmacy District Manager and a loss prevention officer conducted a covert count (where loss prevention officers go to the pharmacy after hours without anyone's knowledge and perform a count on a specific narcotic) of tramadol. After conducting a covert count, they determined that there was a difference between the current on-hand inventory of pills at the pharmacy versus what had been reported to Rite Aid Corporate by Respondent. On October 11, 2017, another covert count was completed at Rite Aid Pharmacy store 5728 and additional losses of tramadol were discovered. Another covert count was conducted on October 26, 2017 and the Pharmacy District Manager and loss prevention officer discovered a shortage of zolpidem. In total, Rite Aid Pharmacy store 5728 reported a loss of 667 tablets of tramadol 50 mg and 178 tablets of zolpidem.

15. On November 6, 2017, Respondent was interviewed by a Senior Manager of Investigations at Rite Aid about the drug losses in the pharmacy. During the interview, Respondent admitted that he diverted tramadol and zolpidem from the pharmacy without a valid prescription for self-use. Respondent stated that he started taking the drugs from the pharmacy approximately eight months prior, following the passing of his father. He stated that the drugs helped take away some of the depression he was feeling while he mourned the loss of his father.

Respondent stated that he did not have a substance abuse problem. He admitted that he would take a few pills during formal and routine audits every few weeks. At the conclusion of the interview, Respondent signed a written statement admitting to diverting drugs from the pharmacy. Respondent was terminated from his position and Rite Aid notified the Board, who initiated their own investigation which included an interview with Respondent by a Board Inspector.

16. During the interview with the Board Inspector, Respondent admitted that he began diverting tramadol and zolpidem from the pharmacy inventory in or around March or April 2017. He stated that he took tramadol to take away the "anger and pain" and that he took zolpidem to help him sleep. He admitted that he never attempted to obtain a legitimate prescription from a prescriber and that he wanted to "fix himself." Respondent also admitted that as PIC, he was required by Rite Aid Corporate to periodically take a physical count of the drug inventory. He stated that he adjusted the on-hand count inventory records to match what corporate reported the pharmacy should have.

17. The controlled substances that Respondent stole from the pharmacy require a legitimate prescription following a good faith exam by the prescriber. However, Respondent never obtained a legitimate prescription from a prescriber.

FIRST CAUSE FOR DISCIPLINE

(Dishonest Act)

18. Respondent has subjected his license to disciplinary action under section 4301, subdivision (f) of the Code in that Respondent committed acts involving dishonesty, fraud, deceit, or corruption, as detailed in paragraphs 14 through 17 which are incorporated herein by reference, when he stole controlled substances from the pharmacy's inventory and attempted to cover-up his dishonest activities by adjusting on-hand count inventory records to match corporate's records, thereby inaccurately reporting information to Rite Aid corporate.

SECOND CAUSE FOR DISCIPLINE

(Use of Controlled Substances in Dangerous Manner)

19. Respondent has subjected his license to disciplinary action under section 4301, subdivision (h) of the Code in that Respondent illegally administered to himself controlled

substances to the extent or in a manner as to be dangerous or injurious to himself or the public, as evidenced by Respondent's admissions that he consumed tramadol and zolpidem, without a legitimate prescription from a prescriber, as detailed in paragraphs 14 through 17, above, and which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Violating Statutes Regulating Controlled Substances)

20. Respondent has subjected his license to disciplinary action under section 4301, subdivision (j) of the Code for violation of Health and Safety Code section 11170 in that Respondent illegally obtained and administered to himself controlled substances, as detailed in paragraphs 14 through 17, above, and which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Violating Laws Governing Pharmacy)

21. Respondent has subjected his license to disciplinary action under section 4301, subdivision (o) of the Code for violation of Code sections 4059 and 4060 in that Respondent furnished controlled substances to himself without a valid prescription and he illegally possessed controlled substances without a prescription, as detailed in paragraphs 14 through 17, above, and which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Making a Document that Falsely Represents Facts)

22. Respondent has subjected his license to disciplinary action under section 4301, subdivisions (g) of the Code in that Respondent knowingly made or signed a document that falsely represented a state of facts, when Respondent purposefully and intentionally adjusted the pharmacy's on-hand count inventory records as detailed in paragraphs 14 through 17, above, and which are incorporated herein by reference.

DISCIPLINE CONSIDERATIONS

23. To determine the degree of discipline, if any, to be imposed on Respondent, Complainant alleges the following:

///

A. On or about September 16, 2016, in a prior action, the Board of Pharmacy issued Citation Number CI 2016 72100 and ordered Respondent to pay the total of $1,500.00. That Citation is now final and is incorporated by reference as if fully set forth.

B. On or about January 4, 2017, in a prior action, the Board of Pharmacy issued Citation Number CI 2016 73422 and ordered Respondent to pay the total of $500.00. That Citation is now final and is incorporated by reference as if fully set forth.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacist License Number RPH 56060, issued to Mark Meinrad Mullins;

2. Ordering Mark Meinrad Mullins to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

3. Taking such other and further action as deemed necessary and proper.

DATED: 3/6/18

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SD2017802767
81957147.doc

12

12A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician IN TRAINING (PTT) Application

Non-Refundable $50 fee

Rev (03/16/2023)

Section 1: General Information

First: Camila Middle: _____ Last: Gonzalez

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted]

City: Sun Valley State: NV Zip: [redacted]

Telephone: [redacted] Email [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you are enrolled in a PT school or training program.) NAC 639.258

Program/School Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Name of Program Director: _____

Signature of Program Director: _____

Section 3: Employment Information

Pharmacy Name: _____ License #: _____

Address: _____

City: _____ State: _____ Zip: _____

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	Yes	No
1. Are you 18 years of age or older?	✓	
2. Are you a high school graduate or the equivalent?	✓	

High School Name: Penn Foster High School Graduation Date OR Date GED obtained (mm/yy): 8/7/24

Address: 925 Oak St

City: Scranton State: PA Zip: 18515

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
04/17/24	01/28/25	NV	Reno	Washoe County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
[redacted]	Reno Municipal Court

Reason/Charge	
Minor in Possession of Alcoholic beverage in Public	
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**
City of Reno / Camila Gonzalez-Marquez	
Name of Business/Industry/Entity	
City of Reno	

Provide explanation below:

On April 17th, 2024, I received a misdemeanor citation in Reno, Nevada, for possession of an alcoholic beverage in public. The matter did not involve violence, drugs, theft, or any risk to public safety. I complied with all instructions from law enforcement & resolved the citation through Reno Municipal Court as required.

This was an isolated incident. I accepted responsibility and have since remained in full compliance with all laws & regulations. I understand the importance of professionalism, sound judgment, and adherence to legal & ethical standards, and I am committed to upholding these principles in my training & future practice.

Camila Gonzalez — 2/10/26

Original Signature (electronic, copies or stamps not accepted) — Date

Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 7: Personal and Professional History		
Before answering the questions below, please INITIAL to the right to attest you have read and understand the following: **WARNING** **You MUST provide truthful and complete responses to the questions on this application. If you omit information or provide false or misleading responses, including any failure to disclose past arrests or expunged convictions, this may be a basis for denial of your application and may result in disciplinary action against any other license or registration you hold from the Board.**	**Initials** CGM	
	Yes	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state even if the case or charge has been dismissed, sealed, acquitted, or expunged?	✓	
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?		✓
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event MUST be provided.

This is in response to Question # 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/23/24	04/29/25	Nv	Reno	Washoe County
Case # [redacted]		Governing, licensing, Arresting Presiding Body/Agency/Court: Reno Municipal Court		
Reason/Charge: DUI 1st				
Plaintiff/Defendant/Claimant/Respondent: City of Reno - Camila Gonzalez		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity: City Of Reno				

Provide explanation below:

On December 23, 2024, I was cited in Reno, Nevada, for a first offense DUI. There was no accident, no injury, and no involvement of controlled substances. I cooperated fully with law enforcement The matter was resolved through Reno Municipal Court, and all court requirements were completed as ordered.

This incident was an isolated lapse in judgment. I accepted responsibility for my actions and have taken this experience seriously. Since that time, I have remained compliant with all laws & understand the importance of sound judgment, responsibility, and adherence to legal & professional standards, particularly in a healthcare setting.

Camila Gonzalez
Original Signature (electronic, copies or stamps not accepted)

7/10/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician in training who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Camila Gonzalez Marquez

Print Name

Camila Gonzalez

Original Signature (electronic, copies or stamps not accepted)

2/10/26

Date

Board Use Only	Date Received: 2/11/26	Amount: $50cc

13

13A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR ADVANCED PRACTICE REGISTERED NURSE TO PRESCRIBE

Rev (01/05/2023)

What types of drug(s) will you be prescribing?

☐ Dangerous Drugs ONLY **(Non-Refundable $80 Fee) (PR)**

☒ Dangerous Drugs AND Controlled Substances (CS) I, II, III, IV and/or V **(Non-Refundable $200 Fee) (CS)**

Select the Controlled Substance Schedules you are applying to prescribe

☐ Schedule I ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

Section 1: Personal Information (NAC 639.850)

First: Frances Anne Middle: Garces Last: Puesta

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Home Address: [redacted]

City: Las Vegas State: NV Zip Code: [redacted]

Telephone: [redacted] Email: [redacted]

APRN License #: 893394 Specialty: Family Nurse Practitioner

(A **current license and active-PRESCRIBING status** with the Nevada State Board of Nursing is required to apply for and maintain a Prescribe or a CS Registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name: VKostanianMD PC

Practice Address: 10001 South Eastern Avenue Suite #: 305

City: Henderson State: NV Zip: 89052

Telephone: 702 749 6688 Fax: 702 201 1256 Email: sknepper9964@gmail.com

Section 3: NRS 632.237 (Complete this section if you are applying to also prescribe SCHEDULED II CS).

An advanced practice registered nurse may apply to prescribe CS listed in schedule II if they meet one of the following qualifications (please mark that apply):

☐ I have at least 2 years or 2,000 hours of clinical experience; OR

☒ The CS will be prescribed pursuant to a protocol approved by a collaborating physician. (If you marked this answer, provide the information as requested below per NAC 639.850.)

Collaborating Physician Name: Dr. Varoujan Kostanian

Collaborating Physician Practice Address: 10001 S Eastern Ave Suite #: 305

City: Henderson State: NV Zip: 89052

Telephone: 702 749 6688 Fax: 702 201 1256 Email: [redacted]

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 6: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Frances Anne G. Puesta

Applicant Print Name (First, Last)

Frances G.

Original Signature (electronic, copies or stamps not accepted)

02/09/2026

Date

COLLABORATING PHYSICIAN's name and signature per Section 3 of the application (if applicable):

VARQUIAN KOSTANIAN, MD

Collaborating Physician's Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-9-2026

Date

Board Use Only: Date Processed: 2/24/26 Amount: $200

ViewReportHeaderTitle

Primary Source Board of Nursing Report Summary for

FRANCES ANNE GARCES PUESTA [NCSBN ID: 22628515]

Wednesday, February 25 2026 02:05:51 PM

The legend below provides details related to the statuses for advanced practice registered nurses (APRNs) only

Active– *ascribed to APRNs who meet the requirements for licensure, but do not meet the requirements, or have not applied for, prescribing privileges.*

Active Prescribing– *ascribed to all APRNs who have been granted authority to prescribe all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and is not required to c protocol with a collaborative physician.*

Active Prescribing-CII-COLL – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and have provided his/her current protocol with a collaborative physician.*

Active Prescribing -D– *ascribed to all APRNs who have been granted authority to prescribe and dispense all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and is to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL –D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, an provided a copy of his/her current protocol with a collaborative physician.*

APRNs must also apply with the Nevada State Board of Pharmacy and/or DEA before they can prescribe in Nevada.

If an APRN wishes to remove the protocol requirement they must submit a letter on letterhead from their employer to the Nevada State Board of Nursing ve they have worked a minimum of 2 years or 2,000 hours as an APRN.

Details related to License / Certificate Status can be found at the bottom of this page.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
PUESTA, FRANCES ANNE GARCES	RN	TRN353227	Expired	05/17/2017	06/27/2017	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
PUESTA, FRANCES ANNE GARCES	RN	RN94506	Active	06/27/2017	02/12/2027	NO

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
PUESTA, FRANCES ANNE GARCES	APRN-CNP	893394	Inactive	08/28/2025	09/16/2025	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Advanced Practice license/recognition information

- **Population Focus / Specialty:**
  - Focus/Specialty: Family Across the Lifespan
  - Has discipline: NO
  - Expiration Date: 09/16/2025
  - Original Issuance Date: 08/28/2025
  - Current Issue Date: 08/28/2025
  - Certification expiration date: 07/21/2030

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
PUESTA, FRANCES ANNE GARCES	APRN-CNP	893394	Active Prescribing - CII - COLL	09/16/2025	02/12/2027	NO

Advanced Practice license/recognition information

- **Population Focus / Specialty:**
  - Focus/Specialty: Family Across the Lifespan
  - Has discipline: NO
  - Expiration Date: 02/12/2027
  - Original Issuance Date: 09/16/2025
  - Current Issue Date: 09/16/2025
  - Certification expiration date: 07/21/2030

License type Information

- **RN:** Registered Nurse
- **PN:** Practical Nurse (aka Licensed Practical Nurse (LPN), Vocational Nurse (VN), Licensed Vocational Nurse (LVN))
- **CNP:** Certified Nurse Practitioner
- **CNS:** Clinical Nurse Specialist
- **CNM:** Certified Nurse Midwife
- **CRNA:** Certified Registered Nurse Anesthetist

I do hereby certify this to be a complete, accurate, and true copy of the document which is on file or is of record in the offices of the Texas Board of Nursing.
Executive Director of the Board

BEFORE THE TEXAS BOARD OF NURSING

****

In the Matter of	§	AGREED ORDER
Registered Nurse License Number 906359	§	
issued to FRANCES ANNE GARCES PUESTA	§	FOR DEFERRED DISCIPLINE

On this day the Texas Board of Nursing, hereinafter referred to as the Board, considered the matter of FRANCES ANNE GARCES PUESTA, Registered Nurse License Number 906359, hereinafter referred to as Respondent.

Information received by the Board produced evidence that Respondent may be subject to discipline pursuant to Section 301.452(b)(10)&(13), Texas Occupations Code. Respondent waived notice and hearing and agreed to the entry of this Order approved by Katherine A. Thomas, MN, RN, FAAN, Executive Director, on March 1, 2018.

FINDINGS OF FACT

1. Prior to the institution of Agency proceedings, notice of the matters specified below in these Findings of Fact was served on Respondent and Respondent was given an opportunity to show compliance with all requirements of the law for retention of the license(s).

2. Respondent waived notice and hearing, and agreed to the entry of this Order.

3. Respondent's license to practice as a professional nurse in the State of Texas is in current status.

4. Respondent received a Baccalaureate Degree in Nursing from Manila Tytana College, Pasay, Philippines, on March 1, 2009. Respondent was licensed to practice professional nursing in the State of Texas on August 8, 2016.

5. Respondent's nursing employment history includes:

08/16 - Present	Registered Nurse	APEX Health Care Professionals Las Vegas, NV

01/17 - 05/17	Staff Nurse	Medical City Alliance Fort Worth, Texas
05/17 - Present	Unknown	

6. At the time of the incident, Respondent was employed as a Staff Nurse with Apex Healthcare, Irving, Texas, and on assignment at Medical City Alliance, Fort Worth, Texas, and had been in that position for two (2) months.

7. On or about March 23, 2017, through March 24, 2017, while employed as a Staff Nurse with Apex Healthcare, Irving, Texas, and on assignment at Medical City Alliance, Fort Worth, Texas, Respondent withdrew one (1) tablet of Xanax 0.25mg from the medication dispensing system for patient medical record number [redacted] but failed to document the administration or wastage of the medication in the patient's medical record. Furthermore, in failing to document withdrawal, administration, and wastage of the one (1) tablet of Xanax 0.25mg from the medication dispensing system, Respondent failed to take precautions to prevent misappropriation of one (1) tablet of Xanax 0.25mg belonging to the facility or patients thereof. Respondent's conduct created an incomplete medical record.

8. On or about May 3, 2017, while employed as a Staff Nurse with Apex Healthcare, Irving, Texas, and on assignment at Medical City Alliance, Fort Worth, Texas, Respondent failed to clarify a physician's order for Oxycodone 5/325mg PO 5 tablets Q4hrs for Patient Medical Record Number [redacted] Subsequently, Respondent administered five (5) tablets of Oxycodone 5/325mg to the patient and patient became confused and disoriented. The physician's order has been verified by another Registered Nurse (RN) and pharmacy prior to Respondents 'administration of the Oxycodone. Respondent's conduct was likely to injure the patient in that failure to administer medication as ordered by a physician could have resulted in non-efficacious treatment.

9. In response to Findings of Facts Number Seven (7), through Eight (8), Respondent states she gave the medication without scanning patient's ID and Xanax. Respondent states she was distracted and forgot to scan the medication administration. Respondent recognized 5 tablets were an unusual dose which is why she checked everything prior to administration including telling her co-workers and checking records so this is not a case of incompetence. Respondent took immediate actions to rectify any deficiencies in her nursing practice.

10. On or about May 16, 2018, Respondent successfully completed an Understanding Board Orders course, which would have been a requirement of this order.

11. On or about May 16, 2018, Respondent successfully completed a Sharpening Critical Thinking Skills course, which would have been a requirement of this order.

CONCLUSIONS OF LAW

1. Pursuant to Texas Occupations Code, Sections 301.451-301.555 , the Board has jurisdiction over this matter.

2. Notice was served in accordance with law.

3. The evidence received is sufficient to prove violation(s) of 22 TEX. ADMIN. CODE §217.11(1)(A),(1)(B),(1)(C),(1)(D)&(1)(N) and 22 TEX. ADMIN. CODE §217.12(1)(A),(1)(B),(1)(C),(4),(6)(G)&(10)(C).

4. The evidence received is sufficient cause pursuant to Section 301.452(b)(10)&(13), Texas Occupations Code, to take disciplinary action against Registered Nurse License Number 906359, heretofore issued to FRANCES ANNE GARCES PUESTA.

5. Pursuant to Section 301.463(d), Texas Occupations Code, this Agreed Order is a settlement agreement under Rule 408, Texas Rules of Evidence, in civil or criminal litigation.

TERMS OF ORDER

I. SANCTION AND APPLICABILITY

IT IS THEREFORE AGREED and ORDERED, subject to ratification by the Texas Board of Nursing, that RESPONDENT SHALL receive the sanction of **REMEDIAL EDUCATION, DEFERRED,** in accordance with the terms of this Order.

A. This Order SHALL apply to any and all future licenses issued to Respondent to practice nursing in the State of Texas.

B. This Order SHALL be applicable to Respondent's nurse licensure compact privileges, if any, to practice nursing in the State of Texas.

C. As a result of this Order, Respondent's license(s) will be designated "single state" and Respondent may not work outside the State of Texas in another nurse licensure compact party state.

II. COMPLIANCE WITH LAW

While under the terms of this Order, RESPONDENT agrees to comply in all respects with the Nursing Practice Act, Texas Occupations Code, §§301.001 *et seq.*, the Rules and

Regulations Relating to Nurse Education, Licensure and Practice, 22 TEX. ADMIN. CODE §§211.1 *et seq.*, and this Order.

Further, RESPONDENT SHALL not commit any violation of the Nursing Practice Act, Texas Occupations Code, §§301.001 et seq., the Rules and Regulations Relating to Nurse Education, Licensure and Practice, 22 TEX. ADMIN. CODE §211.1 et seq. **for a period of three (3) years from the date of this Order.**

III. REMEDIAL EDUCATION COURSE(S)

In addition to any continuing education requirements the Board may require for licensure renewal, RESPONDENT SHALL successfully complete the following remedial education course(s) **within one (1) year of the effective date of this Order, unless otherwise specifically indicated**:

A. **A Board-approved course in Texas nursing jurisprudence and ethics** that shall be a minimum of six (6) hours in length. The course's content shall include the Nursing Practice Act, standards of practice, documentation of care, principles of nursing ethics, confidentiality, professional boundaries, and the Board's Disciplinary Sanction Policies regarding: Sexual Misconduct; Fraud, Theft and Deception; Nurses with Substance Abuse, Misuse, Substance Dependency, or other Substance Use Disorder; and Lying and Falsification. Courses focusing on malpractice issues will not be accepted. Home study courses and video programs will not be approved.

B. **A Board-approved course in medication administration** with a didactic portion of not less than six (6) hours and a clinical component of not less than twenty-four (24) hours. Both the didactic and clinical components must be provided by the same Registered Nurse. The course's content shall include: a review of proper administration procedures for all standard routes; computation of drug dosages; the six (6) rights of medication administration; factors influencing the choice of route; and possible adverse effects resulting from improper administration. The clinical component SHALL focus on tasks of medication administration only. The course description shall indicate goals and objectives for the course, resources to be utilized, and the methods to be used to determine successful completion of the course. Successful completion of this course requires RESPONDENT to successfully complete

both the didactic and clinical portions of the course.

C. **A Board-approved course in nursing documentation** that shall be a minimum of six (6) hours in length. The course's content shall include: nursing standards related to accurate and complete documentation; legal guidelines for recording; methods and processes of recording; methods of alternative record-keeping; and computerized documentation. Home study courses and video programs will not be approved.

In order to receive credit for completion of this/these course(s), RESPONDENT SHALL CAUSE the instructor to submit a Verification of Course Completion form or SHALL submit the continuing education certificate, as applicable, to the attention of Monitoring at the Board's office. RESPONDENT SHALL first obtain Board approval of any course prior to enrollment if the course is not being offered by a pre-approved provider. *Information about Board-approved courses and Verification of Course Completion forms are available from the Board at www.bon.texas.gov/compliance.*

IV. EFFECT OF DEFERRED DISCIPLINE

Upon successful completion of the stipulated requirements of this Order, all encumbrances will be removed from Respondent's license(s) to practice nursing in the State of Texas and, subject to meeting all existing eligibility requirements in Texas Occupations Code Chapter 304, Article III, RESPONDENT may be eligible for nurse licensure compact privileges, if any.

Upon the successful completion of the required three (3) year period of deferral, the complaint or complaints which formed the basis for this action will be dismissed and this Order will be made confidential to the same extent as a complaint filed under Section 301.466, Texas Occupations Code.

Until such time that this Order is made confidential, this Order is subject to disclosure in accordance with applicable law.

Should an additional allegation, complaint, accusation, or petition be reported or filed against Respondent prior to the time this Order is made confidential, the deferral period shall be extended until the allegation, accusation, or petition has been finally acted upon by the Board.

Should RESPONDENT commit a subsequent violation of the Nursing Practice Act or Board Rules, this Order shall be treated as prior disciplinary action.

BALANCE OF THIS PAGE INTENTIONALLY LEFT BLANK.

CONTINUED ON NEXT PAGE.

RESPONDENT'S CERTIFICATION

I understand that I have the right to legal counsel prior to signing this Agreed Order. I have reviewed this Order. I neither admit nor deny the violation(s) alleged herein. By my signature on this Order, I agree to the entry of this Order, and any conditions of said Order, to avoid further disciplinary action in this matter. I waive judicial review of this Order. I understand that when this Order becomes final and the terms of this Order become effective, a copy will be mailed to me. I understand that if I fail to comply with all terms and conditions of this Order, I will be subject to investigation and disciplinary sanction, including possible revocation of my license(s) to practice nursing in the State of Texas, as a consequence of my noncompliance.

Signed this 27th day of June, 2018.

FRANCES ANNE GARCES PUESTA, Respondent

Sworn to and subscribed before me this 27th day of June, 2018.

SEAL

Notary Public in and for the State of Nevada

Approved as to form and substance.

Taralynn R. Mackay, Attorney for Respondent

Signed this 17th day of July, 2018

WHEREFORE, PREMISES CONSIDERED, the Executive Director, on behalf of the Texas Board of Nursing, does hereby ratify and adopt the Agreed Order for Deferred Discipline that was signed on the 29th day of June, 20 18, by FRANCES ANNE GARCES PUESTA, Registered Nurse License Number 906359, and said Order is final.

Effective this 17th day of July, 20 18.

Katherine A. Thomas, MN, RN, FAAN
Executive Director on behalf
of said Board

Texas Board of Nursing

333 Guadalupe Street, Ste. 3-460, Austin, Texas 78701
Phone: (512) 305-7400 Fax: (512) 305-7401 www.bon.texas.gov

Katherine A. Thomas, MN, RN, FAAN
Executive Director

August 2, 2018

Frances Anne Puesta
[redacted]

Dear Ms. Puesta:

Except for the required period of deferral, our file reflects that all other requirements of the Deferred Agreed Order entered on July 17, 2018, have been met.

Please be aware, however, that until you successfully complete the required period of deferral and the order is made confidential, the Deferred Agreed Order will remain in the public record and will be subject to disclosure pursuant to any public information act request.

Upon successfully completing the required period of deferral, the complaint filed against you and the Deferred Agreed Order will be made confidential to the same extent that a complaint is confidential under Section 301.466, TEX. OCC. CODE. Also be aware that although the National Council State Boards of Nursing, Inc., and the National Practitioner Data Bank (NPDB) will be notified of your successful completion of the terms of the Deferred Agreed Order, this disciplinary history may remain accessible to other state boards of nursing and certain members of the public through these databases.

Although having an unencumbered license is no longer a disqualifying event for multistate nurse licensure privileges, your eligibility for multistate nurse licensure privileges may be further affected by any disqualifying event specified in Texas Occupations Code Chapter 304, Article III. You will receive one or more additional letters under separate cover addressing your eligibility for multistate nurse licensure compact privileges. Additional information regarding the uniform licensing requirements may be found at www.bon.texas.gov/enlcnotice.asp.

Good luck in any future endeavors and should you have any questions, please contact me at (512) 305-6827.

Sincerely,

Diane Burell
Compliance Supervisor

/007

Members of the Board

Kathleen Shipp, MSN, RN, FNP
Lubbock, *President*

Nina Almasy, MSN, RN Austin; Deborah Bell, CLU, ChFC Abilene; Patricia Clapp, BA Dallas; Laura Disque, MN, RN Edinburg; Allison Edwards, DrPH, MS Bellaire; Diana Flores, MN, RN Helotes

Monica Hamby, LVN Amarillo; Doris Jackson, DHA, (ABD), MSN, RN Pearland; Kathy Leader-Horn, LVN Granbury; Beverley Jean Nutall, LVN Weatherford; David Saucedo, II El Paso; Francis Stokes Port Arthur

Texas Board of Nursing

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Katherine A. Thomas, MN, RN, FAAN
Executive Director

August 2, 2018

Frances Anne Puesta
[redacted]

Re: RN License Number 906359

Dear Frances Anne Garces Puesta:

Our records indicate that your prior disqualifying event(s) is/are no longer adversely affecting your eligibility to hold a multistate licensure privilege.

Our records further indicate that you may now be eligible to hold a multistate licensure privilege. In order to reinstate your nurse licensure compact privilege(s), you will need to complete and return the enclosed Declaration of Primary State of Residence Form.

Should you have any questions regarding this matter, please contact the customer service department at (512) 305-7400.

Sincerely,

Katherine A. Thomas

Katherine A. Thomas, MN, RN, FAAN
Executive Director

Enclosure: Sworn Declaration of Primary State of Residence form

Members of the Board

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Lubbock, *President*

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Katherine A. Thomas, MN, RN, FAAN
Executive Director

July 22, 2021

Frances Anne Puesta
[redacted]

Dear Ms. Puesta:

Our file reflects that all requirements of the Deferred Agreed Order entered on July 17, 2018, including the required period of deferral, have been met.

The Board has dismissed the complaint filed against you and the Deferred Agreed Order has been made confidential to the same extent that a complaint is confidential under Section 301.466, TEX. OCC. CODE. However, please be aware that the Deferred Agreed Order is a permanent part of your nursing record and, in the event subsequent violations are reported to the Board, the Deferred Agreed Order may be treated as prior disciplinary history.

Further, please be aware that although the National Council State Boards of Nursing, Inc., and the National Practitioner Data Bank (NPDB) have been notified of your successful completion of the terms of the Deferred Agreed Order, this disciplinary history may remain accessible to other state boards of nursing and certain members of the public through these databases.

Good luck in any future endeavors and should you have any questions, please contact me at (512) 305-6827.

Sincerely,

Diane E Dougal

Diane Dougal
Compliance Supervisor

/007

160d3(2021.07.22)

Kathleen Shipp, MSN, RN, FNP
Lubbock, *President*

Allison Porter-Edwards, DrPH, MS, RN, CNE
Bellaire, *Vice-President*

Texas Board of Nursing

333 Guadalupe Street, Ste. 3-460, Austin, Texas 78701
Phone: (512) 305-7400 Fax: (512) 305-7401 www.bon.texas.gov
Katherine A. Thomas, MN, RN, FAAN
Executive Director

July 22, 2021

Frances Anne Puesta
[redacted]

Dear Ms. Puesta:

Our file reflects that all requirements of the Deferred Agreed Order entered on July 17, 2018, including the required period of deferral, have been met.

The Board has dismissed the complaint filed against you and the Deferred Agreed Order has been made confidential to the same extent that a complaint is confidential under Section 301.466, TEX. OCC. CODE. However, please be aware that the Deferred Agreed Order is a permanent part of your nursing record and, in the event subsequent violations are reported to the Board, the Deferred Agreed Order may be treated as prior disciplinary history.

Further, please be aware that although the National Council State Boards of Nursing, Inc., and the National Practitioner Data Bank (NPDB) have been notified of your successful completion of the terms of the Deferred Agreed Order, this disciplinary history may remain accessible to other state boards of nursing and certain members of the public through these databases.

Good luck in any future endeavors and should you have any questions, please contact me at (512) 305-6827.

Sincerely,

Diane E Dougal

Diane Dougal
Compliance Supervisor

/007

160d3(2021.07.22)

Kathleen Shipp, MSN, RN, FNP
Lubbock, *President*

Allison Porter-Edwards, DrPH, MS, RN, CNE
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Phone: (512) 305-7400 Fax: (512) 305-7401 www.bon.texas.gov
Katherine A. Thomas, MN, RN, FAAN
Executive Director

August 2, 2018

Frances Anne Puesta
[redacted]

Re: RN License Number 906359

Dear Frances Anne Garces Puesta:

Our records indicate that your prior disqualifying event(s) is/are no longer adversely affecting your eligibility to hold a multistate licensure privilege.

Our records further indicate that you may now be eligible to hold a multistate licensure privilege. In order to reinstate your nurse licensure compact privilege(s), you will need to complete and return the enclosed Declaration of Primary State of Residence Form.

Should you have any questions regarding this matter, please contact the customer service department at (512) 305-7400.

Sincerely,

Katherine A. Thomas, MN, RN, FAAN
Executive Director

Enclosure: Sworn Declaration of Primary State of Residence form

Members of the Board

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Olivia Mora

From: Frances Puesta <[redacted]>
Sent: Friday, February 27, 2026 12:52 PM
To: Olivia Mora
Subject: Re: APRN Prescribe Controlled Substance - information needed
Attachments: TX BON Board Order (71718).pdf; Completed Requirements of Deferred Order.pdf; Completed Deferral Period.pdf; Privilege for Multistate Licensure.pdf

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Good day, Ms. Mora,

Thank you for taking the time to assist me with my questions regarding the NPDB report related to my Texas RN license. I would like to begin by apologizing for the misunderstanding that occurred when I answered "no" to the question regarding any completed board citation. Both of my previous attorneys in Nevada and Texas had advised me that, because the Deferred Agreed Order from the Texas Board of Nursing had been fully completed, I could appropriately answer "no" to those items. I appreciate the opportunity you have given me to clarify this matter.

For reference, I entered into a Deferred Agreed Order with the Texas Board of Nursing on July 17, 2018. This represents the lowest level of board action in Texas. Details of this are outlined in the attached document titled "TX BON Board Order." I have also included the official correspondence from the Texas Board of Nursing dated August 2, 2018, confirming that I successfully completed all requirements and remained eligible to hold multistate licensure privileges.

Additionally, regarding the date of July 19, 2021, I received a letter from the Texas Board of Nursing on July 22, 2021, stating that I had satisfied all conditions of the three-year Deferred Agreed Order. The letter also confirms that the complaint against me was formally dismissed. This document is also attached for your review.

Please confirm receipt of all attachments at your earliest convenience.

Thank you again for allowing me to provide this explanation. Should you have any additional questions or require further information, please feel free to contact me. I look forward to your response.

Sincerely,
Frances Anne G. Puesta, FNP-C
Cell: [redacted]

On Friday, February 27, 2026 at 09:59:07 AM PST, Olivia Mora <o.mora@pharmacy.nv.gov> wrote:

Good morning,

We have received your application and the fee of $200. The following information is needed to continue the process of your application.

- Provide an explanation and documentation from the Texas State Board of Nursing regarding the date of Actions 7/17/2018, 8/02/2018 and 7/19/21.

Please email the documents to attach to your application.

Thank you,

Olivia Mora

Licensing Specialist

Nevada State Board of Pharmacy

(775) 850-1440 x122

o.mora@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

13B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☐ Schedule I ☒ Schedule II ■ Schedule III ■ Schedule IV ■ Schedule V

TC PLEASE

Section 1: Personal Information

First: Jeffrey Middle: David Last: Gross

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Home Address: [redacted]

City: Henderson State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: MD Practitioner License #: 13807 Specialty: Neurosurgery

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): J.D. Gross Medical Corp, DBA ReCELLebrate, DBA Spine

Practice Address: 1661 W. Horizon Ridge Parkway Suite #: 280

City: Henderson State: NV Zip: 89012

Telephone: 949 364 6888 Fax: _____ Email: jdgross@ifixspines.com

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
8/7/20	8/7/20	CA		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
8:18-CR-00014	US District Court, CDCA

Reason/Charge
18 USC 371

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

On 8/7/2020, I pled guilty to one count of conspiracy to commit honest services fraud, which was not related to controlled substances. This incident resulted in related/reciprocal actions in with other regulatory agencies as detailed in following pages.

Original Signature (electronic, copies or stamps not accepted)

2/21/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey Gross
Print Name (First, Last)

2/21/26
Date

Original Signature (electronic, copies or stamps not accepted)

2/21/26
Date

Board Use Only: Date Processed: 3/27/26 Amount: $150.00

United States District Court
Central District of California

AMENDED 7/21/21 AS TO RESTITITION AMOUNT

UNITED STATES OF AMERICA vs. **Docket No.** SACR 18-00014-JLS

Defendant Jeffrey David Gross **Social Security No.** [redacted]
(Last 4 digits)

akas: None

JUDGMENT AND PROBATION/COMMITMENT ORDER

MONTH	DAY	YEAR
MAY	21	2021

In the presence of the attorney for the government, the defendant appeared in person on this date.

COUNSEL Hamilton Arendsen (Rtd); Mark Mermelstein (Rtd)
(Name of Counsel)

PLEA [X] **GUILTY,** and the court being satisfied that there is a factual basis for the plea. [ ] **NOLO CONTENDERE** [ ] **NOT GUILTY**

FINDING There being a finding/verdict of **GUILTY,** defendant has been convicted as charged of the offense(s) of: Conspiracy in violation of 18 U.S.C. § 371 as charged in Count 1 of the Indictment.

JUDGMENT AND PROB/ COMM ORDER The Court asked whether there was any reason why judgment should not be pronounced. Because no sufficient cause to the contrary was shown, or appeared to the Court, the Court adjudged the defendant guilty as charged and convicted and ordered that: Pursuant to the Sentencing Reform Act of 1984, it is the judgment of the Court that the defendant is hereby committed to the custody of the Bureau of Prisons to be imprisoned for a term of **15 MONTHS:**

It is ordered that the defendant shall pay to the United States a special assessment of $100, which is due immediately. Any unpaid balance shall be due during the period of imprisonment, at the rate of not less than $25 per quarter, and pursuant to the Bureau of Prisons' Inmate Financial Responsibility Program.

Pursuant to Guideline §5E1.2(a), all fines are waived as the Court finds that the defendant has established that he is unable to pay and is not likely to become able to pay any fine.

The Court has entered a money judgment of forfeiture against the defendant, which is hereby incorporated by reference into this judgment and is final.

It is ordered that the defendant shall pay restitution pursuant to 18 U.S.C. § 3663A in the amount of $45,000.

The Court recommends that the Bureau of Prisons conduct a mental health evaluation of the defendant and provide all necessary treatment.

Pursuant to the Sentencing Reform Act of 1984, it is the judgment of the Court that the defendant, Jeffrey David Gross, is hereby committed on Count 1 of the 14-Count Indictment to the custody of the Bureau of Prisons for a term of **15 MONTHS.**

Upon release from imprisonment, the defendant shall be placed on supervised release for a term of three years under the following terms and conditions:

1. The defendant shall comply with the rules and regulations of the United States Probation & Pretrial Services Office and Second Amended General Order 20-04;

2. During the period of community supervision, the defendant shall pay the special assessment in accordance with this judgment's orders pertaining to such payment;

3. The defendant shall cooperate in the collection of a DNA sample from the defendant;

4. The defendant shall participate in mental health treatment, which may include evaluation and counseling, until discharged from the program by the treatment provider, with the approval of the Probation Officer;

5. As directed by the Probation Officer, the defendant shall pay all or part of the costs of the Court-ordered treatment to the aftercare contractors during the period of community supervision. The defendant shall provide payment and proof of payment as directed by the Probation Officer. If the defendant has no ability to pay, no payment shall be required;

6. The defendant shall report this conviction to the Medical Board of California, and to any other state in which the defendant has been licensed as a physician, and thereafter comply with any orders, including any employment or business restrictions. Further, the defendant shall show proof to the Probation Officer of compliance with this order; and

7. As directed by the Probation Officer, the defendant shall provide to the Probation Officer: (1) a signed release authorizing credit report inquiries; (2) federal and state income tax returns and a signed release authorizing their disclosure and (3) an accurate financial statement, with supporting documentation as to all assets, income, expenses, and liabilities of the defendant.

The drug testing condition mandated by statute is suspended based on the Court's determination that the defendant poses a low risk of future substance abuse.

The Court authorizes the Probation Office to disclose the Presentence Report and any previous mental health evaluations or reports to the mental health treatment provider. The treatment provider may provide information, excluding the Presentence Report, to State or local social service agencies for the purpose of the client's rehabilitation.

It is further ordered that the defendant surrender herself to the institution designated by the Bureau of Prisons on or before 12 noon on **August 16, 2021.** In the absence of such designation, the defendant shall report on or before the same date and time to the United States Marshal located at United States Court House, 411 W. Fourth Street, Santa Ana, CA 92701.

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The Court strongly recommends that the defendant be housed at FCI Lompoc in Southern California to facilitate visitation with family, friends, and loved ones.

USA vs. Jeffrey David Gross Docket No.: SACR 18-00014-JLS

On government's motion, all remaining counts dismissed.

Bond is exonerated upon surrender.

The Court advised the defendant of his right to appeal.

In addition to the special conditions of supervision imposed above, it is hereby ordered that the Standard Conditions of Probation and Supervised Release within this judgment be imposed. The Court may change the conditions of supervision, reduce or extend the period of supervision, and at any time during the supervision period or within the maximum period permitted by law, may issue a warrant and revoke supervision for a violation occurring during the supervision period.

July 21, 2021
Date

JOSEPHINE L. STATON
U. S. District Judge Josephine L. Staton

It is ordered that the Clerk deliver a copy of this Judgment and Probation/Commitment Order to the U.S. Marshal or other qualified officer.

Clerk, U.S. District Court

July 21, 2021
Filed Date

By M. Kunig
Deputy Clerk

USA vs. Jeffrey David Gross Docket No.: SACR 18-00014-JLS

The defendant must comply with the standard conditions that have been adopted by this court (set forth below).

STANDARD CONDITIONS OF PROBATION AND SUPERVISED RELEASE

While the defendant is on probation or supervised release pursuant to this judgment:

1. The defendant must not commit another federal, state, or local crime;
2. The defendant must report to the probation office in the federal judicial district of residence within 72 hours of imposition of a sentence of probation or release from imprisonment, unless otherwise directed by the probation officer;
3. The defendant must report to the probation office as instructed by the court or probation officer;
4. The defendant must not knowingly leave the judicial district without first receiving the permission of the court or probation officer;
5. The defendant must answer truthfully the inquiries of the probation officer, unless legitimately asserting his or her Fifth Amendment right against self-incrimination as to new criminal conduct;
6. The defendant must reside at a location approved by the probation officer and must notify the probation officer at least 10 days before any anticipated change or within 72 hours of an unanticipated change in residence or persons living in defendant's residence;
7. The defendant must permit the probation officer to contact him or her at any time at home or elsewhere and must permit confiscation of any contraband prohibited by law or the terms of supervision and observed in plain view by the probation officer;
8. The defendant must work at a lawful occupation unless excused by the probation officer for schooling, training, or other acceptable reasons and must notify the probation officer at least ten days before any change in employment or within 72 hours of an unanticipated change;
9. The defendant must not knowingly associate with any persons engaged in criminal activity and must not knowingly associate with any person convicted of a felony unless granted permission to do so by the probation officer. This condition will not apply to intimate family members, unless the court has completed an individualized review and has determined that the restriction is necessary for protection of the community or rehabilitation;
10. The defendant must refrain from excessive use of alcohol and must not purchase, possess, use, distribute, or administer any narcotic or other controlled substance, or any paraphernalia related to such substances, except as prescribed by a physician;
11. The defendant must notify the probation officer within 72 hours of being arrested or questioned by a law enforcement officer;
12. For felony cases, the defendant must not possess a firearm, ammunition, destructive device, or any other dangerous weapon;
13. The defendant must not act or enter into any agreement with a law enforcement agency to act as an informant or source without the permission of the court;
14. As directed by the probation officer, the defendant must notify specific persons and organizations of specific risks posed by the defendant to those persons and organizations and must permit the probation officer to confirm the defendant's compliance with such requirement and to make such notifications;
15. The defendant must follow the instructions of the probation officer to implement the orders of the court, afford adequate deterrence from criminal conduct, protect the public from further crimes of the defendant; and provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner.

USA vs. Jeffrey David Gross Docket No.: SACR 18-00014-JLS

[X] The defendant must also comply with the following special conditions (set forth below).

STATUTORY PROVISIONS PERTAINING TO PAYMENT AND COLLECTION OF FINANCIAL SANCTIONS

The defendant must pay interest on a fine or restitution of more than $2,500, unless the court waives interest or unless the fine or restitution is paid in full before the fifteenth (15th) day after the date of the judgment under 18 U.S.C. § 3612(f)(1). Payments may be subject to penalties for default and delinquency under 18 U.S.C. § 3612(g). Interest and penalties pertaining to restitution, however, are not applicable for offenses completed before April 24, 1996.

If all or any portion of a fine or restitution ordered remains unpaid after the termination of supervision, the defendant must pay the balance as directed by the United States Attorney's Office. 18 U.S.C. § 3613.

The defendant must notify the United States Attorney within thirty (30) days of any change in the defendant's mailing address or residence address until all fines, restitution, costs, and special assessments are paid in full. 18 U.S.C. § 3612(b)(l)(F).

The defendant must notify the Court (through the Probation Office) and the United States Attorney of any material change in the defendant's economic circumstances that might affect the defendant's ability to pay a fine or restitution, as required by 18 U.S.C. § 3664(k). The Court may also accept such notification from the government or the victim, and may, on its own motion or that of a party or the victim, adjust the manner of payment of a fine or restitution under 18 U.S.C. § 3664(k). See also 18 U.S.C. § 3572(d)(3) and for probation 18 U.S.C. § 3563(a)(7).

Payments will be applied in the following order:

1. Special assessments under 18 U.S.C. § 3013;
2. Restitution, in this sequence (under 18 U.S.C. § 3664(i), all non-federal victims must be paid before the United States is paid):
   Non-federal victims (individual and corporate),
   Providers of compensation to non-federal victims,
   The United States as victim;
3. Fine;
4. Community restitution, under 18 U.S.C. § 3663(c); and
5. Other penalties and costs.

CONDITIONS OF PROBATION AND SUPERVISED RELEASE PERTAINING TO FINANCIAL SANCTIONS

As directed by the Probation Officer, the defendant must provide to the Probation Officer: (1) a signed release authorizing credit report inquiries; (2) federal and state income tax returns or a signed release authorizing their disclosure and (3) an accurate financial statement, with supporting documentation as to all assets, income and expenses of the defendant. In addition, the defendant must not apply for any loan or open any line of credit without prior approval of the Probation Officer.

When supervision begins, and at any time thereafter upon request of the Probation Officer, the defendant must produce to the Probation and Pretrial Services Office records of all bank or investments accounts to which the defendant has access, including any business or trust accounts. Thereafter, for the term of supervision, the defendant must notify and receive approval of the Probation Office in advance of opening a new account or modifying or closing an existing one, including adding or deleting signatories; changing the account number or name, address, or other identifying information affiliated with the account; or any other modification. If the Probation Office approves the new account, modification or closing, the defendant must give the Probation Officer all related account records within 10 days of opening, modifying or closing the account. The defendant must not direct or ask anyone else to open or maintain any account on the defendant's behalf.

The defendant must not transfer, sell, give away, or otherwise convey any asset with a fair market value in excess of $500 without approval of the Probation Officer until all financial obligations imposed by the Court have been satisfied in full.

These conditions are in addition to any other conditions imposed by this judgment.

USA vs. Jeffrey David Gross Docket No.: SACR 18-00014-JLS

RETURN

I have executed the within Judgment and Commitment as follows:

Defendant delivered on _____ to _____

Defendant noted on appeal on _____

Defendant released on _____

Mandate issued on _____

Defendant's appeal determined on _____

Defendant delivered on _____ to _____

at _____

the institution designated by the Bureau of Prisons, with a certified copy of the within Judgment and Commitment.

United States Marshal

By _____

Date Deputy Marshal

USA vs. Jeffrey David Gross Docket No.: SACR 18-00014-JLS

CERTIFICATE

I hereby attest and certify this date that the foregoing document is a full, true and correct copy of the original on file in my office, and in my legal custody.

Clerk, U.S. District Court

Filed Date

By
Deputy Clerk

FOR U.S. PROBATION OFFICE USE ONLY

Upon a finding of violation of probation or supervised release, I understand that the court may (1) revoke supervision, (2) extend the term of supervision, and/or (3) modify the conditions of supervision.

These conditions have been read to me. I fully understand the conditions and have been provided a copy of them.

(Signed)
Defendant Date

U. S. Probation Officer/Designated Witness Date

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
09/08/2023	09/08/2023	CA		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
800-2018-045045	Medical Board of California

Reason/Charge
Related to conviction in CA federal court.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

On 9/8/23, the Medical Board of California revoked my medical license as a result of my conviction in federal court.

Original Signature (electronic, copies or stamps not accepted)

2/21/26
Date

Summary

FORMAL COMPLAINT Case No. 22-38073-1 April 12, 2022

The Investigative Committee of the Nevada State Board of Medical Examiners filed a formal Complaint against Jeffrey David Gross, M.D. alleging four (4) violations of Nevada Revised Statutes (NRS) Chapter 630. Count I: Alleges a violation of NRS 630.301(1) Conviction of a Felony Relating to the Practice of Medicine. Count II: Alleges a violation of NRS 630.301(9) Disreputable Conduct. Count III: Alleges a violation of NRS 630.301(11)(g) Conviction of an Offense Involving Moral Turpitude. Count IV: Alleges a violation of NRS 630.306(a)(b)(1) Engaging in Conduct Which is Intended to Deceive.

Complaint: five (5) pages.

COMPLIANCE Case No. 22-38073-1 June 18, 2024

Completed all terms of the settlement agreement for the above case as of June 7, 2024.

****

SETTLEMENT AGREEMENT Case No. 22-38073-1 September 16, 2022

On September 16, 2022, the Nevada State Board of Medical Examiners (Board) accepted and approved a Settlement Agreement which allowed for an order to be entered finding that Dr. Gross violated NRS 630.301(9) and NRS 630.301(11)(g), as set forth in Counts II and III of the Complaint, and ordering the following: that his license to practice medicine in the State of Nevada be suspended, with the suspension immediately stayed and his license placed on probation for a period of 48months from the date of the Board's acceptance, adoption and approval of the Agreement, subject to various terms and conditions, including the following: he shall receive a public reprimand; pay a total fine in the amount of $5,000; complete 20 hours of Continuing Medical Education (CME), in addition to his statutory CME requirements for licensure; he shall perform 300 hours of community service without compensation; he shall successfully complete all requirements as established by the U.S. District Court Central District of California in Case No. 8:18-cr-00014-JLS and the rules and regulations of the U.S. Probation and Pretrial Services Office, and the Second Amended General Order 20-04; he shall submit to the Board documentation regarding the terms, requirements and compliance of his supervised release; he shall submit to and pass all 5 sections of the Ethics and Boundaries Assessment Services (EBAS) examination, at his own expense; and he shall reimburse the Board's fees and costs incurred in the investigation and prosecution of the case against him. Counts I and IV of the Complaint were dismissed with prejudice.

Settlement Agreement: ten (10) pages

Attachments

Complaint 22-38073-1.pdf (/rest/public/data/downloadannotation/index.php?id=6259b13dfee7346d8463fef3&entity=$2y$10$iXyh35HoggO1UZjJft4.te6m2QGLcuY/ul/gil1yt7LAZvsF7Ejl

Settlement Agreement 22-38073-1.pdf (/rest/public/data/downloadannotation/index.php?id=6334662381edb50d4492cd94&entity=$2y$10$krPg7YEZ13dfSqGtx/Bs6..cnM1Nag1wtON7vtVX0Bq66G

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary Attachments

None.

Malpractice Information

Summary Attachments

None.

Supervisor To

Licensee	Relationship	Date of Association
Patrick DAVIS	Additional Supervisor	May-08-2018

Jeffrey David GROSS

License Number:
13807

License Type:
Medical Doctor

License Status:
Active

Initial License Date:
Feb-01-2011

Expiration Date:
Jun-30-2027

Public Address:
1661 WEST HORIZON RIDGE PARKWAY Suite 280

Public City:
Henderson

Public State:
Nevada

Public ZIP Code:
89012

Public Country:
United States

Public Phone Number:
9493646888

Credential:
M.D.

Specialties

Specialty
Surgery, Neurological

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
George Washington Univ SOM / Washington , DC	Medical Doctor Degree	N/A	May-29-1992

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
Univ of California, Irvine Med Center / Orange, CA	Internship	Surgery,General	Jun-24-1992	Jun-30-1993
Univ of California, Irvine Med Center / Orange, CA	Residency	Surgery,Neurological	Jul-01-1993	Jun-30-1997
University of New Mexico , Albuquerque , NM	Fellowship	Surgery,Spine	Jul-01-1997	Jun-30-1998
University of New Mexico , Albuquerque , NM	N/A	Surgery,Neurological	Jul-01-1998	Jun-30-1999

Board Actions

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: Jeffrey David Gross, M.D. Physician's and Surgeon's Certificate No. G 79394 Respondent.	Case No. 800-2018-045045

DECISION

The attached Proposed Decision is hereby adopted as the Decision and Order of the Medical Board of California, Department of Consumer Affairs, State of California.

This Decision shall become effective at 5:00 p.m. on September 8, 2023.

IT IS SO ORDERED August 10, 2023.

MEDICAL BOARD OF CALIFORNIA

Laurie Rose Lubiano, J.D., Chair
Panel A

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

JEFFREY DAVID GROSS, M.D.

Physician's and Surgeon's Certificate No. G 79394,

Respondent.

Agency Case No. 800-2018-045045

OAH No. 2022080683

PROPOSED DECISION

Thomas Heller, Administrative Law Judge, Office of Administrative Hearings (OAH), State of California, heard this matter by videoconference on May 8, 2023.

Peggy Bradford Tarwater, Deputy Attorney General, represented complainant Regi Varghese, Interim Executive Director, Medical Board of California (Board), Department of Consumer Affairs.

Craig B. Garner, Esq., Garner Health Law Corporation, represented respondent Jeffrey David Gross, M.D.

Oral and documentary evidence was received, and the parties also stipulated to certain facts. On May 15, 2023, respondent requested official notice of a United States Supreme Court decision issued after the hearing, and complainant objected to the request. In an order dated June 6, 2023, the administrative law judge overruled the objection, reopened the record to take official notice of the decision, and took the matter under submission.

SUMMARY

Complainant requests that the Board revoke respondent's physician's and surgeon's certificate due to his federal criminal conviction in 2021 of conspiring to commit honest-services mail and wire fraud. The conviction arose from a scheme in which respondent accepted bribes and kickbacks that were paid to induce him to refer patients to a hospital for spinal surgeries and other medical procedures between 2008 and 2013. Complainant argues respondent's conduct and criminal conviction are grounds for revocation because they are substantially related to the qualifications, functions, or duties of a physician and surgeon, and revocation is necessary to protect the public due to the dishonest and corrupt nature of the crime and respondent's alleged lack of rehabilitation.

Respondent argues that any disciplinary action against his certificate should be limited to a stayed revocation with probation rather than an outright revocation. Respondent has complied with the terms of his criminal sentence, and he accepted responsibility for his crime by pleading guilty to it. Furthermore, respondent contends his criminal conduct did not arise from or occur during patient care, treatment, management, or billing, and it is therefore less serious for disciplinary purposes than a

crime that did. According to respondent, the crime never affected patient care or influenced respondent's medical decision making.

Complainant proved respondent's conduct and criminal conviction are grounds for disciplinary action against respondent's certificate. Respondent's years-long conspiracy to commit honest-services fraud was serious, dishonest, and substantially related to the qualifications, functions, and duties of a physician and surgeon. Furthermore, the conspiracy arose from patient care, treatment, management, or billing, despite respondent's contention to the contrary. Respondent conspired to defraud patients of their right to honest services by accepting bribes and kickbacks intended to influence their care and treatment.

In addition, respondent's evidence does not show he is rehabilitated. While respondent's criminal conduct ended in 2013, the criminal conviction itself is recent, and respondent was released from prison just last year, leaving only a limited time in which to assess his rehabilitation. Respondent is also still on supervised release, and his good behavior while under supervision is accorded little weight in analyzing his rehabilitation because he is required to behave in exemplary fashion while under supervision. In addition, respondent's testimony does not show he has had a substantial change in attitude from that which existed at the time of the conspiracy. Instead, respondent downplayed the gravity of his criminal conduct, at times appearing to challenge the factual basis for his criminal conviction.

Considering the entire record, revocation of respondent's certificate is warranted. Complainant also requests an order directing respondent to pay the Board's investigative and enforcement costs; that request will be granted in part.

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FACTUAL FINDINGS

Background

1. On July 6, 1994, the Board issued respondent physician's and surgeon's certificate number G 79394. The certificate is renewed and current with an expiration date of November 30, 2023.

2. Respondent is a neurosurgeon who formerly operated Oasis Medical Providers, Inc. (Oasis), a medical practice based in Laguna Niguel, California. He is also a licensed physician in Nevada and Utah; he became licensed in those states in February 2011 and September 2021, respectively. Respondent earned his medical degree from George Washington University in Washington, D.C., and he started his private practice in Laguna Niguel in 1999. From 2005 through 2013, respondent performed surgeries and other medical procedures on some of his patients at Pacific Hospital of Long Beach, California (Pacific Hospital).

Criminal Conviction

3. Pacific Hospital closed in the fall of 2013 following a raid by federal authorities in a criminal investigation of alleged healthcare fraud. On January 23, 2018, an Indictment was filed against respondent in the United States District Court, Central District of California, Case No. SA CR 18-00014-CJC. Count One of the Indictment charged respondent with conspiring with Pacific Hospital's owner, Michael D. Drobot, and others to defraud patients of their right to honest services by accepting bribes and kickbacks that were paid to induce respondent to refer patients to Pacific Hospital for spinal surgeries and other medical services.

4. On July 16, 2020, respondent agreed to plead guilty to Count One of the Indictment. In his plea agreement, respondent admitted he conspired to commit honest-services mail and wire fraud in violation of 18 U.S.C. section 371, a felony, by receiving bribes and kickbacks disguised as legitimate payments under three agreements with Pacific Hospital and Pacific Specialty Physician Management, Inc. (PSPM), an affiliated company that Drobot also controlled. First, in February 2008, respondent agreed to sublease Oasis's medical office space to PSPM in return for monthly payments of $15,000. Second, in November 2008, respondent agreed to an option contract under which PSPM promised to pay $15,000 per month to Oasis for the option to purchase the accounts receivable and all other tangible assets of Oasis. Respondent knew that one unstated purpose of both agreements was to induce him to bring certain spinal surgery patients to Pacific Hospital, but respondent did not disclose that information to patients. PSPM paid Oasis $145,000 under the sublease agreement and $105,000 under the option agreement.

5. Third, in April 2009, respondent entered into an outsourced collections agreement with Pacific Hospital in which he agreed to assist with collections on some of the spinal surgery cases he performed at the hospital in exchange for 15 percent of any amounts the hospital collected for those surgeries. The agreement, later amended, also called for respondent to be paid 10 percent of the collected amount on other outpatient surgeries. During surgeries, if respondent used hardware from International Implants, a Drobot-formed hardware distribution company, he was advanced $5,000 regardless of subsequent collections. Once again, respondent knew that one purpose of the agreement was to induce him to bring certain spinal surgery patients to Pacific Hospital, and he did not disclose this information to his patients. Pacific Hospital paid Oasis $372,936 under this agreement.

6. As part of his guilty plea, respondent admitted Drobot paid him a total of $622,936 under the agreements between April 2008 and May 2013. During that time, respondent referred dozens of patients to Pacific Hospital for spinal surgeries based in part on payments made to him under those agreements. Respondent admitted he understood the amounts paid to him by Drobot constituted bribes and kickbacks to induce him to refer his patients to Pacific Hospital. Respondent also admitted that in furtherance of the scheme, he and his co-conspirators transmitted items by mail and interstate wire communications.

7. On May 21, 2021, the court accepted the plea agreement as to Count One, dismissed the other charges in the Indictment, and sentenced respondent to 15 months in federal prison to be followed by three years of supervised release. The court also ordered respondent to forfeit $622,936 to the government, to pay a fine of $100, and to report the conviction to the Board. On July 21, 2021, the court ordered respondent to pay a total of $45,000 in victim restitution to three patients who received implant hardware for which respondent received kickbacks from Drobot, with payments to be credited against the amount of the forfeiture order.

8. In August 2021, respondent surrendered to federal correctional authorities to begin his prison sentence. He was released in January 2022 to a halfway house in Las Vegas, Nevada, which was followed by a period of home confinement. On July 5, 2022, respondent was released from home confinement and placed on supervised release.

Procedural History

9. In late April 2022, the Board notified respondent that his physician's and surgeon's certificate was automatically suspended due to his incarceration on the

criminal conviction. On May 2, 2022, respondent objected to the suspension because he had already been released from prison to the halfway house in Las Vegas. On the same day, William Prasifka, complainant's predecessor as the Board's executive director, filed the accusation in his official capacity charging respondent with four causes for disciplinary action: (1) conviction of a crime; (2) dishonest or corrupt acts/healthcare fraud; (3) unprofessional conduct; and (4) fraudulent/false claims and statements. Respondent timely filed a notice of defense. On July 13, 2022, the Board notified respondent that the automatic suspension was dissolved, allowing respondent to resume practice within the state. Complainant served a notice of hearing on respondent in late August 2022.

Hearing

COMPLAINANT'S CASE

10. At the hearing, complainant amended the accusation to delete the fourth cause for discipline for fraudulent/false claims and statements. As to the three remaining causes for discipline, complainant presented court records of respondent's plea, his criminal conviction, and his sentencing hearing to support the disciplinary charges. At the sentencing hearing, respondent expressed regret for making a "grand mistake," while stating the bribes and kickbacks did not affect the quality of patient care. (Exhibit 9, p. A196.) But when stating the reasons for the sentence, the court noted that "[p]atients who are undergoing serious and potentially life-threatening procedures are entitled to the peace of mind that comes from knowing that their doctor is considering only their best interest in deciding that surgery is called for and in selecting a facility and in selecting the hardware to be used in that surgery." (*Id.* at pp. A223-224.) Respondent nonetheless "picked the facility [i.e., Pacific Hospital] and the physical hardware that earned him upfront payments. He participated in trading

patient referrals for regular substantial kickbacks and that robbed his patients . . . of the peace of mind that they need when going through a procedure like this. And it was for money. There's no other reason to have engaged in this conduct." (*Id.* at p. A224.) "Quite simply, this scheme introduced greed into the physician-patient relationship." (*Id.* at p. A223.)

11. Complainant also presented a cost certification stating that the Department of Justice billed the Board for $23,327.50 in case-related costs through April 18, 2023, and the Department of Justice expected to bill the Board another $1,730 in costs up to the start of the hearing. The costs are attributable to 107 hours of attorney and paralegal work, plus eight hours of anticipated additional work. Based on the cost certification, complainant requests an order directing respondent to pay costs totaling $25,057.50 to the Board.

RESPONDENT'S CASE

12. Respondent testified that when he first read the Indictment, he did not believe he had done anything wrong. An attorney for the hospital, Michael Tichon, drafted and negotiated the agreements between respondent and Pacific Hospital and PSPM. Respondent trusted Tichon to provide good advice, and respondent had no reason to believe the agreements were unlawful. Tichon died before respondent was indicted.

13. In addition, respondent testified he never let the agreements affect his medical decision making for any patients. According to respondent, he always considered surgery to be a last resort for his patients, and the agreements with Pacific Hospital and PSPM did not change that conservative approach. Respondent's plea agreement includes a statement that it is "not meant to indicate that [respondent]

provided any patients with substandard medical or surgical care or that any treatment he recommended, prescribed, and/or delivered was not medically necessary." (Exhibit 3, pp. A144-145.) Respondent testified he never did. Respondent also noted he had a sign posted in his office between approximately 2007 until 2016 disclosing to patients that Oasis provided "contract/billing/collections/negotiations services for a number of professionals and entities, including . . . health care facilities where you may have had or are recommended to have treatment." (Exhibit Q.) According to respondent, the disclosure pertained to Oasis' agreements with PSPM and Pacific Hospital, among others.

14. Respondent fought the criminal charges for about two years before agreeing to plead guilty. Respondent testified that during plea negotiations, he became aware of "certain challenges" in the case and of a jury instruction for honest-services fraud that led him to believe he faced a "very uphill battle" for an acquittal at trial. Therefore, he admitted to conspiring with Drobot and others to commit honest-services mail and wire fraud. Drobot and other physicians have also been convicted of crimes related to the conspiracy, but respondent testified he did not know other physicians were involved in the conspiracy at the time.

15. Respondent explained that the surgeries he performed at Pacific Hospital were on personal injury lien patients, i.e., patients with injury claims against third parties. For such patients, respondent would operate on the patient in return for a lien on any recovery in the patient's personal injury case. Pacific Hospital also received a lien for its costs on the patient's personal injury recovery. If the patient lost the personal injury case, respondent had the right to pursue payment from the patient, but respondent testified he never did.

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16. Respondent treated personal injury lien patients at Pacific Hospital because his primary hospital, Hoag Hospital in Newport Beach, California, would not admit those patients, who were often uninsured and unable to pay out of pocket for their care. According to respondent, his staff privileges at Pacific Hospital allowed him to provide surgical care to persons who otherwise may not have received it. Furthermore, respondent testified he generally was not paid his entire bill for a surgery on a personal injury lien patient. Respondent estimates he discounted over two million dollars from his usual and customary charges for surgeries on such patients at Pacific Hospital.

17. Respondent is current on payments on the criminal court's restitution and forfeiture orders, although "some amount" is still owing. Respondent currently resides and practices in Nevada. He is in solo practice and primarily treats patients with private insurance, although he still treats some personal injury lien patients. He also treats Medicare and Medicaid patients without charge, something he testified he has done since 2005 as a way of giving back to the community. Before the criminal conviction, he could have billed the government but never did; after the criminal conviction, he has been excluded from billing federal entities for 10 years.

18. In September 2022, the Nevada State Board of Medical Examiners suspended respondent's medical license in that state, stayed the suspension, and placed respondent on probation for four years. Similarly, in early November 2022, the Division of Licensing of the Department of Commerce of the State of Utah revoked respondent's license in that state, stayed the revocation, and placed respondent on probation for three years. Both orders were stipulated resolutions of disciplinary charges based on the same criminal conviction and underlying conduct at issue in this

case. There have been no allegations of other misconduct against respondent since the criminal conviction.

19. Respondent testified he is in compliance with the terms of conditions of the probation orders in Nevada and Utah. Among other requirements, the Nevada order required him to pass an Ethics and Boundary Assessment examination. The Utah order also required respondent to take up to six additional hours of continuing education over and above the minimum continuing education requirements. In mid-November 2022, respondent completed a two-day continuing education course in medical ethics and professionalism.

20. Supplementing his testimony, respondent presented letters from patients, two attorneys for personal injury lien patients, the landlord for Oasis, and a treating psychotherapist attesting to respondent's exemplary medical care and good character. The letters are from 2021 and pertain to his sentencing in the criminal case. The patients and attorneys describe respondent as a highly skilled and professional surgeon who went above and beyond what was expected in providing medical care. The landlord for Oasis describes respondent as a dedicated and caring physician and human being. Respondent's psychotherapist wrote that through their work together, respondent has "realized a long history of over-compliance with requests and demands of others" and now knows that "escaping discomfort and trying to meet the demands of financial pressure" caused a major lapse in judgment. (Exhibit J.)

21. Regarding the Board's costs, two Deputy Attorneys General worked on the case, and respondent argues the work of the first Deputy Attorney General was unnecessary and duplicative of the work of the second Deputy Attorney General who represented complainant at the hearing. The costs attributable to the first Deputy Attorney General total $14,225 for 64.75 hours billed between April and August 2022.

Analysis of Evidence

22. Respondent contends his criminal conduct did not arise from or occur during patient care, treatment, management, or billing, making it less serious for disciplinary purposes than a crime that did. But respondent conspired to defraud patients of their right to honest services in their medical care and treatment by accepting bribes and kickbacks intended to influence their care. In the words of the judge in his criminal case, respondent "participated in trading patient referrals for regular substantial kickbacks," which "introduced greed into the physician/patient relationship" and "robbed his patients . . . of the peace of mind that they need when going through a [surgical] procedure." (Exhibit 9, pp. A223-224.) Therefore, respondent's crime arose from patient care, management, treatment, or billing for purposes of assessing the appropriate disciplinary action.

23. In his testimony, respondent also downplayed the gravity of his crime, at times appearing to challenge the facts underlying his guilty plea and conviction. Respondent portrayed his plea agreement as borne of necessity due to an unfavorable jury instruction about honest-services fraud, rather than due to a realization of wrongdoing. Respondent also emphasized the role of the attorney for Pacific Hospital in drafting and negotiating the sham agreements, seeming to imply the attorney was at fault for respondent's unwitting participation in a crime. But in his plea agreement, respondent admitted he understood the amounts paid to him by Drobot constituted bribes and kickbacks to induce him to refer his patients to Pacific Hospital. Similarly, respondent's emphasis on the sign in his office stating that Oasis provided "contract/billing/collections/negotiations services for a number of professionals and entities" appeared to imply that respondent believes he adequately notified patients about the agreements with Pacific Hospital and PSPM. But in his plea agreement,

respondent admitted he did not disclose to patients that an unstated purpose of the agreements was to induce respondent to refer patients to Pacific Hospital.

24. Furthermore, respondent did not acknowledge that the bribery and kickback scheme "robbed his patients . . . of the peace of mind that they need when going through a [surgical] procedure." (Exhibit 9, p. A223.) Instead, respondent claimed there was no harm to patients because the agreements with Pacific Hospital and PSPM never affected respondent's medical decision making. The court's award of $45,000 in victim restitution to three patients who received implant hardware for which respondent received kickbacks is inconsistent with respondent's claim. Furthermore, respondent's belief that his crime was technical and victimless is not much different than his original belief when he first learned of the Indictment that he had done nothing wrong. This weighs against a finding that he has had a substantial change in attitude from that which existed at the time of the conspiracy.

25. As to costs, complainant's certification lacks sufficient detail to support a finding that the full amount of the original Deputy Attorney General's costs is reasonable. The hours (64.75) and costs ($14,225) of the work of the original Deputy Attorney General are more than half of the costs and hours described in the certification. This seems disproportionate to what occurred in the case during the time period of the work (April through August 2022), which was complainant's filing of the accusation, a request to OAH to schedule a hearing, and a notice of hearing. Complainant's cost certification does not explain why the hours and costs for the period are higher than expected for what occurred during that time.

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LEGAL CONCLUSIONS

Legal Standards

1. "The board shall take action against any licensee who is charged with unprofessional conduct." (Bus. & Prof. Code, § 2234; undesignated statutory references are to this code.) For criminal offenses of a licensee, "[t]he conviction of any offense substantially related to the qualifications, functions, or duties of a physician and surgeon constitutes unprofessional conduct. . . ." (§ 2236, subd. (a); see also § 490, subd. (a).) Unprofessional conduct also "includes, but is not limited to," "[t]he commission of any act involving dishonesty or corruption that is substantially related to the qualifications, functions, or duties of a physician and surgeon." (§ 2234, subd. (e).)

2. A plea of guilty is deemed to be a conviction within the meaning of section 2236. (§ 2236, subd. (d); see also § 490.) A crime, professional misconduct, or act is considered substantially related to the qualifications, functions, or duties of a licensee "if to a substantial degree it evidences present or potential unfitness of a person holding a license to perform the functions authorized by the license in a manner consistent with the public health, safety or welfare." (Cal. Code Regs., tit. 16, § 1360, subd (a).) "Such crimes, professional misconduct, or acts shall include but not be limited to the following: Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate any provision of state or federal law governing the applicant's or licensee's professional practice." (*Ibid.*) "In making the substantial relationship determination required under subdivision (a) for a crime, the board shall consider the following criteria: [¶] (1) The nature and gravity of the crime; [¶] (2) The number of years elapsed since the date of the crime; and [¶] (3)

The nature and duties of the profession." (Cal. Code Regs., tit. 16, § 1360, subd. (b); see also § 493, subd. (b)(1).)

3. "A licensee whose matter has been heard by an administrative law judge of the Medical Quality Hearing Panel as designated in Section 11371 of the Government Code . . . and who is found guilty, . . . may, in accordance with the provisions of this chapter: [¶] (1) Have his or her license revoked . . . . [¶] (2) Have his or her right to practice suspended for a period not to exceed one year . . . . [¶] (3) Be placed on probation and be required to pay the costs of probation monitoring . . . . [¶] (4) Be publicly reprimanded . . . . [¶] (5) Have any other action taken in relation to discipline as part of an order of probation, as the board or an administrative law judge may deem proper." (§ 2227, subd. (a).)

4. Complainant bears the burden of proving the alleged grounds for disciplinary action by clear and convincing evidence to a reasonable certainty. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) Clear and convincing evidence "requires a finding of high probability," and has been described as "requiring that the evidence be '"so clear as to leave no substantial doubt"; "sufficiently strong to command the unhesitating assent of every reasonable mind."' [Citation.]" (*In re Angelia P.* (1981) 28 Cal.3d 908, 919.) "Evidence of a charge is clear and convincing so long as there is a 'high probability' that the charge is true. [Citations.] The evidence need not establish the fact beyond a reasonable doubt." (*Broadman v. Commission on Judicial Performance* (1998) 18 Cal.4th 1079, 1090.)

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Analysis

CAUSES FOR DISCIPLINE

First Cause for Discipline – Criminal Conviction

5. In the first cause for discipline, complainant alleges respondent is subject to disciplinary action because he was convicted of a crime substantially related to the qualifications, functions, or duties of a physician and surgeon. (§ 2236, subd. (a).)

6. Complainant proved this cause for discipline by clear and convincing evidence. Respondent's criminal conviction for conspiracy to commit honest-services mail and wire fraud is substantially related to the qualifications, functions, or duties of a physician and surgeon considering the nature and gravity of the crime, the time elapsed since the crime, and the nature and duties of the profession. (Cal. Code Regs., tit. 16, § 1360, subd. (b.) With respect to the nature of the crime, respondent accepted bribes and kickbacks that were paid to induce him to refer patients to Pacific Hospital for spinal surgeries and other medical procedures. While accepting the bribes and kickbacks, respondent referred dozens of patients to Pacific Hospital for spinal surgeries based in part on the payments. Given these facts, the crime bore a direct and substantial relationship to respondent's medical practice.

7. With respect to the gravity of respondent's crime, it was a felony that resulted in a 15-month federal prison sentence and three years of supervised release. Respondent committed the crime between April 2008 and May 2013, and respondent admitted he received a total of $622,936 in bribes and kickbacks during that time. While considerable time has elapsed since then, respondent was not convicted of the crime until 2021, and complainant could not proceed with disciplinary charges based on the criminal conviction until it became final. (§§ 490, subd. (c), 2236.1, subd. (d).)

Under these circumstances, the time elapsed since respondent committed the crime does not preclude disciplinary action for the criminal conviction.

8. The nature and duties of the profession also support the conclusion that respondent's criminal conviction is substantially related to the qualifications, functions, or duties of a physician and surgeon. The doctor-patient relationship "is based on utmost trust and confidence in the doctor's honesty and integrity." (*Windham v. Board of Medical Quality Assurance* (1980) 104 Cal.App.3d 461, 470.) "Although referring to a real estate license, the following quotation applies with even greater force to a medical license: '[T]here is more to being a licensed professional than mere knowledge and ability. Honesty and integrity are deeply and daily involved in various aspects of the practice.' [Citation.]" (*Griffiths v. Superior Court* (2002) 96 Cal.App.4th 757, 772.) Respondent demonstrated a lack of honesty and integrity by "participat[ing] in trading patient referrals for regular substantial kickbacks and that robbed his patients . . . of the peace of mind that they need when going through a [surgical] procedure . . . . And it was for money. There's no other reason to have engaged in this conduct." (Exhibit 9, p. A224.)

9. After the hearing, the United States Supreme Court decided *Percoco v. United States* (May 11, 2023) 598 U.S. ---, 143 S.Ct. 1130 (*Percoco*), which concerns the correct legal standard for finding that a private citizen owes the government a duty of honest services. Before the hearing, respondent argued the decision in *Percoco* could "potentially eliminate[] the only basis by which Complainant brought the Accusation." (Respondent's Trial Brief, p. 9, fn. 6.) After the hearing, respondent requested official notice of the decision, and the administrative law judge granted the request. But the decision does not eliminate the criminal conviction that is the basis for the accusation, and respondent may not challenge that conviction in this administrative case.

(*Matanky v. Board of Medical Examiners* (1978) 79 Cal.App.3d 293, 302 (*Matanky*); see also *Arneson v. Fox* (1980) 28 Cal.3d 440, 452.) The specific legal issue decided in *Percoco* is also irrelevant to this case.

Second Cause for Discipline – Dishonest and Corrupt Acts

10. In the second cause for discipline, complainant charges respondent with committing acts involving dishonesty and corruption that are substantially related to the qualifications, functions or duties of a physician and surgeon. (§ 2234, subd. (e).) The alleged acts involving dishonesty and corruption are respondent's acts in furtherance of the conspiracy to commit honest-service mail and wire fraud. Complainant also charges respondent with committing healthcare fraud under Welfare and Institutions Code section 14107, but complainant did not present any legal argument about that additional charge at the hearing.

11. . Complainant proved the charge of dishonest and corrupt acts under section 2234, subdivision (e) by clear and convincing evidence. Respondent's participation in the conspiracy was a dishonest and corrupt course of conduct that related directly and substantially to respondent's qualifications, functions, and duties as a physician and surgeon, for the reasons stated in the analysis of the first cause for discipline above.

Third Cause for Discipline – Unprofessional Conduct

12. In the third cause for discipline, complainant charges respondent with general unprofessional conduct based on the same allegations as in the first and second causes for discipline. (§ 2234, subd. (a).)

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13. Complainant proved by clear and convincing evidence that respondent committed specific forms of unprofessional conduct as charged in the first and second causes for discipline. That proof also proves the charge of general unprofessional conduct in the third cause for discipline to the same extent.

DISCIPLINARY ACTION

14. With causes for disciplinary action established, the Board has discretion to determine the suitable discipline, "subject to the Legislative mandate that the Board's highest priority be protection of the public; and, secondarily, discipline should 'aid in the rehabilitation of the licensee.' (§ 2229, subds. (a) & (b).)" (*Pirouzian v. Superior Court* (2016) 1 Cal.App.5th 438, 448.) In exercising its discretion, the Board considers the Manual of Model Disciplinary Orders and Disciplinary Guidelines (12th Edition 2016) (Guidelines) that it has adopted. (Cal. Code Regs., tit. 16, § 1361, subd. (a).) "Deviation from these orders and guidelines, including the standard terms of probation, is appropriate where the Board in its sole discretion determines by adoption of a proposed decision or stipulation that the facts of the particular case warrant such a deviation – for example: the presence of mitigating factors; the age of the case; evidentiary problems." (*Ibid.*)

15. If a physician's criminal conviction or dishonest act is substantially related to the qualifications, functions, or duties of a physician and surgeon and "arises from or occurs during patient care, treatment, management, or billing," the Guidelines recommend a minimum disciplinary action of stayed revocation, a one-year suspension, and at least seven years' probation. For a felony criminal conviction not arising from or occurring during patient care, treatment, management, or billing, the Guidelines recommend a minimum disciplinary action of stayed revocation and at least seven years' probation without a suspension. If the dishonest act does not arise from

or occur during patient care, treatment, management, or billing, the Guidelines recommend a minimum disciplinary action of stayed revocation and five years' probation. The maximum disciplinary action for all of these forms of unprofessional conduct is license revocation. (Guidelines, pp. 24-25.)

16. In assessing the disciplinary action to take, the Board must also consider whether respondent made a showing of rehabilitation. "When considering the suspension or revocation of a license under Section 490 of the code on the ground that a person holding a license has been convicted of a crime, the board shall consider whether the licensee made a showing of rehabilitation," by applying criteria that differ depending on whether "the licensee completed the criminal sentence at issue without a violation of parole or probation." (Cal. Code Regs., tit. 16, § 1360.1.) The Accusation does not reference section 490, but the charge of unprofessional conduct under section 2236 based on a criminal conviction is analogous to a disciplinary charge under section 490. Therefore, the Board applies these criteria to respondent's showing of rehabilitation.

17. Respondent's crime arose from patient care, management, treatment, or billing for purposes of assessing the appropriate disciplinary action, despite respondent's argument to the contrary. Respondent dishonestly "participated in trading patient referrals for regular substantial kickbacks," which "introduced greed into the physician/patient relationship" and "robbed his patients . . . of the peace of mind that they need when going through a [surgical] procedure." (Exhibit 9, pp. A223-224.) In addition, respondent remains on supervised release, meaning he has not completed the criminal sentence at issue. Therefore, the Board must apply the rehabilitation criteria in California Code of Regulations, title 16, section 1360.1, subdivision (b). The evidence about those criteria is as follows:

(1) The nature and gravity of the act(s), professional misconduct, or crime(s). Respondent's crime was a serious felony involving dishonest and corrupt acts in respondent's medical practice. It resulted in a 15-month federal prison sentence and three years of supervised release.

(2) The total criminal record, or record of professional misconduct. Respondent has no other criminal record or prior record of professional misconduct.

(3) The time that has elapsed since commission of the act(s), professional misconduct, or crime(s). Respondent committed the crime between April 2008 and May 2013. Over 10 years have elapsed since then.

(4) Whether the licensee has complied with any terms of parole, probation, restitution, or any other sanctions lawfully imposed against such person. Respondent is on supervised release. Complainant did not contend or prove respondent has violated any terms of that release. He is current on payments on the forfeiture and restitution orders against him, but an unspecified amount is still owing.

(5) The criteria in subdivisions (a)(1)-(5), as applicable. Subdivision (a)(1) of the regulation concerns the nature and gravity of the crime, which is addressed above. Subdivisions (a)(2)-(5) concern parole or probation and any modification of terms of parole or probation. There was no showing of any modification of the terms of respondent's supervised release.

(6) If applicable, evidence of dismissal proceedings pursuant to section 1203.4 of the Penal Code. This criterion is inapplicable since respondent's federal criminal conviction is not subject to dismissal under Penal Code section 1203.4.

(7) Evidence, if any, of rehabilitation submitted by the licensee. Respondent agreed to plead guilty and completed his prison sentence on the conviction. He has

not committed any similar misconduct since his criminal conviction, and he is gainfully employed in private medical practice in Nevada. Respondent has also completed ethics and continuing education training in relation to the probation orders for his medical licenses in Nevada and Utah.

18. Considering these criteria, respondent has not made a showing of rehabilitation. Respondent abused his position of trust as a physician and surgeon to profit illegally in a sophisticated and years-long conspiracy to commit honest-services mail and wire fraud. His criminal conviction and misconduct are serious and evidence bad character, and "the more serious the misconduct and the bad character evidence, the stronger the applicant's showing of rehabilitation must be. [Citations.]" (*In re Gossage* (2000) 23 Cal.4th 1080, 1096.) While respondent's criminal conduct ended in 2013, the criminal conviction itself is much more recent, and respondent was released from prison just last year, leaving only a limited time in which to assess his rehabilitation. Respondent is also still on supervised release, and his good behavior while under supervision is accorded "little weight" in proving rehabilitation because a person under supervised release is "required to behave in exemplary fashion." (*Id.* at p. 1099.) In addition, respondent's testimony does not demonstrate he has had a substantial change in attitude from that which existed at the time of the conspiracy. Instead, respondent downplayed the gravity of his criminal conduct, at times appearing to challenge the factual basis for his criminal conviction.

19. License revocation is a "drastic penalty." (*Cooper v. State Board of Medical Examiners* (1950) 35 Cal.2d 242, 252.) But with serious misconduct and limited evidence of rehabilitation, allowing respondent to continue practicing would not be protective of the public, which is the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. Under these circumstances, revocation

is the appropriate disciplinary action and is within the Board's discretion. (See *Matanky, supra*, 79 Cal.App.3d at pp. 297-298 [revoking license of a physician convicted of submitting fraudulent Medicare claims for convalescent hospital patient services].)

COSTS

20. Complainant also requests an award of $25,057.50 for the Board's costs of investigation and enforcement of the case. Unless otherwise provided by law, "in any order issued in resolution of a disciplinary proceeding before any board within the [Department of Consumer Affairs] . . . upon request of the entity bringing the proceeding, the administrative law judge may direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case." (§ 125.3, subd. (a).)

21. In evaluating a request for costs, the administrative law judge must consider whether complainant's investigation was "disproportionately large" compared to the violation, and whether the licensee: (1) committed some misconduct but "used the hearing process to obtain dismissal of other charges or a reduction in the severity of the discipline imposed;" (2) had a "'subjective good faith belief in the merits of his or her position;'" (3) raised a "'colorable challenge'" to the proposed discipline; and (4) "will be financially able to make later payments." (*Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, 45 [quoting *California Teachers Assn. v. State of California* (1999) 20 Cal.4th 327, 342, 345].)

22. Complainant's counsel offered certifications of the Board's investigation and enforcement costs, which are prima facie evidence that those costs are reasonable. (§ 125.3, subd. (c).) Complainant's investigation was not disproportionately

large compared to the violations, and respondent did not obtain a reduction in the severity of the discipline imposed. Respondents' subjective belief in the merits of his position does not justify a reduction, and respondent did not argue he will be financially unable to pay the Board's costs.

23. However, complainant's certification of costs lacks sufficient detail to support a finding that the full amount of the original Deputy Attorney General's costs is reasonable. The hours and costs of the work of the original Deputy Attorney General seem disproportionate to what occurred in the case during the time period of the work (April through August 2022). (Factual Finding 25.) Considering what occurred during that time, $5,000 will be awarded for the work of the original Deputy Attorney General. The remaining $9,225 in costs claimed for that work are disallowed. With this reduction, the costs claimed are reasonable. Therefore, the total costs awarded to the Board are $15,832.50.

ORDER

Physician's and Surgeon's Certificate No. G 79394 issued to respondent Jeffrey David Gross, M.D., is revoked.

Respondent shall pay the Board $15,832.50 in costs within 30 days of the effective date of this order.

DATE: 07/05/2023

Thomas Heller (Jul 5, 2023 11:57 PDT)

THOMAS HELLER
Administrative Law Judge
Office of Administrative Hearings

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section S of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
09/16/2022	09/16/2022	NV		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
22-38073-1	NV Board of Medical Examiners

Reason/Charge

Related to conviction in CA federal court.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

On 9/16/22, I entered into a settlement agreement with the NV Board of Medical Examiners where my medical license was suspended, with the suspension stayed. I satisfied the terms of this agreement on or about 6/7/24.

Original Signature (electronic, copies or stamps not accepted)

2/21/26

Date

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BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **JEFFREY DAVID GROSS, M.D., Respondent.**	**Case No. 22-38073-1**

FILED
SEP 16 2022
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Donald K. White, J.D., Senior Deputy General Counsel for the Board and attorney for the IC, and Jeffrey David Gross, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorney, Kathleen T. Janssen, Esq., of the Law Offices of Cook & Kelesis, LTD., hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. BACKGROUND

1. Respondent is a medical doctor currently licensed in active status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act) to practice medicine in Nevada. His license was originally issued on February 1, 2011 (License No. 13807).

2. On April 12, 2022, in Case No. 22-38073-1, the IC filed a formal Complaint (Complaint) charging Respondent with violating the Medical Practice Act. The Complaint alleges one (1) violation of NRS 630.301(1) – Conviction of a Felony Relating to the Practice of Medicine (Count I), one (1) violation of NRS 630.301(9) – Disreputable Conduct (Count II), one (1) violation NRS 630.301(11)(g) – Conviction of an Offense Involving Moral Turpitude (Count

[1] All agreements and admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

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III), and one (1) violation of NRS 630.306(1)(b)(1) – Engaging in Conduct Which is Intended to Deceive (Count IV). By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352. Respondent was properly served with a copy of this Complaint, has reviewed and understands this Complaint, and has had the opportunity to consult with competent counsel concerning the nature and significance of this Complaint.

3. Respondent is hereby advised of his rights regarding this administrative matter, and of his opportunity to defend against the allegations in the Complaint. Specifically, Respondent has certain rights in this administrative matter as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in NRS Chapter 233B and 622A. These rights include the right to a formal hearing on the allegations in the Complaint, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is adverse to him.

4. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

5. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent

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further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

B. TERMS & CONDITIONS

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaint, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent is, and at all times relevant to the Complaint has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is represented by counsel, and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection with this administrative matter. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him or that may apply to him in connection with the administrative proceedings resulting from the Complaint filed in this matter, including defense of the Complaint, adjudication of the allegations set forth in the Complaint, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaint as set out by this Agreement, without a hearing or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. As of the time of entering into this Settlement Agreement, the allegations of the Complaint remain unproven. Respondent

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acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges Respondent is not admitting that the IC's claims/counts as alleged in the Complaint have merit and Respondent is agreeing to resolve this matter to avoid the costs of hearing and potential subsequent litigation. Respondent asserts if this matter were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaint, but for the purposes of resolving the matter and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement. Notably, the events underlying the formal Complaint and this subsequent agreement do not indicate any patient harm occurred.

5. **Consent to Entry of Order**. In order to resolve this Complaint pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. For the purposes of this Settlement Agreement, Respondent admits that sufficient evidence exists to prove Count II, one (1) violation of NRS 630.301(9) – Disreputable Conduct and Count III, one (1) violation NRS 630.301(11)(g) – Conviction of an Offense Involving Moral Turpitude and agrees that the Board may enter a finding that he violated Counts II and III.

b. Respondent's license to practice medicine in the State of Nevada shall be suspended with the suspension to be immediately stayed. Respondent's license shall be subject to suspension upon a term of probation for a period of forty-eight (48) months from the date of the Board's acceptance, adoption, and approval of this Agreement (Probationary Period). Respondent must complete the following terms and conditions within the Probationary Period and demonstrate compliance to the good faith satisfaction of the Board before or within forty-eight (48) months, including but not limited to, payment in full of costs and fees imposed, and at that time he may petition the Board to lift the probationary status of his license. If Respondent fails to demonstrate compliance with the terms and conditions of this Agreement, or otherwise violates the terms of

this Agreement or the Medical Practice Act, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing on immediate suspension of his license, which hearing will be duly noticed.

c. Respondent shall successfully complete all requirements as established by the United States District Court Central District of California in Case No. 8:18-cr-00014-JLS and the rules and regulations of the United States Probation & Pretrial Services Office and the Second Amended General Order 20-04. Respondent agrees he shall submit to the Board any and all documentation (of which he has the legal ability to obtain) regarding the terms, requirements and compliance of his supervised release, including but not limited to, reports from the United States Probation & Pretrial Services Office. Respondent agrees that if he fails to complete his supervised release in his criminal matter or is dishonorably discharged from his supervised release, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing, which will be duly noticed.

d. Respondent shall submit to and pass all five (5) sections of the Ethics and Boundaries Assessment Services (EBAS) examination within one hundred twenty (120) days of the Board's approval of this agreement, which examination shall be paid for at the expense of the Respondent.

e. Respondent shall pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matter within sixty (60) days of the Board's acceptance, adoption and approval of this Agreement, the current amount being seven hundred two dollars and seventy-three cents ($702.73).

f. Respondent shall pay a fine of two thousand five hundred dollars ($2,500.00) for Count II and two thousand five hundred dollars ($2,500.00) for Count III, for a total fine of five thousand dollars ($5,000.00) to be paid in five (5) equal payments of one thousand dollars ($1,000.00). The first payment is due on or before December 1, 2022, with each successive payment due on or before the first of each month thereafter, and must be paid in full on or before April 1, 2023, upon the Board's acceptance, adoption and approval of this Agreement.

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g. Respondent shall perform twenty (20) hours of Continuing Medical Education (CME), related to the subject matter of ethics, in addition to the required CMEs for licensure. These CME hours must be completed within six (6) months of the Board's acceptance, adoption and approval of this Agreement.

h. Respondent shall perform three hundred (300) hours of community service without compensation pursuant to the terms and conditions set forth in the attached community service proposal. The 300 hours must be completed within the probationary period of 48 months upon the Board's acceptance, adoption and approval of this Agreement.

i. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

j. Respondent shall receive a Public Letter of Reprimand.

k. Counts I and IV, and any other claims arising from the Board's corresponding investigative case file, shall be dismissed with prejudice.

6. **Release from Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement or the administration of the case referenced herein.

7. **Procedure for Adoption of Agreement**. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of this Complaint. In the course of seeking Board acceptance, approval and adoption of

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this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex-parté, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaint and any and all information of every nature whatsoever related to this matter. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves and adopts this Agreement, the Board shall issue a final order, making this Agreement an order of the Board, and, pending full compliance with the terms herein, the case shall be closed and all remaining claims arising out of the Complaint shall be dismissed with prejudice.

9. **Effect of Rejection of Agreement by Board**. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering this Complaint and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

10. **Binding Effect**. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. **Forum Selection Clause**. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the party's consent to such

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jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

12. **Attorneys' Fees and Costs**. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

13. **Failure to Comply with Terms**. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing, which will be duly noticed. Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a). Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to civil collection efforts.

DATED this 16th day of August, 2022.

INVESTIGATIVE COMMITTEE OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
DONALD K. WHITE, J.D.
Senior Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: dwhite@medboard.nv.gov
Attorney for the Investigative Committee

DATED this 16th day of August, 2022.

COOK & KELESIS, LTD.

By: _____
KATHLEEN T. JANSSEN, ESQ.
517 S. 9th Street
Las Vegas, NV 89101
Tel: (702) 737-7702
Email: kjanssen@bckltd.com
Attorney for Respondent

DATED this 1st day of August, 2022.

By: _____
JEFFREY DAVID GROSS, M.D.,
Respondent

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

ORDER

IT IS HEREBY ORDERED that, the foregoing Settlement Agreement (Case No. 22-38073-1) was approved and accepted by the Nevada State Board of Medical Examiners on the 16th day of September, 2022.

DATED this 16th day of September, 2022.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: V M Muro MD

VICTOR M. MURO, M.D.
Board President

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 895521
(775) 688-2559

COMMUNITY SERVICE PROPOSAL
(required hours: 240)

Jeffrey D. Gross, M.D.
NSBME Case No. 22-38073-1

The following is a non-exhaustive list of the types of community service that may be provided by Dr. Gross to satisfy the 300 hours of community service requirement which is referenced at paragraph 5.h. of page 6 to the *Settlement Agreement* in Case No. 22-38073-1:

1. Provide free lecture to physician groups and other health care specialists regarding spine surgery or general surgery matters.

2. Provide surgical or non-surgical clinical patient care to indigent patients throughout the State of Nevada, at no cost.

3. Assist rural hospitals to develop new spine surgery or general surgery-based services.

4. Provide free public seminars to citizen groups on spine surgery or general surgery related topics.

5. Provide free lectures on spine surgery or general surgical issues to hospitals, clinics, and/or nursing home staff and/or patients.

6. Attend local health fairs, public television or radio shows, telethons, or other similar gathering, events, or shows and provide free lectures, discussions, question and answer sessions, or facilitate discussions on spine surgery, general surgery, or other medical related topics.

7. Provide no cost "case review" for local physicians who are treating indigent patients.

8. Provide surgical and non-surgical patient care to indigent patients in the rural areas of Nevada.

9. Provide second opinions and assistance, without compensation, to other physicians providing free services or services at reduced fees.

10. Provide surgical and non-surgical patient care, without compensation, in disaster relief / emergency situations in Nevada.

11. Volunteering to provide medical/surgical related services with religious/charitable organizations in Nevada.

12. Volunteering for a nonprofit of his choice.

NOTICE OF INTENT TO PROVIDE AND PROOF OF COMPLIANCE WITH COMMUNITY SERVICE REQUIREMENTS

Except as otherwise provided herein, Dr. Gross agrees to submit written notification, via email, to Johnna LaRue, Compliance Officer, for the NSBME of any community service that he desires to perform to complete his 300 hours of community service. Ms. LaRue then has three (3) calendar days to provide any written comment or concerns, via email, to Dr. Gross pertaining to the proposed community service. If Dr. Gross does not receive any such written comments or concerns from Ms. LaRue, Dr. Gross may proceed to perform the proposed community service.

With regards to the community service referenced in paragraphs 2, 7, 8, 9, 10, and 11 above, prior written notification and pre-approval of the same is not required where time constraints are an issue or prohibit the same, including, but not limited to, emergency care being provided by Dr. Gross.

With regards to the community service referenced in paragraph 3 ("Assist rural hospitals to develop new spine surgery or general surgery-based services"), Dr. Gross agrees to submit written notification, via email, to Ms. LaRue of the proposed itinerary/schedule with regards to providing rural hospitals to develop new spine surgery or general surgery based services.

Proof of compliance of any community service required under this community service proposal shall be submitted in writing (can be scanned and emailed) directly to Ms. LaRue of the NSBME. Such written proof shall contain the following information: a description of what the community service consisted of; identify any organization, group, or individual that was the recipient of the community service; identify when and where the community service was performed; and describe the number of hours provided.

Jeffrey David GROSS

License Number:
13807

License Type:
Medical Doctor

License Status:
Active

Initial License Date:
Feb-01-2011

Expiration Date:
Jun-30-2027

Public Address:
1661 WEST HORIZON RIDGE PARKWAY Suite 280

Public City:
Henderson

Public State:
Nevada

Public ZIP Code:
89012

Public Country:
United States

Public Phone Number:
9493646888

Credential:
M.D.

Specialties

Specialty
Surgery, Neurological

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
George Washington Univ SOM / Washington , DC	Medical Doctor Degree	N/A	May-29-1992

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
Univ of California, Irvine Med Center / Orange, CA	Internship	Surgery,General	Jun-24-1992	Jun-30-1993
Univ of California, Irvine Med Center / Orange, CA	Residency	Surgery,Neurological	Jul-01-1993	Jun-30-1997
University of New Mexico , Albuquerque , NM	Fellowship	Surgery,Spine	Jul-01-1997	Jun-30-1998
University of New Mexico , Albuquerque , NM	N/A	Surgery,Neurological	Jul-01-1998	Jun-30-1999

Board Actions

Summary	Attachments
FORMAL COMPLAINT Case No. 22-38073-1 April 12, 2022 The Investigative Committee of the Nevada State Board of Medical Examiners filed a formal Complaint against Jeffrey David Gross, M.D. alleging four (4) violations of Nevada Revised Statutes (NRS) Chapter 630. Count I: Alleges a violation of NRS 630.301(1) Conviction of a Felony Relating to the Practice of Medicine. Count II: Alleges a violation of NRS 630.301(9) Disreputable Conduct. Count III: Alleges a violation of NRS 630.301(11)(g) Conviction of an Offense Involving Moral Turpitude. Count IV: Alleges a violation of NRS 630.306(a)(b)(1) Engaging in Conduct Which is Intended to Deceive. Complaint: five (5) pages.	Complaint 22-38073-1.pdf (/rest/public/data/downloadannotation/index.php?id=6259b13dfee7346d8463fef3&entity=$2y$10$93Aph7o5Kml0.HIF5BZNJejlv2lDN/KV4oUutDCPdl.F/DcMdA
COMPLIANCE Case No. 22-38073-1 June 18, 2024 Completed all terms of the settlement agreement for the above case as of June 7, 2024. ********** **SETTLEMENT AGREEMENT Case No. 22-38073-1 September 16, 2022** On September 16, 2022, the Nevada State Board of Medical Examiners (Board) accepted and approved a Settlement Agreement which allowed for an order to be entered finding that Dr. Gross violated NRS 630.301(9) and NRS 630.301(11)(g), as set forth in Counts II and III of the Complaint, and ordering the following: that his license to practice medicine in the State of Nevada be suspended, with the suspension immediately stayed and his license placed on probation for a period of 48months from the date of the Board's acceptance, adoption and approval of the Agreement, subject to various terms and conditions, including the following: he shall receive a public reprimand; pay a total fine in the amount of $5,000; complete 20 hours of Continuing Medical Education (CME), in addition to his statutory CME requirements for licensure; he shall perform 300 hours of community service without compensation; he shall successfully complete all requirements as established by the U.S. District Court Central District of California in Case No. 8:18-cr-00014-JLS and the rules and regulations of the U.S. Probation and Pretrial Services Office, and the Second Amended General Order 20-04; he shall submit to the Board documentation regarding the terms, requirements and compliance of his supervised release; he shall submit to and pass all 5 sections of the Ethics and Boundaries Assessment Services (EBAS) examination, at his own expense; and he shall reimburse the Board's fees and costs incurred in the investigation and prosecution of the case against him. Counts I and IV of the Complaint were dismissed with prejudice. Settlement Agreement: ten (10) pages	Settlement Agreement 22-38073-1.pdf (/rest/public/data/downloadannotation/index.php?id=6334662381edb50d4492cd94&entity=$2y$10$K8NhG7VS8JzJ4mROo5bcCO3rcE/pklp4lR7a2hJevPZxKbE

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
None.	

Malpractice Information

Summary	Attachments
None.	

Supervisor To

Licensee	Relationship	Date of Association
Patrick DAVIS	Additional Supervisor	May-08-2018

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Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
01/15/25	01/15/25	NV		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
22-417-CS-S	NV State Board of Pharmacy

Reason/Charge
Related to conviction in CA federal court.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

On 1/15/25, I entered into a stipulated order with the NV State Board of Pharmacy where my certificate of registration was revoked, with the ability to petition for reinstatement after one year.

Original Signature (electronic, copies or stamps not accepted)

2/21/26
Date

FILED
JAN 15 2025
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. JEFFREY D. GROSS, MD, Certificate of Registration No. CS20182, Respondent.	CASE NO. 22-417-CS-S STIPULATION AND ORDER

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Jeffrey D. Gross, MD, Certificate of Registration No. CS20182, by and through counsel, Ilene Albala, Esq., **HEREBY STIPULATE AND AGREE THAT:**

1. The Board has jurisdiction over Respondent and this matter.

2. On October 22, 2024, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing by certified mail addressed to Respondent at his last address of record in conformance with NRS 639.242(2).

3. Respondent timely filed an Answer and Notice of Defense to the Accusation on November 14, 2024.

4. Respondent is aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act),

NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondent contests the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit*:

A. On or about August 7, 2020, in *United States of America v. Jeffrey David Gross*, United States District Court for the Central District of California, Case 8:18-cr-00014-JLS, Respondent pled guilty pursuant to a plea agreement and was convicted on one felony count of conspiracy, in violation of 18 U.S. Code § 371; and

B. By his conviction, Respondent engaged in unprofessional conduct as defined in NAC 639.945(1)(h), has committed acts that would render his Nevada controlled substance registration inconsistent with the public interest, and is therefore subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

8. The alleged violations described in Paragraph 7(B) are pled with particularity in the Accusation, and are grounds for action pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.255.

9. On or about October 18, 2024, and subsequent to the filing and service of the Accusation, Respondent surrendered his DEA Registration No. [redacted] by executing a DEA Form 104, entitled "Surrender for Cause," consistent with the terms of a Memorandum of Agreement with the DEA executed on October 17, 2024. Pursuant to NRS 639.2107, the surrender of DEA Registration No. [redacted] operated as an immediate suspension of his Certificate of Registration No. CS20182 with the Board, and Respondent is no longer authorized by federal law to dispense controlled substances and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

10. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Jeffrey D. Gross, MD, Certificate of Registration No. CS20182, stipulate to the following penalties:

A. The certificate of registration of Respondent Jeffrey D. Gross, MD, Certificate of Registration No. CS20182, is revoked pursuant to NRS 453.241(1)(b);

B. Respondent may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance in Nevada until he has petitioned the Board for reinstatement pursuant to NRS 639.257 and the Board reinstates his certificate of registration;

C. Pursuant to NRS 622A.410(1) and 639.257(1), Respondent may not petition for reinstatement of his certificate of registration for a period of one (1) year from the effective date of this Order;

D. In the event Respondent applies for reinstatement of his certificate of registration, or applies for any other certificate, license or permit with the Board, he shall appear

before the Board to answer questions and give testimony regarding his application, his compliance with this Order, and the facts and circumstances underlying this matter;

E. Pursuant to NRS 639.255(1)(f), Respondent shall pay a fine of Five Thousand Dollars ($5,000.00), by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by July 1, 2025; and

F. Pursuant to NRS 622.400, Respondent shall pay One Thousand Dollars ($1000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by July 1, 2025.

11. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

12. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on January 15, 2025. Respondent will appear at the meeting to answer questions from the Board Members and/or

Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

13. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

14. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

15. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein and/or the Notice of Suspension dated November 6, 2024, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

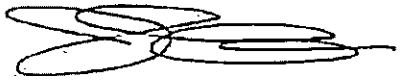
Signed this 30th **day of** December, **2024**

JEFFREY D. GROSS, MD,
Certificate of Registration No. CS20182

Signed this 15th **day of** JANUARY **2025**

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 30th day of December 2024



ILENE ALBALA, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Jeffrey D. Gross, MD, Certificate of Registration No. CS20182, in Case No. 22-417-CS-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this 15th day of January 2025.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

FILED
OCT 14 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFFREY D. GROSS, MD,** **Certificate of Registration No. CS20182,** **Respondent.**	**Case No. 22-417-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the alleged events, Respondent Jeffrey D. Gross, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS20182, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about July 21, 2021, in *United States of America v. Jeffrey David Gross*, United States District Court for the Central District of California, Case 8:18-cr-00014-JLS, Respondent pled guilty to and was convicted on one felony count of conspiracy to violate patients' rights to honest services, in violation of 18 U.S. Code § 371. The conviction resulted from Respondent accepting bribes and/or kickbacks for patient referrals to specific entities for medical care.

APPLICABLE LAW

3. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

4. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

5. Conviction of a felony related to holding a controlled substance registration or any other crime involving moral turpitude, dishonesty or corruption is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(7)(a) and (c).

COUNT ONE

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

6. By his conviction on one felony count of conspiracy to violate patients' rights to honest services, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(h) and is therefore subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT TWO

Felony Convictions for Conspiracy to Violate Patients' Rights to Honest Services

7. By his conviction on one felony count of conspiracy to violate patients' rights to honest services, Respondent is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or 639.210(7)(a) and (c).

COUNT THREE

Commission of Acts that Render Registration Inconsistent with the Public Interest

8. By his conviction on one felony count of conspiracy to violate patients' rights to honest services, Respondent has committed acts that render his Nevada controlled substance

registration inconsistent with the public interest and is therefore subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 16 day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/07/2022	08/02/2024	UT		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
DOPL 2022-146	Division of Professional Licensing of the Department of Commerce

Reason/Charge
Related to conviction in CA federal court.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

On 11/7/22, I entered into a stipulated order with the UT Division of Professional Licensing of the Department of Commerce where my medical license was revoked, with the revocation stayed with a period of probation for three years. On 8/2/24, I satisfied my period of probation and my medical license (and ability to prescribe controlled substances) was reinstated.

Original Signature (electronic, copies or stamps not accepted)

2/21/26
Date

VALERIE M. WILDE (U.S.B. 7345)
Assistant Attorney General
SEAN D. REYES (U.S.B. 7969)
Utah Attorney General
Commercial Enforcement Division
Heber M. Wells Building
Box 140872
Salt Lake City, UT 84114-6741
TEL: (801) 530-6412

BEFORE THE DIVISION OF PROFESSIONAL LICENSING

OF THE DEPARTMENT OF COMMERCE

OF THE STATE OF UTAH

IN THE MATTER OF THE LICENSE OF **JEFFREY GROSS** UTAH LICENSES #12393859-1205 & 8905 TO PRACTICE AS A PHYSICIAN/SURGEON AND TO PRESCRIBE AND ADMINISTER CONTROLLED SUBSTANCES IN THE STATE OF UTAH	)))))))	**STIPULATION AND ORDER** CASE NO. DOPL 2022- 146

JEFFREY GROSS ("Respondent") and the **DIVISION OF PROFESSIONAL LICENSING** of the Department of Commerce of the State of Utah ("Division") stipulate and agree as follows:

1. Respondent admits the jurisdiction of the Division over Respondent and over the subject matter of this action.

2. Respondent acknowledges that Respondent enters into this Stipulation knowingly and voluntarily.

3. Respondent understands that Respondent has the right to be represented by counsel in this matter and Respondent's signature below signifies that Respondent has either consulted with an

attorney or Respondent waives Respondent's right to counsel in this matter.

4. Respondent understands that by signing this document Respondent hereby waives the right to a hearing, the right to present evidence on Respondent's own behalf, the right to call witnesses, the right to confront adverse witnesses, and any other rights to which Respondent may be entitled in connection with said hearing. Respondent understands that by signing this document Respondent waives all rights to any administrative and judicial review as set forth in Utah Code Ann. §§ 63G-4-301 through 63G-4-405 and Utah Administrative Code R151-4-901 through R151-4-902. Respondent and the Division hereby express their intent that this matter be resolved expeditiously through stipulation as contemplated in Utah Code Ann. § 63G-4-102(4).

5. Respondent and the Division hereby express their intent that this matter be resolved expeditiously through stipulation as contemplated in Utah Code Ann. § 63G-4-102(4).

6. Respondent understands that this Stipulation and Order, if adopted by the Director of the Division, will be classified as a public document. The Division may release this Stipulation and Order, and will release other information about this action against Respondent's license, to other persons and entities.

7. Respondent neither admits nor denies the following, but agrees that the Division shall make the following findings of fact:

a. On or about September 16, 2021, Respondent was first licensed to practice as physician/surgeon and to administer and prescribe controlled substances in the State of Utah.

b. Respondent pled guilty to one count of the indictment, which charged Respondent with conspiracy in violation of 18 U.S.C. § 371, and specifically to violate honest services by mail and/or wire fraud (the "Plea Agreement") in the matter *United States of America v. Jeffrey David Gross*, Case No. SA Cr 18-00014-CJC. The Plea Agreement, originally filed under seal, was unsealed in in and around April 2022.

8. Respondent admits that Respondent's conduct described above is unprofessional conduct as defined in Utah Code Ann. § 58-1-501(2)(a), (b), and (c). Respondent agrees that by engaging in such conduct the Division is justified in taking disciplinary action against Respondent's licenses pursuant to Utah Code Ann. § 58-1-401(2)(a). Respondent agrees that an Order, which constitutes disciplinary action against Respondent's licenses by the Division pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. § 58-1-401(2), may be issued in this matter providing for the following action against Respondent's licenses:

(1) Respondent's license shall be revoked. That revocation shall be immediately stayed. Respondent's license shall be subject to a term of probation for a period of three years. The period of probation shall commence when the Division Director signs the attached Order. During the period of probation Respondent's licenses shall be subject to all of the following terms and conditions. If the Board or Division later deems any of the conditions are unnecessary such deletions may be made by an amended order issued unilaterally by the Division. Respondent acknowledges that Respondent has no right to modification of this Stipulation and Order, but Respondent may make a request to terminate the probation and/or Stipulation and Order early if certain conditions are met. Respondent agrees that if Respondent requests modification, the Division or Board, within their sole discretion, may agree or refuse to modify this Stipulation and Order or Respondent's request.

a. **Meeting with Board and Compliance Specialist.** Respondent shall meet with Division Compliance Specialist Jenny Johnson within two weeks of the signing of this Stipulation and Order and prior to Respondent's first meeting with the Board to review this agreement. Ms. Johnson may be reached at (801) 530-6740, or by

email at jennyajohnson@utah.gov. For the remainder of the duration of probation, Respondent shall meet with the Board or with the Division, as directed by the Division, quarterly or at such other greater or lesser frequency as the Division may direct.

b. **Completion of Criminal Sanctions.** Respondent shall complete all terms and conditions of any criminal sanctions, incurred before or during the period of this agreement, including probation or parole. If Respondent has not successfully completed all the terms and conditions of Respondent's criminal probation at the time Respondent's administrative probationary period ends, the period of Respondent's administrative probation shall be extended until all the conditions of Respondent's criminal probation have been successfully completed.

c. **Additional Continuing Education.** Respondent shall successfully complete up to six additional hours of continuing education, pre-approved by the Division and Board, focusing upon areas determined by the Board. The additional continuing education courses shall be completed within one year of the effective date of this Stipulation and Order. The additional continuing education courses shall not count toward Respondent's regular continuing education requirement and shall include ethics and boundaries.

d. **Notify Division if Further Criminal Arrest, Charge, Conviction or Mental or Substance Abuse Treatment.** If Respondent is arrested or charged with a criminal offense by any law enforcement agency, in any jurisdiction, inside or outside the State of Utah, for any reason, or should Respondent be admitted as a patient to any institution in this state or elsewhere for treatment regarding the abuse of or dependence on any chemical substance, or for treatment for any emotional or psychological disorder, Respondent agrees to cause the Division and Board to be notified immediately. If Respondent at any time during the period of this agreement is convicted of a criminal offense of any kind, or enters a plea in abeyance to a criminal offense of any kind, including a pending criminal charge, the Division may take appropriate action against Respondent, including imposing appropriate sanctions, after notice and opportunity for hearing. Such sanctions may include revocation or suspension of Respondent's license, or other appropriate sanctions.

e. **Maintain Active License.** Respondent shall maintain an active license at all times during the period of this agreement.

f. **Change of Address.** Respondent shall immediately notify the Division in writing of any change in Respondent's residential or business address.

g. **Timely Submission of Reports.** Respondent shall submit reports on the date they are due and shall appear at scheduled meetings with the Division and Board promptly. Failure to do so shall be considered a violation of this Stipulation and Order.

9. Upon approval by the Director of the Division, this Stipulation and Order shall be the final compromise and settlement of this non-criminal administrative matter. Respondent acknowledges that the Director is not required to accept the terms of this Stipulation and Order and that if the Director does not do so, this Stipulation and the representations contained therein shall be null and void, except that the Division and the Respondent waive any claim of bias or prejudgment they might otherwise have with regard to the Director by virtue of his having reviewed this Stipulation, and this waiver shall survive such nullification.

10. Respondent shall abide by and comply with all applicable federal and state laws, regulations, rules and orders related to the Respondent's licensed practice. If the Division files a Petition alleging that Respondent has engaged in new misconduct or files an Order to Show Cause Petition alleging that Respondent has violated any of the terms and conditions contained in this Stipulation and Order, the period of Respondent's probation shall be tolled during the period that the Petition or Order to Show Cause Petition has been filed and is unresolved.

11. This document constitutes the entire agreement between the parties and supersedes and cancels any and all prior negotiations, representations, understandings or agreements between the parties regarding the subject of this Stipulation and Order. There are no verbal agreements that modify, interpret, construe or affect this Stipulation. Respondent agrees not to take any action or make any public statement, that creates, or tends to create, the impression that any of the matters set forth in this Stipulation and Order are without factual basis. A public statement

includes statements to one or more Board members during a meeting of the Board. Any such action or statement shall be considered a violation of this Stipulation and Order.

12. The accompanying Order becomes effective immediately upon the approval of this Stipulation and signing of the Order by the Division Director. Respondent shall comply with all the terms and conditions of this Stipulation immediately following the Division Director's signing of the Order page of this Stipulation and Order. Respondent shall comply with and timely complete all the terms and conditions of probation. If a time period for completion of a term or condition is not specifically set forth in the Stipulation and Order, Respondent agrees that the time period for completion of that term or condition shall be set by the Board or Division. Failure to comply with and timely complete a term or condition shall constitute a violation of the Stipulation and Order and may subject Respondent to revocation or other sanctions. If Respondent violates any term or condition of this Stipulation and Order, the Division may take action against Respondent, including imposing appropriate sanction, in the manner provided by law. Such sanction may include revocation or suspension of Respondent's license, or other appropriate sanction.

13. Respondent understands that the disciplinary action taken by the Division in this Stipulation and Order may adversely affect any license that Respondent may possess in another state or any application for licensure Respondent may submit in another state.

14. Respondent has read each and every paragraph contained in this Stipulation and Order. Respondent understands each and every paragraph contained in this Stipulation and Order. Respondent has no questions about any paragraph or provision contained in this Stipulation and

Order.

DIVISION OF
PROFESSIONAL LICENSING

BY: _____
LARRY MARX
Bureau Manager

DATE: 11/3/2022

RESPONDENT

BY: _____
JEFFREY GROSS

DATE: 11/3/22

SEAN D. REYES
UTAH ATTORNEY GENERAL

BY: _____
VALERIE M. WILDE
Counsel for the Division

DATE: 11/3/2022

ORDER

THE ABOVE STIPULATION, in the matter of **JEFFREY GROSS,** is hereby approved by the Division of Professional Licensing, and constitutes my Findings of Fact and Conclusions of Law in this matter. The issuance of this Order is disciplinary action pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. § 58-1-401(2). The terms and conditions of the Stipulation are incorporated herein and constitute my final Order in this case.

DATED this 7th day of November, 2022.

DIVISION OF
PROFESSIONAL LICENSING

MARK B. STEINAGEL
Director

BEFORE THE DIVISION OF PROFESSIONAL LICENSING

OF THE DEPARTMENT OF COMMERCE

OF THE STATE OF UTAH

IN THE MATTER OF THE LICENSES OF JEFFREY GROSS TO PRACTICE AS A PHYSICIAN/SURGEON AND TO PRESCRIBE AND ADMINISTER CONTROLLED SUBSTANCES IN THE STATE OF UTAH	ORDER REINSTATING LICENSE Case No. DOPL-2022-146

BY THE DIVISION:

Respondent has satisfied the terms and conditions as set forth in the Division's Stipulation and Order, dated November 7, 2022, in the above-referenced case number.

IT IS HEREBY ORDERED the probation on the licenses of JEFFREY GROSS to practice as a physician/surgeon and to administer and prescribe controlled substances is terminated and said licenses be reinstated effective the date of this Order.

Dated this 2 day of August 2024.

Mark B. Steinagel
Division Director

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/12/2022	12/12/2022	WA		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
M2022-791	State of Washington Department of Health

Reason/Charge

Related to conviction in CA federal court.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

On 12/12/22 the State of Washington Department of Health denied my application for a medical license due to my conviction in federal court.

Original Signature (electronic, copies or stamps not accepted)

2/21/26

Date

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

RE: Jeffrey David Gross
Master Case No.: M2022-791
Document: Notice of Decision

Regarding your request for information about the above-named practitioner; attached is a true and correct copy of the document on file with the State of Washington, Department of Health, Adjudicative Clerk Office. These records are considered Certified by the Department of Health.

Certain information may have been withheld pursuant to Washington state laws. While those laws require that most records be disclosed on request, they also state that certain information should not be disclosed.

The following information has been withheld: **NONE**

If you have any questions or need additional information regarding the information that was withheld, please contact:

Customer Service Center
P.O. Box 47865
Olympia, WA 98504-7865
Phone: (360) 236-4700
Fax: (360) 586-2171

You may appeal the decision to withhold any information by writing to the Privacy Officer, Department of Health, P.O. Box 47890, Olympia, WA 98504-7890.

WASHINGTON
Medical
Commission
Licensing. Accountability. Leadership.

Notice of Decision on Application

December 12, 2022

Jeffrey David Gross
[redacted]

Application Number: MD.MD.61173267

Dear Dr. Gross:

Thank you for your application for a license to practice as a physician in the State of Washington. Following review of your application file, the Washington Medical Commission (Commission) has decided to deny your application.

Basis for this Decision.
The Commission based its decision on a 2020 plea agreement involving conspiracy and fraud. The factual basis for the decision is noted below.

> Your application file contains your original license application received on or about April 18, 2021 and includes the Addendum 4 -- Applicant's Attestation which, by your signature dated on or about March 8, 2021, attests that answers to your application questions are truthful and complete, and that documentation provided in support of your application is accurate to the best of your knowledge.
>
> In your license application, you answered "Yes" to question #3 ("*Have you* ***ever*** *been convicted, entered a plea of guilty, no contest, or a similar plea, or had prosecution or a sentence deferred or suspended as an adult or juvenile in any state or jurisdiction?*).
>
> Your application file includes reports from the Federation of State Medical Boards and the National Practitioner Data Bank which each state that on or about January 19, 2022, the Department of Health and Human Services took action to exclude you from Medicaid and Medicare based on felony conviction related to health care fraud.
>
> Your application file includes PLEA AGREEMENT FOR DEFENDANT JEFFREY DAVID GROSS from the United States District Court for the Central District of

California, No. SA CR 18-014-JLS, in the matter of *United States of America, Plaintiff, v. Jeffrey David Gross, Defendant.* That plea agreement was accepted by United States Attorney Nicola T. Hanna and was signed by you and your attorney on or about July 12, 2020 and signed by an Assistant United States Attorney on or about July 13, 2020. That plea agreement became effective upon signature and execution of all required certifications by defendant, defendant's counsel, and an Assistant United States Attorney. The following was included in the plea agreement.

> Defendant understands that for defendant to be guilty of the crime charged in count one of the indictment, that is, conspiracy, in violation of Title 18, United States Code, Section 371, the following must be true: (1) between in or about February 2008 and in or about May 2013, there was an agreement between two or more persons to commit violations of Title 18, United States Code, Section 1341, 1343, and 1346 (Honest Services Mail and Wire Fraud); (2) the defendant became a member of the conspiracy knowing of at least one of its objects and intending to help accomplish it; and (3) one of the members of the conspiracy performed at least one overt act for the purpose of carrying out the conspiracy.
>
> Defendant understands that Honest Services Mail and Wire Fraud, in violation of Title 18, United States Code, Sections 1341 and 1346, and 1343, and 1346, the objects of the conspiracy, has the following elements: (1) the defendant devised or participated in a scheme or plan to deprive a patient of his or her right to honest services; (2) the scheme or plan included payments of bribes or kickbacks to a medical professional in exchange for medical services or items; (3) the defendant owed a fiduciary duty to his patients; (4) the defendant acted with the intent to defraud by depriving the patients of their right of honest services of the medical profession; (5) the defendant's act was material, that is, it had a natural tendency to influence, or was capable of influencing, a patient's acts; and (6) the defendant used, or caused someone to use, the mails and/or an interstate wire communication to carry out or attempt to carry out the scheme or plan.

You and the United States Attorney's Office for the Central District of California agreed that the statement of facts stated in that plea agreement were sufficient to support a plea of guilty to the charge described in the agreement.

You agreed in the plea agreement that you were, indeed, guilty of the charge described in the plea agreement.

The legal basis for this decision is Section 18.130.055(1)(c) of the Revised Code of Washington (RCW) because you have been convicted of a crime involving moral turpitude as a result of the plea of guilty described above.

RCW 18.130.055 Authority of disciplining authority—Denial of applications.

(1) The disciplining authority may deny an application for licensure ...if the applicant:

...

(c) Has been convicted or is subject to current prosecution or pending charges of a crime involving moral turpitude .... For purposes of this section, conviction includes all instances in which a plea of guilty or nolo contendere is the basis for the conviction and all proceedings in which the prosecution or sentence has been deferred or suspended....

Alternative legal bases for this decision include Section 18.130.055(1)(b) of the Revised Code of Washington (RCW) with RCW 18.130.180(1), (13), and (17) based on unprofessional conduct involving moral turpitude, dishonesty, or corruption relating to the practice of your profession in violation of federal law involving fraud in the conduct of the profession.

RCW 18.130.055 Authority of disciplining authority—Denial of applications.

(1) The disciplining authority may deny an application for licensure ...if the applicant:

...

(b) Has committed any act defined as unprofessional conduct for a license holder under RCW 18.130.180....

RCW 18.130.180 Unprofessional Conduct.

The following conduct, acts, or conditions constitute unprofessional conduct for any license holder under the jurisdiction of this chapter:

(1) The commission of any act involving moral turpitude, dishonesty, or corruption relating to the practice of the person's profession, whether the act constitutes a crime or not. If the act constitutes a crime, conviction in a criminal proceeding is not a condition precedent to disciplinary action. Upon such a conviction, however, the judgment and sentence is conclusive evidence at the ensuing disciplinary hearing of the guilt of the license holder of the crime described in the indictment or information, and of the person's violation of the statute on which it is based. For the purposes of this section, conviction includes all instances in which a plea of guilty or nolo contendere is the basis for the conviction and all proceedings in which the sentence has been deferred or suspended....

...

(13) Misrepresentation or fraud in any aspect of the conduct of the business or profession;

...

(17) Conviction of any gross misdemeanor or felony relating to the practice of the person's profession. For the purposes of this subsection, conviction includes all instances in which a plea of guilty or nolo contendere is the basis for conviction and all proceedings in which the sentence has been deferred or suspended....

....

Your Right to a Hearing. If you disagree with this decision, you may request a hearing by completing the enclosed Request for Hearing form and sending it to the Department of Health, Adjudicative Clerk Office, at the following address:

Adjudicative Clerk Office
Department Of Health
P.O. Box 47879
Olympia, WA 98504-7879

Your request must be in writing, stating your basis for contesting the decision, and include a copy of this Notice of Decision on Application.

The Adjudicative Clerk Office must receive your completed Request for Hearing within 28 days of the date this Notice was sent to you or your Request for Hearing will not be considered and you will not be entitled to a hearing. If the Adjudicative Clerk Office

does not receive your Request for Hearing within 28 days of the date this Notice was sent to you, the decision to deny your application will be final.

What Happens at a Hearing? If you decide to present your application to a hearing panel, you will have the burden of proving, more probably than not, that you are qualified for licensure under the Uniform Disciplinary Act (RCW 18.130), Chapter 18.71 RCW, and the rules adopted by the Commission.

Your Right to an Interpreter at Hearing. You may request an interpreter to translate at the hearing if English is not your primary language or the primary language of any of any witness who will testify at hearing. You may also request interpretive assistance if you or any witness has a hearing or speech impairment.

Questions? If you have questions, please contact Staff Attorney Dr. Pamela Kohlmeier by email at Pamela.Kohlmeier@wmc.wa.gov. If Dr. Kohlmeier is unavailable, please contact the Licensing Manager Marisa Courtney at Marisa.Courtney@wmc.wa.gov.

Sincerely,

Melanie de Leon

MELANIE DE LEON
EXECUTIVE DIRECTOR

Enclosure

WASHINGTON
Medical
Commission
Licensing. Accountability. Leadership.

DECLARATION OF SERVICE BY MAIL

I declare that today, at Tumwater, Washington, I served a copy of the Notice of Decision on Application and Request for Hearing form by placing same into the U.S. mail, first class, postage prepaid, on to the following parties in this case:

Jeffrey David Gross
[redacted]

RESPONDENT'S ATTORNEY NAME AND ADDRESS

DATED: December 12, 2022.

FATIMA MIRZA, HEALTH SERVICES CONSULTANT

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/17/2024	10/17/2024	NA		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
NA	Drug Enforcement Administration

Reason/Charge
Related to conviction in CA federal court.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

On 10/17/24, I entered into a Memorandum of Agreement with the DEA where I surrendered my DEA registration for CA and NV with the ability to reapply in one year.

Original Signature (electronic, copies or stamps not accepted)

2/21/26
Date

MEMORANDUM OF AGREEMENT

This Memorandum of Agreement ("Agreement") is entered into by and between the U.S. Department of Justice, Drug Enforcement Administration ("DEA"), on the one hand, and Jeffrey D. Gross, M.D. ("Dr. Gross"), on the other hand (each a "Party" and collectively, the "Parties").

I. BACKGROUND

WHEREAS on July 11, 2024, DEA, by Assistant Administrator Thomas W. Prevoznik, issued an Order to Show Cause ("OSC") directing Dr. Gross to show cause why DEA should not revoke DEA Certificate of Registration ("COR") No. [redacted] (the "California COR"), pursuant to 21 U.S.C. § 824(a)(3), and deny any applications for renewal or modification of such registrations and any applications for any other DEA registrations, pursuant to 21 U.S.C. § 824(a)(3), because Dr. Gross has no state authority to handle controlled substances (the "California OSC");

WHEREAS on July 11, 2024, DEA, by Assistant Administrator Prevoznik, issued an OSC directing Dr. Gross to show cause why DEA should not revoke DEA COR No. [redacted] (the "Nevada COR"), pursuant to 21 U.S.C. § 824(a)(5), and deny any applications for renewal or modification of such registrations and any applications for any other DEA registrations, pursuant to 21 U.S.C. § 824(a)(5), because Dr. Gross has been excluded from participation in all Federal health care programs pursuant to 42 U.S.C. § 1320a-7(a) (the "Nevada OSC");

WHEREAS, DEA served the California OSC and the Nevada OSC on Dr. Gross on or about July 19, 2024;

WHEREAS, on August 9, 2024, Dr. Gross timely requested an administrative hearing on the California OSC and the Nevada OSC;

WHEREAS, the DEA Office of Administrative Law Judges assigned both matters to DEA Administrative Law Judge Teresa A. Wallbaum, who consolidated the administrative proceedings as Docket Nos. 24-59 and 24-60;

WHEREAS, on September 13, 2024, DEA filed a Prehearing Statement in the Nevada administrative proceeding (Docket No. 24-60) (the "DEA Prehearing Statement"), which included new allegations that the Nevada COR should be revoked pursuant to 21 U.S.C. § 824(a)(1);

WHEREAS, on September 27, 2024, the Parties finalized an agreement-in-principle to settle this matter after extensive arm's length negotiations;

WHEREAS, on September 30, 2024, Dr. Gross surrendered the California COR as a gesture of good faith in anticipation of the execution of this Agreement;

WHEREAS, the Parties believe that continued cooperation between the Parties, including, but not limited to, the sharing of information relating to the dispensing of controlled substances, is in the public interest;

WHEREAS, the Parties believe that a settlement in this matter is in the public interest and desire to settle and resolve all outstanding claims and/or issues with respect to Dr. Gross's eligibility to hold a DEA registration to manufacture, distribute, or dispense controlled substances;

WHEREAS, DEA believes that Dr. Gross's agreement to, and compliance with, the terms and conditions of this Agreement alleviate the need for the current administrative action pursuant to 21 U.S.C. § 824; and

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and for good and valuable consideration, the adequacy of which the Parties hereby expressly acknowledge, and intending to be legally bound by, the Parties hereby agree as follows:

II. GENERAL TERMS

1. Intention of Parties to Effect Settlement. To avoid the uncertainty and expense of litigation, the Parties agree to resolve this matter according to the Terms and Conditions below.

2. Stipulations of Fact. The Parties stipulate to, and Dr. Gross accepts responsibility for, the following facts:

a. On August 7, 2020, in the U.S. District Court for the Central District of California, under docket number 8:18-CR-00014, Dr. Gross pleaded guilty to one count of conspiracy to commit honest services mail fraud and honest services wire fraud.

b. Effective twenty (20) days from December 30, 2021, the U.S. Department of Health and Human Services, Office of Inspector General, pursuant to Section 1128(a)(3) of the Social Security Act, excluded Dr. Gross from participation in all Federal health care programs, as defined in Section 1128B(f) of the Social Security Act, for a minimum period of 10 years.

c. On August 9, 2022, Dr. Gross submitted a renewal application for the California COR. Dr. Gross's response to the first liability question disclosed Dr. Gross's 2020 guilty plea. It did not disclose that he also had been excluded from participation in all Federal health care programs.

d. Dr. Gross's response to the third liability question on the August 9, 2022 renewal application for the California COR did not also disclose that the Board of Medical Examiners of the State of Nevada (April 12, 2022), the Medical Board of California (May 2, 2022), and the Utah Department of Commerce, Division of Professional Licensing (June 22, 2022), had each filed disciplinary actions against his respective state medical licenses, which actions were then pending and subjected those licenses to potential revocation, suspension, restriction, or probation.

e. Based on Dr. Gross's conviction, the Medical Board of California revoked Dr. Gross's Physician's and Surgeon's Certificate Number G 79394 effective September 8, 2023.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following:

a. the conduct alleged in the California OSC;

b. the conduct alleged in the Nevada OSC;

c. the conduct alleged in the DEA Prehearing Statement;

d. the conduct in the Stipulations of Fact; and

e. all other conduct or information concerning or relating to Dr. Gross that is or was known to DEA on or before the Effective Date.

III. TERMS AND CONDITIONS

1. Obligations of Dr. Gross.

a. When DEA sends the executed Agreement to Dr. Gross in accordance with Paragraph IV(7), Dr. Gross will surrender the Nevada COR by 5:00 p.m. Pacific Time on the next business day.

b. Dr. Gross may apply for DEA registration to manufacture, distribute, or dispense controlled substances no earlier than one (1) year from the Effective Date.

c. Dr. Gross acknowledges that when he applies for DEA registration to manufacture, distribute, or dispense controlled substances, he must disclose all information required by the Liability Questions on the Form DEA 224 or Form DEA 224A, including, but not necessarily limited to:

i. The surrender of the California COR and the Nevada COR in response to any question whether he has "ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied";

ii. The HHS-OIG exclusion referenced in Paragraph II(2)(b) in response to any question regarding whether he has "been excluded or directed to be excluded from participation in a medicare or state health care program";

iii. The California, Nevada, and Utah disciplinary proceedings referenced in Paragraph II(2)(d), and the decision of the Washington Medical Commission denying Dr. Gross's Application No. MD.61173267, dated December 12, 2022, in response to any question whether he has "ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation."

d. Dr. Gross agrees that, when DEA again registers Dr. Gross to manufacture, distribute, or dispense controlled substances:

i. Any DEA registration held by Dr. Gross shall be limited to prescribing controlled substances in Schedules III through V (i.e., no Schedule II or IIN);

ii. Dr. Gross will maintain electronic medical charts, with automated timestamping, for any patients to whom he prescribes controlled substances;

iii. Dr. Gross will not prescribe any controlled substances to (A) his family members, (B) a romantic partner of his or the family members of any such romantic partner, or (C) any friends who are not bona fide patients; and

iv. Dr. Gross will provide to DEA every 90 days a list of all controlled substances prescriptions that he has issued in that reporting period.

e. For purpose of this Agreement, the term "family members" shall mean persons related by birth, adoption, marriage, or legal custody, including spouse, offspring, dependent, mother, father, sibling, aunt, uncle, niece, nephew, and first cousin.

f. For purpose of this Agreement, the term "friends" shall include any person with whom Dr. Gross holds a bond of attachment by feelings of affection or personal regard.

g. For purpose of this Agreement, the term "bona fide patients" shall include persons with whom Dr. Gross has a physician-patient relationship and for whom Dr. Gross maintains medical records in the due course of treatment.

h. The obligations imposed on Dr. Gross by this Agreement shall be in addition to, not in derogation of, all other requirements set forth in any applicable federal, state, and local laws and regulations. This includes, but is not limited to, the requirements set forth in Title 21 of the United States Code, the Comprehensive Drug Abuse Prevention and Control Act of 1970, and any implementing regulations promulgated by DEA.

i. Any material breach by Dr. Gross of Paragraph III(1) after the Effective Date may be a basis upon which the DEA can issue an Order to Show Cause seeking the revocation of Dr. Gross's DEA certificate(s) of registration.

j. Nothing in this Agreement shall be construed as precluding DEA from referring to any of the matters referenced herein for the purpose of establishing Dr. Gross's past conduct in the event of a future administrative action to deny, revoke, or suspend a controlled substances registration based on non-Covered Conduct. DEA is not precluded from introducing in any such administrative proceeding this Agreement, any breach of this Agreement, and any other relevant allegations during or after the term of this Agreement.

2. Obligations of DEA.

a. DEA represents that it has reviewed its records for investigations or inspections initiated or conducted prior to the Effective Date, which may allege, among other

things, that Dr. Gross was excluded from a Federal healthcare program and that he lacks authority under California law to engage in the manufacturing, distribution, or dispensing of controlled substances. DEA has not referred and agrees not to refer any conduct occurring before the Effective Date for civil penalty proceedings under 21 U.S.C. § 842 that would be based on the Covered Conduct to any other agency within the Department of Justice.

b. DEA agrees that, upon expiration of this Agreement, Dr. Gross will be eligible to apply for a modification to any registration(s) then held by Dr. Gross to include the handling of Schedule II and IIN controlled substances. DEA agrees that such modification will be granted absent any breaches of this Agreement, any violations of law or regulation relating to controlled substances identified after the Effective Date, or any pending actions against Dr. Gross by any other state or federal agency relating to authority to manufacture, dispense, or distribute controlled substances.

3. Joint Obligations of the Parties.

a. Dr. Gross and DEA agree that, upon execution of this Agreement, Dr. Gross and DEA shall file a joint motion with the DEA Administrative Law Judge to terminate the pending administrative proceeding against the Nevada COR, and DEA will deem the Nevada OSC to be a disposed of matter.

4. Release by DEA.

a. In consideration of the fulfillment of the obligations of Dr. Gross under this Agreement, DEA agrees:

i. To fully, finally, and forever release Dr. Gross from any administrative or civil claims within DEA's enforcement authority for the Covered Conduct, except as outlined in this Agreement;

ii. To refrain from filing any administrative or civil claims against Dr. Gross within DEA's enforcement authority based, in whole or in part, on the Covered Conduct or any other conduct that was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date, and the review of the reports and records Dr. Gross submitted to DEA prior to that date, except as outlined in this Agreement;

iii. That DEA will not deny any future DEA registration application filed by or on behalf of Dr. Gross, or limit, suspend, revoke, or modify any DEA certificate(s) of registration held by Dr. Gross, or attempt or seek to do any of the foregoing, based, in whole or in part, on the Covered Conduct or any other conduct that was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date, and the review of the reports and records Dr. Gross submitted to DEA prior to that date, except as outlined in this Agreement; and

iv. That DEA will not seek to admit evidence of the Covered Conduct in any other civil or administrative proceeding against Dr. Gross for non-Covered conduct, except as outlined in this Agreement.

b. Nothing in this Agreement shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof ("law enforcement agency"), from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any law enforcement agency that initiates an investigation, action, or proceeding involving the Covered Conduct.

5. Release by Dr. Gross. Dr. Gross fully and finally releases DEA, its agencies, employees, servants, and agents (the "DEA Released Parties") from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Dr. Gross has asserted, could have asserted, or may assert in the future against the DEA Released Parties related to the Covered Conduct and DEA's investigation and prosecution thereof.

6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of the Agreement as to any entity or person (including Dr. Gross) are the following:

   a. Any potential criminal liability;

   b. Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code); or

   c. Any claims based upon such obligations as are created by this Agreement.

IV. MISCELLANEOUS

1. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

2. No Additional Releases. This Agreement is intended to be for the benefit of the Parties only, and by this instrument, the Parties do not release any claims against any other person or entity.

3. Complete Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the Parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement.

4. Modifications. Any modifications to this Agreement shall be set forth in writing and signed by all Parties.

5. Advice of Counsel. The Parties represent that they enter into this Agreement with advice of counsel and knowledge of the events described herein.

6. Voluntary Agreement. The Parties represent that they enter into this Agreement voluntarily in order to avoid litigation, without any degree of duress or compulsion.

7. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory ("Effective Date"). DEA agrees to send the executed Agreement to Dr. Gross immediately upon its execution by the final DEA signatory.

8. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

9. Term. This Agreement and the obligations created by this Agreement, including, but not limited to, the obligations and limitations in Paragraph III(1), shall expire five (5) years from the Effective Date, except that the covenants and releases described in Paragraphs III(2), III(4)(a), and III(5) shall continue *ad infinitum*.

10. Authorizations. The individual(s) signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement and bind DEA to the terms herein.

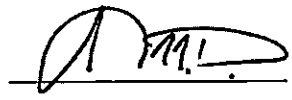
11. Disclosure. Dr. Gross and DEA may each disclose the existence of this Agreement and information about this Agreement to the public.

12. Choice of Law. This Agreement shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

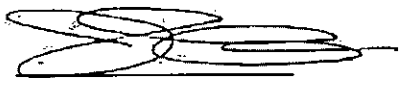
IN WITNESS WHEREOF, the Parties hereto have duly executed this Memorandum of Agreement as of the dates written below.

JEFFREY D. GROSS, M.D.

By: 

Jeffrey D. Gross, M.D.

Dated: 10/17/24

By: 

Ilene Albala
Counsel for Jeffrey D. Gross, M.D.
Goodwin Procter LLP

Dated: 10/17/24

THE UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

By: _____

Marlon C. Whitfield
Diversion Program Manager
Los Angeles Field Division
Drug Enforcement Administration

Dated: _____

13C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (05/19/2021)

(This application cannot be used by PA's or APRN's)

4

Section 1: Personal Information

First: Kelly Middle: James Last: Turner

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Home Address: [redacted]

City: Ridgway State: CO Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: MD Practitioner License #: 17670 Specialty: Emergency Medicine

(You MUST have a current and active license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Henderson Hospital

Practice Address: 1050 W Galleria Dr Suite #:

City: Henderson State: NV Zip: 89011

Telephone: 7029637000 Fax: 630-792-5636 Email: nicole.leard@uhsinc.com

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

N/A

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

2

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:
Reprimand	Nevada	03042922	21478021

Criminal Action:	State:	Date:	Case #:	County:	Court:
DUI	TX	08042018	1594484	Tarrant	Tarrant CO

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

KELLY TURNER
Print Name (First, Last)

11-21-2025
Date

Kelly Turner
Original Signature (electronic, copies or stamps not accepted)

11-21-2025
Date

Board Use Only: Date Processed: _____ Amount: _____

Institution	Program Type	Specialty Type	Start Date	End Date
William Beaumont Hospital / Royal Oak, MI	Residency	Emergency Medicine	Jul-01-1998	Jun-30-2001

Board Actions

Summary	Attachments
FORMAL COMPLAINT Case No. 21-47802-1 October 26, 2021 The Investigative Committee of the Nevada State Board of Medical Examiners filed a formal Complaint against Kelly James Turner, M.D. alleging one (1) violation of Nevada Revised Statutes (NRS) Chapter 630.301(3) Count I: Out of State Discipline. Complaint: twenty (20) pages.	Complaint 21-47802-1.PDF (/rest/public/data/downloadannotation/index.php?id=61a7bee2fee73402bcbec182&entity=$2y$10$wojRMtpsO59B3.peHXgcO..y/QYd2AONT/lPGxlddYBYv258odV3O)

Kelly James TURNER

License Number:
17670

License Type:
Medical Doctor

License Status:
Active-Probation

Initial License Date:
Jan-25-2018

Expiration Date:
Jun-30-2027

Public Address:
PO Box 15

Public City:
Ridgway

Public State:
Colorado

Public ZIP Code:
81432

Public Country:
United States

Public Phone Number:
[redacted]

Credential:
M.D.

Specialties

Specialty
Emergency Medicine

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
Loma Linda University	Medical Doctor Degree	N/A	May-24-1998

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
william beaumont hospital	Internship/Residency	Emergency Medicine	Jul-01-1998	Jun-30-2001

Summary	Attachments
SETTLEMENT AGREEMENT AND ORDER Case No. 21-47802-1 March 4, 2022 On March 4, 2022, the Nevada State Board of Medical Examiners accepted and approved a Settlement Agreement which allowed for an order to be entered finding that Dr. Turner violated NRS 630.301(3), as set forth in the Complaint, and ordering that he receive a public reprimand; he shall pay a fine in the amount of five hundred dollars ($500.00); and he is to reimburse the Board's fees and costs incurred in the investigation and prosecution of the case against him. Dr. Turner's license to practice medicine in the State of Nevada is currently in inactive status. Prior to requesting to change his licensure status from "inactive" to "active," Dr. Turner agrees to complete a "fitness for duty" evaluation to address his competence to practice medicine, as well as his possible substance abuse issues. If his request to change licensure status is granted by the Board, from the date that his licensure status is changed to "active," his license shall be subject to a term of probation for a period not to exceed thirty-six (36) months from the date of the Board's acceptance, adoption and approval of the Agreement. During the probationary period, Dr. Turner shall successfully complete all requirements and comply with all orders, past or future, of the Texas Medical Board, and shall not supervise any physician assistant or collaborate with any advanced practice registered nurse in the State of Nevada. Settlement Agreement and Order: ten (10) pages.	Settlement Agreement and Order - 21-47802-1.pdf (/rest/public/data/downloadannotation/index.php?id=622f97bf81edb569d7f35c56&entity=$2y$10$o0k6wkUkskIv8rS1LmX0AeSNkVQvaGU0j9PITLDKoBJgjwV/YPid.)

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
None.	

Malpractice Information

Summary	Attachments
None.	

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **KELLY JAMES TURNER, M.D.,** **Respondent.**	**Case No. 21-47802-1** **FILED** MAR 0 4 2022 NEVADA STATE BOARD OF MEDICAL EXAMINERS By:

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Sarah A. Bradley, J.D., MBA, Deputy Executive Director and Robert G. Kilroy, J.D., Senior Deputy General Counsel for the Board and attorney for the IC, and Kelly James Turner, M.D. (Respondent), a licensed physician in Nevada, hereby enter into this Settlement Agreement (Agreement) based on the following.[1]

A. BACKGROUND

1. Respondent is a medical doctor currently licensed in inactive status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC), collectively, the Medical Practice Act (MPA), to practice medicine in Nevada. His license was originally issued on January 25, 2018 (License No. 17670).

2. On October 26, 2021, in Case No. 21-47802-1, the IC filed a formal Complaint (Complaint) charging Respondent with violating the MPA. Specifically, the Complaint alleges one (1) violation of NRS 630.301(3), Out of State Discipline (Count I). By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

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[1] All agreements and admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

3. Respondent was properly served with a copy of this Complaint, has reviewed and understands this Complaint, and has had the opportunity to consult with competent counsel concerning the nature and significance of this Complaint.

4. Respondent is hereby advised of his rights regarding this administrative matter, and of his opportunity to defend against the allegations in the Complaint. Specifically, Respondent has certain rights in this administrative matter as set out by the United States Constitution, the Nevada Constitution, the MPA, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in NRS Chapter 233B and 622A. These rights include the right to a formal hearing on the allegations in the complaint, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is averse to him.

5. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the MPA.

6. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

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B. TERMS & CONDITIONS

NOW, THEREFORE, to resolve the matters addressed herein, i.e., the matters about the Complaint, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent is, and always relevant to the Complaint has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is represented by counsel and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly, and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly, and intelligently waives all rights in connection with this administrative matter. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the MPA, the OML, the APA, and any other legal rights that may be available to him or that may apply to him in connection with the administrative proceedings resulting from the Complaint filed in this matter, including defense of the Complaint, adjudication of the allegations set forth in the Complaint, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaint as set out by this Agreement, without a hearing or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. As of the time of entering into this Settlement Agreement, the allegations of the Complaint remain unproven. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the MPA. The IC acknowledges Respondent is not admitting that the IC's claims/counts as alleged in the Complaint have merit and Respondent

is agreeing to resolve this matter to avoid the costs of hearing and potential subsequent litigation. Respondent asserts if this matter were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaint, but for the purposes of resolving the matter and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses to effectuate this Agreement.

5. **Consent to Entry of Order**. To resolve this Complaint pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the MPA. Accordingly, the following terms and conditions are hereby agreed upon:

a. Respondent admits to Count I of the Complaint, violation of NRS 630.301(3), Out of State Discipline.

b. Respondent will pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matter within sixty (60) days of the Board's acceptance, adoption, and approval of this Agreement in the amount of five hundred sixty-eight dollars and four cents ($568.04).

c. Respondent shall pay a fine of $500 within sixty (60) days of the Board's acceptance, adoption, and approval of this Agreement.

d. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

e. Respondent shall receive a Public Letter of Reprimand.

f. From the date that Respondent's license is changed to "active" status, Respondent's license shall be subject to a term of probation for a period not to exceed thirty-six (36) months from the date of the Board's acceptance, adoption, and approval of this Agreement (Probationary Period).

g. During the Probationary Period, Respondent shall successfully complete all requirements and comply with all Orders, past or future, of the Texas Medical Board, specifically including, but not limited to, the Texas Medical Board's Order Granting Modification issued on October 15, 2021, in its Case No. L-4152.

h. During the Probationary Period, Respondent shall not supervise any Physician Assistant, or collaborate with any Advanced Practice Registered Nurse in the State of Nevada.

i. At the time of the execution of this Agreement, Respondent's license is in an "inactive" status. Prior to changing his licensure status in Nevada from "inactive" to "active," Respondent agrees to complete a 'fitness for duty' evaluation which addresses his competence to practice medicine, as well as his possible substance abuse issues. If this evaluation results in any recommendations, then before Respondent's license may be changed from "inactive" to "active," Respondent will come before the Board at a public Board meeting for the Board to review these recommendations and potentially order Respondent to complete those recommendations, which may result in the Board placing conditions, limitations, or other requirements upon Respondent's license.

6. **Release from Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement or the administration of the case referenced herein.

7. **Procedure for Adoption of Agreement**. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of this Complaint. While seeking Board acceptance, approval, and adoption of this

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Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex-parté, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaint and all information of every nature whatsoever related to this matter. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves, and adopts this Agreement, the Board shall issue a final order, making this Agreement an order of the Board, and, pending full compliance with the terms herein, the case shall be closed and all remaining claims arising out of the Complaint shall be dismissed with prejudice.

9. **Effect of Rejection of Agreement by Board**. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering this Complaint and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

10. **Binding Effect**. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. **Forum Selection Clause**. The parties agree that in the event either party is required to seek enforcement of this Agrcement in district court, the party's consent to such

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jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

12. **Attorneys' Fees and Costs**. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

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13. **Failure to Comply with Terms**. Should Respondent fail to comply with any term or condition of this Agreement after the Agreement has been accepted, approved, and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing, which will be duly noticed. Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses, or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. *See* NRS 630.3065(2)(a). Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to civil collection efforts.

DATED this 4th day of February 2022.

INVESTIGATIVE COMMITTEE OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: Sarah A. Bradley
SARAH A. BRADLEY, J.D., MBA
Deputy Executive Director
ROBERT G. KILROY, J.D.
Senior Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Attorney for the Investigative Committee

DATED this 2nd day of February, 2022.

By: Kelly James Turner, M.D.
KELLY JAMES TURNER, M.D.,
Respondent

State of _____
County of _____
This instrument was acknowledged before me on this _____ day of _____, 2022, by KELLY JAMES TURNER, M.D.

_____
NOTARY PUBLIC

X SEE ATTACHED
Notary Public

ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of San Bernardino)

On 2.2.2022 before me, Claudia Melendez, Notary Public
(insert name and title of the officer)

personally appeared Kelly James Turner,
who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

CLAUDIA MELENDEZ
COMM. #2376643
Notary Public - California
SAN BERNARDINO COUNTY
My Comm. Exp. Sep. 26, 2025

Signature _____ (Seal)

ORDER

IT IS HEREBY ORDERED that, the foregoing Settlement Agreement (Case No. 21-47802-1) was approved and accepted by the Nevada State Board of Medical Examiners on the 4th day of March, 2022

DATED this 4th day of March, 2022.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

VICTOR M. MURO, M.D.
Board President

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

Explanation to Question #7

On 04 August 2018, I was involved in a minor accident in the 200 block of Grand Ave, Southlake, TX. The area in question is an outdoor mall parking lot and I had backed into another vehicle while trying to park my truck. After the attempt at parking, it was obvious I couldn't park my truck in the small space and I drove around the corner, parked, and then walked back to contact the owner of the vehicle. The police had responded to the scene as bystanders initially thought this was a hit and run. As I was sharing the auto insurance and driver info with the other owner, the police contacted me. I did have the odor of alcohol on my breath and after their investigation, I was arrested for DUI. I was not charged with Leaving the scene of the accident however. My BAC was 0.02 well under the legal limit, but also positive for Benzodiazepines. I ultimately was charged with DUI. I pled guilty to the offense in October, 2019, and received a 15 month probationary sentence and as of January 2021, the probationary period has ended without further issues.

11-21-25

3-24-21

LAW ENFORCEMENT USE (TxDOT USE ONLY)

☐ FATAL ☐ CMV ☐ SCHOOL BUS ☐ RAILROAD ☒ MAB ☐ SUPPLEMENT ☐ ACTIVE SCHOOL ZONE

Total Num. Units	Total Num. Persons	TxDOT Crash ID
2	2	16551353.1 /2018353352

Texas Peace Officer's Crash Report (Form CR-3 1/1/2018)

Mail to: Texas Department of Transportation, Crash Data and Analysis, P.O. Box 149349, Austin, TX 78714. Questions? Call 844/274-7457

Refer to Attached Code Sheet for Numbered Fields

*These fields are required on all additional sheets submitted for this crash (ex.: additional vehicles, occupants, injured, etc.).

IDENTIFICATION & LOCATION

*Crash Date (MM/DD/YYYY)	*Crash Time (24HRMM)	Case ID	Local Use
05/04/2018	1202	[redacted]	Dist 5

*County Name	*City Name	Outside City Limit
TARRANT	SOUTHLAKE	☐

In your opinion, did this crash result in at least $1,000 damage to any one person's property?	Latitude (Decimal Degrees)	Longitude — (Decimal Degrees)
☒ Yes ☐ No	32.948714	-97.131737

ROAD ON WHICH CRASH OCCURRED

*1 Rdwy. Sys.	*Hwy. Num.	2 Rdwy. Part	Block Num.	3 Street Prefix	*Street Name	4 Street Suffix
LR		1	250		GRAND	AVE

☐ Crash Occurred on a Private Drive or Road/Private Property/Parking Lot	☐ Toll Road/ Toll Lane	Speed Limit	Const. Zone	Workers Present	Street Desc.
		30	☐ Yes ☒ No	☐ Yes ☒ No	2-LANE CITY STREET W/PARALLEL PARKING

INTERSECTING ROAD, OR IF CRASH NOT AT INTERSECTION, NEAREST INTERSECTING ROAD OR REFERENCE MARKER

At Int.	1 Rdwy. Sys.	Hwy. Num.	2 Rdwy. Part	Block Num.	3 Street Prefix	Street Name	4 Street Suffix
☐ Yes ☒ No	LR		1	1600		CIVIC	PL

Distance from Int. or Ref. Marker	☒ FT ☐ MI	S Dir. from Int. or Ref. Marker	Reference Marker	Street Desc.	RRX Num.
250		NB		2-LANE CITY STREET	

VEHICLE, DRIVER, & PERSONS

Unit 1

Unit Num.	# Unit Desc.	Parked Vehicle	Hit and Run	LP State	LP Num.	VIN
1	1	☐	☒	TX	LBK6236	1GNSKFEC7GR443440

Veh. Year	6. Veh. Color	Veh. Make	Veh. Model	7 Body Style	Pol., Fire, EMS on Emergency (Explain in Narrative if checked)
2016	BLK	CHEVROLET	TAHOE	SV	☐

8 DL/ID Type	DL/ID State	DL/ID Num.	9 DL Class	10 CDL End.	11 DL Rest.	DOB (MM/DD/YYYY)
1	TX	[redacted]	C	95	96	[redacted]

Address (Street, City, State, ZIP): [redacted] KELLER, TX [redacted]

Person Num.	12 Pers. Type	13 Seat Position	Name: Last, First, Middle (Enter Driver or Primary Person for this Unit on first line)	14 Injury Severity	Age	15 Ethnicity	16 Sex	17 Ejct.	18 Restr.	19 Airbag	20 Helmet	21 Sol.	22 Alc. Spec.	Alc. Result	23 Drug Spec.	24 Drug Result	25 Drug Category
1	1	1	TURNER, KELLY J	K	58	W	1	1	99	1	97	N	2		2	99	99

Not Applicable - Alcohol and Drug Results are only reported for Driver/Primary Person for each Unit.

☒ Owner ☐ Lessee	Owner/Lessee Name & Address	Proof of Fin. Resp.	26 Fin. Resp. Type	Fin. Resp. Name	Fin. Resp. Num.
	TURNER, KELLY J, [redacted] KELLER, TX [redacted]	☐ Yes ☒ No ☐ Expired ☐ Exempt			

Fin. Resp. Phone Num.	27 Vehicle Damage Rating 1	27 Vehicle Damage Rating 2	Vehicle Immobilized
	CC-BD-1		☒ Yes ☐ No

Towed By	Towed To
Euless B&B Wrecker	1201 W Euless Blvd., Euless, TX 76040

Unit 2

Unit Num.	# Unit Desc.	Parked Vehicle	Hit and Run	LP State	LP Num.	VIN
2	1	☒	☐	TX	KVB4944	1GNSKBKC0JR221837

Veh. Year	6. Veh. Color	Veh. Make	Veh. Model	7 Body Style	Pol., Fire, EMS on Emergency (Explain in Narrative if checked)
2018	SIL	CHEVROLET	SUBURBAN	SV	☐

8 DL/ID Type	DL/ID State	DL/ID Num.	9 DL Class	10 CDL End.	11 DL Rest.	DOB (MM/DD/YYYY)

Address (Street, City, State, ZIP):

Person Num.	12 Pers. Type	13 Seat Position	Name: Last, First, Middle (Enter Driver or Primary Person for this Unit on first line)	14 Injury Severity	Age	15 Ethnicity	16 Sex	17 Ejct.	18 Restr.	19 Airbag	20 Helmet	21 Sol.	22 Alc. Spec.	Alc. Result	23 Drug Spec.	24 Drug Result	25 Drug Category

Not Applicable - Alcohol and Drug Results are only reported for Driver/Primary Person for each Unit.

☒ Owner ☐ Lessee	Owner/Lessee Name & Address	Proof of Fin. Resp.	26 Fin. Resp. Type	Fin. Resp. Name	Fin. Resp. Num.
	BRAND, CHRISTIE K, [redacted] WICHITA FALLS, TX 76308	☒ Yes ☐ No ☐ Expired ☐ Exempt	2	AAA TX. COUNTY MUTUAL INS. CO.	TPA120566190

Fin. Resp. Phone Num.	27 Vehicle Damage Rating 1	27 Vehicle Damage Rating 2	Vehicle Immobilized
(800) 824-614[illegible]	[illegible]		☐ Yes ☒ No

Towed By	Towed To
NOT TOWED	DRIVEN AWAY

Copy from Custodial File

Form CR-3 (Rev. 9/2018) | ID 188968766 | Crash ID 16881353.1/20183533352

DISPOSITION OF NONRECOVERED

Unit Num.	Prop. Num.	Taken To	Taken By	Date of Death (MM/DD/YYYY)	Time of Death (24HRS/MM)

CHARGES

Unit Num.	Prop. Num.	Charge	Citation/Reference Num.
1	1	Driving While Intoxicated	
2	1	DUTY UPON STRIKING UNATTENDED VEHICLE	

DAMAGE

Damaged Property Other Than Vehicles	Owner's Name	Owner's Address

CMV

Unit Num. | ☐ Hazmat Plac. | ☐ TRANSPORTING HAZARDOUS MATERIAL | ☐ 9+ CAPACITY | CMV Disabling Damage? ☐ Yes ☐ No | 29 Veh. Oper. | 29 Carrier ID Type | Carrier ID Num.

Carrier's Corp. Name | Carrier's Primary Addr. | 30 Veh. Type

31 Bus Type ☐ RGVW ☐ GVWR | Hazmat Released ☐ Yes ☐ No | 32 Hazmat Class Num. | Hazmat ID Num. | 32 Hazmat Class Num. | Hazmat ID Num. | 33 Cargo Body Type

Unit Num. ☐ RGVW ☐ GVWR | 34 Trlr. Type | CMV Disabling Damage? ☐ Yes ☐ No | Unit Num. ☐ RGVW ☐ GVWR | 34 Trlr. Type | CMV Disabling Damage? ☐ Yes ☐ No

Sequence Of Events | 35 Seq. 1 | 35 Seq. 2 | 35 Seq. 3 | 35 Seq. 4 | Intermodal Shipping Container Permit ☐ Yes ☐ No | Actual Gross Weight | Total Num. Axles

FACTORS & CONDITIONS

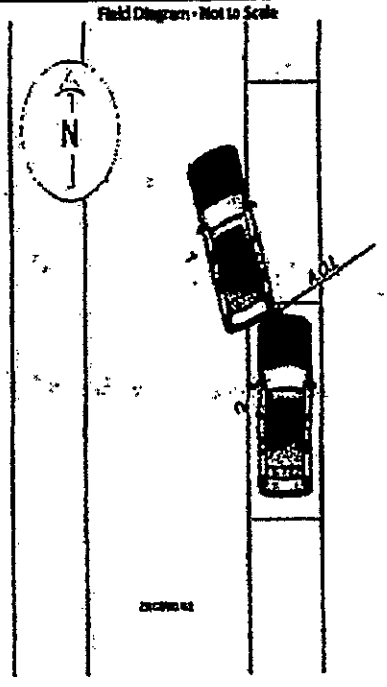
36 Contributing Factors (Investigator's Opinion)				37 Vehicle Defects (Investigator's Opinion)				38 Weather Cond.	39 Light Cond.	40 Defining Roads	41 Roadway Type	42 Roadway Alignment	43 Surface Condition	44 Traffic Control
Unit #	Contributing		May Have Contrib.		Contributing		May Have Contrib.							
1	82													
								1	1	87	1	1	1	98

NARRATIVE AND DIAGRAM

Investigator's Narrative Opinion of What Happened (Attach Additional Sheets If Necessary)

UNIT 1 WAS TRAVELING NORTHBOUND IN THE 200 BLOCK OF GRAND AVENUE. THE DRIVER OF UNIT 1 ATTEMPTED TO PARALLEL PARK IN FRONT OF 257 GRAND AVENUE. WHILE BACKING, UNIT 1 REAR BUMPER STRUCK UNIT 2 FRONT BUMPER CAUSING DAMAGE. DRIVER OF UNIT 1 THEN FLED THE SCENE AND PARKED IN A PARKING GARAGE AT 1451 FEDERAL WAY. DRIVER OF UNIT 1 WAS SUBSEQUENTLY ARRESTED FOR DRIVING WHILE INTOXICATED AND DUTY UPON OR STRIKING AN UNATTENDED VEHICLE. FRESH DAMAGE WAS LOCATED ON ALL 4 CORNERS OF UNIT 1. SOME OF THE DEBRIS ON THE FRONT BUMPER APPEARED TO POSSIBLY BE CONCRETE DUST FROM STRIKING A WALL. THE DRIVER ADMITTED TO DRINKING ALCOHOLIC.

Field Diagram - Not to Scale



INVESTIGATION

Time Notified (24HRS/MM) 1204 | How Notified Dispatched | Time Arrived (24HRS/MM) 1206 | Report Date (MM/DD/YYYY) 08/04/2018

Invest. Comp. ☒ Yes ☐ No | Investigator Name (Print) | Supervisor | ID Num. 151

ORI Num. WA | Agency Submitting Report

Copy from Custodial File

DPS SID: 10235632 TC CID: 0922227

TRN: 9263773726 TRS: A001

CASE NO. 1594484 COUNT ONE

THE STATE OF TEXAS §
§
V. §
§
KELLY JAMES TURNER §
TRUE NAME: KELLY JAMES TURNER §
§

IN THE COUNTY CRIMINAL

COURT NO. THREE

TARRANT COUNTY, TEXAS

JUDGMENT OF CONVICTION BY COURT—WAIVER OF JURY TRIAL

Judge Presiding:	HON. CHARLES L. VANOVER	Date Judgment Entered:	10/24/2019
Attorney for State:	DANI WOJCIAK	Attorney for Defendant:	JOSHUA D ROSS

Offense for which Defendant Convicted:
DRIVING WHILE INTOXICATED

Charging Instrument:
INFORMATION

Statute for Offense:
49.04 PC

Date of Offense:
08/04/2018

Degree of Offense:
CLASS B MISDEMEANOR

Plea to Offense:
GUILTY

Findings on Family Violence:
N/A

Terms of Plea Bargain:
FINE: $N/A, PLUS COURT COSTS, 90 DAYS JAIL, PROBATED FOR 15 MONTHS, PLUS CONDITIONS OF PROBATION

Plea to 1st Enhancement Paragraph:	N/A	Findings on 1st Enhancement Paragraph:	N/A
Plea to 2nd Enhancement Paragraph:	N/A	Findings on 2nd Enhancement Paragraph:	N/A

Date Sentence Imposed: 10/24/2019 Date Sentence to Commence: 10/24/2019

Punishment and Place of Confinement: 90 Days TARRANT COUNTY JAIL

THIS SENTENCE SHALL RUN CONCURRENTLY.

☒ SENTENCE OF CONFINEMENT SUSPENDED, DEFENDANT PLACED ON COMMUNITY SUPERVISION FOR 15 Months.

Fine:	Court Costs:	Restitution:	Restitution Payable to:
$ N/A	$ 395.10	$ N/A	☐ VICTIM (see below) ☐ AGENCY/AGENT (see below)

Victim Impact Statement was not returned to the attorney for State. Tex. Code Crim. Proc. Article 56.03(e)

Sex Offender Registration Requirements do not apply to the Defendant. TEX. CODE CRIM. PROC. chapter 62

The age of the victim at the time of the offense was N/A.

Time Credited: If Defendant is to serve sentence in county jail or is given credit toward fine and costs, enter days credited below. 3 DAYS NOTES: N/A

All pertinent information, names and assessments indicated above are incorporated into the language of the judgment below by reference.

This cause was called for trial in Tarrant County, Texas. The State appeared by her District Attorney.

Counsel / Waiver of Counsel (select one)

☒ Defendant appeared in person with Counsel.
☐ Defendant knowingly, intelligently, and voluntarily waived the right to representation by counsel in writing in open court.

Both parties announced ready for trial. Defendant waived the right of trial by jury and entered the plea indicated above. The Court then admonished Defendant as required by law. It appeared to the Court that Defendant was mentally competent to stand trial, made the plea freely and voluntarily, and was aware of the consequences of this plea. The Court received the plea and entered it of record. Having heard the evidence submitted, the Court found Defendant guilty of the offense indicated above. In the presence of Defendant, the Court pronounced sentence against Defendant.

The Court FINDS Defendant committed the above offense and ORDERS, ADJUDGES AND DECREES that Defendant is GUILTY of the above offense. The Court FINDS the Presentence Investigation, if so ordered, was done according to the applicable provisions of TEX. CODE CRIM. PROC. art. 42A, Subchaptor F.

CASE NO. 1594484

The Court ORDERS Defendant punished as indicated above. The Court ORDERS Defendant to pay all fines, court costs, and restitution as indicated above.

Punishment Options (select one)

☒ **County Jail—Confinement / Confinement in Lieu of Payment.** The Court ORDERS Defendant immediately committed to the custody of the Sheriff of Tarrant County, Texas on the date the sentence is to commence. Defendant shall be confined in the Tarrant County Jail for the period indicated above. The Court ORDERS that upon release from confinement, Defendant shall proceed immediately to the Office of the Tarrant County Clerk. Once there, the Court ORDERS Defendant to pay, or make arrangements to pay, any remaining unpaid fines, court costs, and restitution as ordered by the Court above.

☐ **Fine Only Payment.** The punishment assessed against Defendant is for a FINE ONLY. The Court ORDERS Defendant to proceed immediately to the Office of the Tarrant County Clerk. Once there, the Court ORDERS Defendant to pay or make arrangements to pay all fines and court costs as ordered by the Court in this cause.

Execution / Suspension of Sentence (select one)

☐ The Court ORDERS Defendant's sentence EXECUTED.

☒ The Court ORDERS Defendant's sentence of confinement SUSPENDED. The Court ORDERS Defendant placed on community supervision for the adjudged period (above) so long as Defendant abides by and does not violate the terms and conditions of community supervision. The order setting forth the terms and conditions of community supervision is incorporated into this judgment by reference.

The Court ORDERS that Defendant is given credit noted above on this sentence for the time spent incarcerated.

Furthermore, the following special findings or orders apply:

/S/ CHARLES L. VANOVER

JUDGE PRESIDING

Clerk: TRK

[redacted]

FILED
October 24, 2019 2:22 PM
MARY LOUISE NICHOLSON
COUNTY CLERK, TARRANT CO., TEXAS
By: _____ Deputy

Defendant signed and entered on 10/24/2019

$25.00 Time Payment Fee assessed if case balance is not paid within 30 days of judgment. (GC 133.103)
$2.00 Transaction Fee assessed for each payment. (CCP 102.072)

MARY LOUISE NICHOLSON, TARRANT COUNTY CLERK

By: _____
Deputy Clerk

F I L E D
October 24, 2019 2:22 PM
MARY LOUISE NICHOLSON
COUNTY CLERK,
TARRANT CO., TEXAS

By: _____
Deputy

14

15

15A

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

Workshop – April 16, 2026

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[~~omitted material~~]** is material to be omitted. and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: § 1, NRS 639.070

A REGULATION relating to pharmacy; establishing record keeping requirements of controlled substances by a pharmacy; and providing other matters properly relating thereto.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

1. In addition to any other requirements for keeping records, a pharmacy shall maintain the following records on paper or in a computer system used by the pharmacy:

a. A copy of the order placed on an order form approved by the Drug Enforcement Administration (DEA) or a copy of the electronic order through the Controlled Substance Ordering System (CSOS), properly dated and initialed, copies of each unaccepted or defective order form, and any attached statements or other documents.

i. If the copy of the electronic order through CSOS is maintained in a computer system used by the pharmacy, then an electronic initial is acceptable.

b. Suppliers' invoices of controlled substances and dangerous drugs.

i. A pharmacist of the pharmacy shall clearly record on each invoice or make a paper or electronic record of the actual date on which the controlled substance was received.

ii. A pharmacist or other personnel of the pharmacy shall clearly record on each invoice or make a paper or electronic record of the actual date on which the dangerous drug was received.

c. Suppliers' credit memos for controlled substances and dangerous drugs.

d. The biennial inventory of controlled substances required by the DEA.

a. Any reports of theft or significant loss of controlled substances submitted to the DEA and the Board pursuant to 21 CFR 1301.74(c) and NRS 453.568, respectively.

b. Reports of the surrender or destruction of controlled substances to an appropriate state or federal agency.

2. *In addition to the requirements pursuant to NRS 453.568, a pharmacy shall:*

a. Maintain an electronic or paper perpetual inventory of any controlled substance listed in schedules II through IV, which must be maintained and can only be modified or changed by a registered pharmacist;

b. Initiate an investigation within 72 hours to determine cause of discrepancy or loss or theft of any controlled substance and determine the cause within 30 days.

3. *A pharmacy shall maintain the records as required in subsection 1 and 2:*

a. In a readily retrievable manner; and

b. In a manner that establishes the receipt, distribution, destruction, loss, or theft of all controlled substances handled by the pharmacy.

4. *As used in this chapter, "perpetual inventory" means a system of accounting used to track and record stock levels, in which every purchase, dispensation, administration, loss, theft, return and sale of stock is logged immediately.*

15B

Proposed Regulation of the Nevada State Board of Pharmacy

April 16, 2026

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 453.146; NRS 453.221; NRS 639.070

A REGULATION relating to controlled substances adding mitragynine, hydroxymitragynine and mitragynine pseudoindoxyl to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.

NAC 453.510 is hereby amended to read as follows:

1. Schedule I consists of the drugs and other substances listed in this section by whatever official, common, usual, chemical or trade name designated

2. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including, without limitation, their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

Acetylmethadol;

Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide) (some trade or other names: acryloylfentanyl);

Allylprodine;

Alpha' -methyl butyryl fentanyl (2-methyl-N-(1-phenethylpiperidin-4-yl)-phenylbutanamide);

Alphacetylmethadol (except levo-alphacetylmethadol, commonly referred to as levo-alpha-

acetylmethadol, levomethadyl acetate or “LAAM”);

Alphameprodine;

Alphamethadol;

Alphamethylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

Benzethidine;

Betacetylmethdol;

Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxythiofentanyl (trade or other names: N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide; N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide);

Betameprodine;

Beta-methylacetyl fentanyl (N-phenyl-N-(1-(2-phenylpropyl)piperidin-4-yl)acetamide);

Betamethadol;

Betaprodine;

Butyryl fentanyl (trade or other names: N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide; N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Clonitazene;

Cyclopentylfentanyl(N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide);

Cyclopropylfentanyl(N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide);

Dextromoramide;

Diampromide;

*2',5'-dimethoxyfentanyl (*N *-(1-(2,5 dimethoxyphenethyl)piperidin-4-yl)* N*-phenylpropionamide);*

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

Dimethylthiambuten;

Dioxaphetyl butyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxeridine;

Eutylone (bk-EBDB, 1-(1,3-Benzodioxol-5-yl)-2-(ethylamino)butan-1-one, b-keto-ethylbenzodioxolylbutanamine);

Fentanyl carbamate (Ethyl-(1-phenethylpiperidin-4-yl)(phenyl)carbamate);

Fluoro furanyl fentanyl;

Fluoroacryl fentanyl;

Fluorobutyryl fentanyl;

Fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]propanamide);

Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide);

3-furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-3-carboxamide);

Furethidine;

Hydroxymitragynine (some trade or other names: 7-hydroxymitragynine; 7-HMG (αE,2S,3S,7aS,12bS)-3-ethyl-1,2,3,4,6,7,7a,12b-octahydro-7a-hydroxy-8-methoxy-α-(methoxymethylene)-indolo[2,3-a]quinolizine-2-acetic acid, methyl ester; 9-methoxy Corynantheidine hydroxyindolenine; mitragynine hydroxyindolenine);

Hydroxypethidine;

Isobutyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide);

Isovaleryl fentanyl (3-methyl-N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Isotonitazene;

Ketobemidone;

Levomoramide;

Levophenacylmorphan;

Meta -fluorofentanyl (N-(3-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide);

Meta-fluorofuranyl fentanyl (N-(3-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Meta -fluoroisobutyryl fentanyl (N-(3-fluorophenyl)- N-(1-phenethylpiperidin-4-yl) isobutyramide);

Methoxyacetyl fentanyl;

Methyl acetyl fentanyl;

2-Methyl-AP-237 (some trade or other names: 1-(2-methyl-4-(3- phenyl-2-propen-1-yl)-1-piperazinyl)-1-butanone; 2-MAP);

Methyl methoxyacetyl fentanyl (some trade or other names: 2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl));

Methylfentanyl;

Methylthiofentanyl;

Mitragynine (some trade or other names: methyl (E)-2-[(2s,3s,12bs)-3-ethyl-8-methoxy-1,2,3,4,6,7,12,12b-octahydroindolo[2,3-a]quinolizin-2-yl]-3-methoxyprop-2-enoate; (αE,2S,3S,12bS)-3-ethyl-1,2,3,4,6,7,12,12b-octahydro-8-methoxy-α-(methoxymethylene)-indolo[2,3-a]quinolizine-2-acetic acid, methyl ester; (E)-16,17-Didehydro-9,17-dimethoxy-17,18-seco-20α-yohimban-16-carboxylic acid methyl ester; 9-methoxy Corynantheidine);

Mitragynine pseudoindoxyl (some trade or other names: (αE,6'S,7'S,8'aS)-6'-ethyl 1,2',3,3',6',7',8',8'a-octahydro-4-methoxy-α-(methoxymethylene)-3-oxo-spiro[2H-indole-2,1'(5'H)-indolizine]-7'-acetic acid, methyl ester; methyl (2E)-2-[(1'S,4'R,6'S,7'S,8'aS)-6'-ethyl-4-methoxy-3-oxo-1,2',3,3',6',7',8',8'a-octahydro-5'H-spiro[indole-2,1'-indolizin]-7'-yl]-3-methoxyprop-2-enoate; MP);

Morpheridine;

MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

Noracymethadol;

Norlevorphanol;

Normethadone;

N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide (2'-fluoro ortho-fluorofentanyl; 2'-fluro 2'-fluorofentanyl);

N-pyrrolidino metonitazene (some trade or other names: metonitazepyne or 2-(4-methoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzo[d]imidazole, 2-hydroxy-1,2,3-propanetricarboxylate)

N-pyrrolidino protonitazene (some trade or other names: protonitazepyne or 5-nitro-2-(4-propoxybenzyl)-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzo[d]imidazole)

Norpipanone;

Ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide;

Ortho-chlorofentanyl (N-(2-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide);

Ortho-fluorofuranyl fentanyl (N-(2-fluorophenyl)- N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Ortho-methylcyclopropyl fentanyl (N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide);

Para chlorofentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide);

Para-chloroisobutyryl fentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Para-fluorobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

Para-fluoro valeryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)pentanamide);

Para-methoxybutyryl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

Para-methoxyfuranyl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Para-methylcyclopropyl fentanyl (N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-

yl)cyclopropanecarboxamide);

PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);

Phenadoxone;

Phenampromide;

Phenomorphan;

Phenoperidine;

Phenyl fentanyl (some trade or other names: benzoyl fentanyl);

Phenylpropanoyl fentanyl;

Piritramide;

Proheptazine;

Properidine;

Propiram;

Racemoramide;

Tetrahydrofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide);

Tetrahydrothiofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrothiophene-2-carboxamide);

Tianeptine;

Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide);

Thiofuranyl fentanyl (some trade or other names: thiophene fentanyl);

Tilidine;

Trimeperidine; or

Valeryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide).

3. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Acetorphine;

Acetyl fentanyl;

Acetyldihydrocodeine;

Benzylmorphine;

Codeine methylbromide;

Codeine-N-Oxide;

Cyprenorphine;

Desomorphine;

Dihydromorphine;

Drotebanol;

Etorphine (except hydrochloride salt);

Heroin;

Hydromorphinol;

Methyldesorphine;

Methyldihydromorphine;

Morphine methylbromide;

Morphine methylsulfonate;

Morphine-N-Oxide;

Myrophine;

Nicocodeine;

Nicomorphine;

Normorphine;

Pholcodine; or

Thebacon.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

ADB–BUTINACA (some trade or other names: N -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1 H -indazole-3-carboxamide

ADB-4en-PINACA (some trade or other names: N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1H-indazole-3-carboxamide)

Adinazolam (some trade or other names: 8-chloro-1-((dimethylamino)methyl)-6-phenyl-4H-s-triazlo(4,3-a)(1,4)benzodiazepine; adinazolamum; Deracyn);

Alpha-ethyltryptamine (some trade or other names: ET, Trip);

Alpha-methyltryptamine (some trade or other names: AMT);

Alpha -PiHP (some trade or other names: 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one)

Bromazolam (some trade or other name: 8-bromo-1-methyl-6-phenyl H[1,2,4]triazolo[4,3a][1,4]benzodiazepine; XLI-268);

1,4-Butanediol (some trade or other names: 1,4-butyleneglycol, dihydroxybutane, tetramethylene glycol, butane 1,4-diol, SomatoPro, Soma Solutions, Zen);

~~3~~-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-

dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA);

4-bromo-2,5-dimethoxyphenethylamine (some trade or other names: Nexus, 2C-B);

1-Butyl-3-(1-naphthoyl)indole-7173 (some trade or other names: JWH-073);

2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-C);

4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine (some trade or other names: Etizolam);

Clonazolam (some trade or other names: 6-(2-chlorophenyl)-1-methyl-8-nitro-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; clonitrazolam);

1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (some trade or other names: SR-18; BTM-8; RCS-8);

CUMYL-PEGACLONE (some trade or other names: SGT-151; 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one; 2,5-dihydro-2-(1-methyl-1-phenylethyl)-5-pentyl-1H-pyrido[4,3-b]indol-1-one)

Diclazepam (some trade or other names: 7-chloro-5-(2-chlorophenyl)-1,3-dihydro-1-methyl-2H-1,4-benzodiazepine-2-one; 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2H-benzo[e][1,4]diazepin-2-one; 2'-chlorodiazepam; Chlorodiazepam; Ro 5-3448);

2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA);

2,5-dimethoxy-4-ethylamphet-amine (some trade or other names: DOET);

2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (some trade or other names: 2C-E);

2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (some trade or other names: 2C-D);

2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (some trade or other names: 2C-N);

2,5-Dimethoxy-N-(2-methoxybenzyl) phenethylamine (NBOMe) and any derivative thereof

(some trade or other names: 2C-X-NBOMe; N-benzylated phenethylamines; N- o-methoxybenzyl analogs; NBOMe; 25H-NBOMe; 25B-NBOMe; 25C-NBOMe; 25D-NBOMe; 25E-NBOMe; 25I-NBOMe; 25N-NBOMe; 25P-NBOMe; 25T2-NBOMe; 25T4-NBOMe; 25T7-NBOMe);

2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (some trade or other names: 2C-P);

2,5-dimethoxy-4-(n)-propylthiophenethylamine (some trade or other names: 2C-T-7);

2-(2,5-Dimethoxyphenyl)ethanamine (some trade or other names: 2C-H);

3-[(2-Dimethylamino)ethyl]-1H-indol-4-yl acetate (some trade or other names: 4-acetoxy- N, N-dimethyltryptamine;4-AcO-DMT; psilacetin; O-acetylpsilocin; 4-acetoxy-DMT);

5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7297 (some trade or other names: CP-47,497);

5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7298 (some trade or other names: cannabicyclohexanol; CP-47,497 C8 homologue);

Ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-EDMB-PINACA);

4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone (some trade or other names: (4- ethyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone; JWH-210);

2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-2);

4F-MDMB-BUTICA (some trade or other names: 4F-MDMB-BICA; Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate; N-[[1-(4-fluorobutyl)-1H-indol-3-yl]carbonyl]-3-methyl-L-valine, methyl)

5F-EDMB-PICA (some trade or other names: 5F-EDMB-2201; Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate; N-[[1-(5-fluoropentyl)-

1H-indol-3-yl]carbonyl]-3-methyl-L-valine, ethyl ester)

Flualprazolam (some trade or other names: 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; 8-chloro-6-(2-fluoro-phenyl)-1-methyl-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; 2'-fluoro alprazolam; ortho-fluoro alprazolam);

Flubromazepam (some trade or other names: 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-Bromo-5-(2-fluorophenyl)-1H-benzo[e][1,4]diazepin- 2(3H)-one; 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one);

Flubromazolam (some trade or other names: 8-bromo-6-(2-fluorophenyl)-1-methyl-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine);

Flunitrazolam (some trade or other names: 6-(2-fluorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine);

(1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: FUB-144);

2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (Some trade or other names: FUB-AMB; MMB-FUBINACA);

[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (some trade or other names: THJ-2201; 5-fluoro THJ 018; AM2201 indazole analog; fluorpentyl JWH-018 indazole);

[1-(5-fluoropentyl)-1H-indol-3-yl]-1-naphthalenyl-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(1-naphthoyl)indole; AM-2201);

[1-(5-fluoropentyl)-1H-indol-3-yl]-(2-iodophyenyl)-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole; AM-694);

(1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: XLR-11);

1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (some trade or other names: 5F-CUMYL-PINACA; SGT-25);

1-(5-fluoropentyl)-N-(tricyclo[3.3.1.13,7]dec-1-yl)-1H-indazole-3-carboxamide (some trade or other names: N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide; APINACA 5-fluoropentyl analog; 5F-AKB48; 5-Fluoro-AKB48; 5F-APINACA; 5-Fluoro-APINACA;

1-(5-fluoropentyl)-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-(5-fluoropentyl)-1H-indole-3-carboxylic acid 8-quinolinyl ester; 5-Fluoro-PB-22; 5F-PB-22);

Flutoprazepam (some trade or other names: 7-chloro-1-(cyclopropylmethyl)-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one);

2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-I);

2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-4);

1-hexyl-3-(1-naphthoyl)indole (some trade or other names: JWH-019);

MDMB-4en-PINACA (some trade or other names: Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1H-indazole-3-carboxamido)butanoate)

Meclonazepam (some trade or other names: (3S)-5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one; Ro 11-3128);

Methoxetamine (some trade or other names: MXE; 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone)

3–MMC (some trade or other names: 3-methylmethcathinone; 2-(methylamino)-1-(3-methylphenyl)propan-1-one)

4-methoxyamphetamine (some trade or other names: 4-methoxy-alpha-methylphenethylamine; para-methoxyamphetamine; PMA);

(4-methoxy-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-081);

5-methoxy-3,4-methylenedioxyamphetamine (some trade or other names: MMDA);

5-methoxy-N, N-diisopropyltryptamine (some trade or other names: 5-meO-DIPT);

4-methyl-2,5-dimethoxyamphetamine (some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; “DOM”; “STP”);

(4-methyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-122);

Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-ADB; 5F-MDMB-PINACA);

Methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-MDMB-PICA);

Methylenedioxyamphetamine (some trade or other names: MDA);

Methylenedioxymethamphetamine (MDMA);

Methylenedioxy-N-ethylamphetamine (commonly referred to as N-ethyl-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-ethyl MDA, MDE, MDEA);

1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole-7200 (some trade or other names: JWH-200);

MMB-FUBICA ester (some trade or other names: Methyl 2-(1-(4-fluorobenzyl)-1H-indole-3-

carboxamido)-3-methyl butanoate; N-[[1-[(4-fluorophenyl)methyl]-1H-indol-3-yl]carbonyl]-L-valine, methyl ester

N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (some trade or other names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-fluorobenzyl);

N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indazole-3-carboxamide; APINACA; AKB48);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other names: ADB-CHMINACA; MAB-CHMINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (trade or other name: ADB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: AB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (trade or other name: AB-FUBINACA);

N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other name: AB-CHMINACA);

N-hydroxy-3,4-methylenedioxyamphetamine (commonly referred to as N-hydroxy-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-hydroxy MDA);

2-(2-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone (some trade or other names: 1-(1-pentyl-1H-indol-3-yl)-2-(2-methoxyphenyl)-ethanone; 1-pentyl-3-(2-methoxyphenylacetyl)indole; JWH-250);

Nifoxipam (some trade or other names: 5-(2-fluorophenyl)-1,3-dihydro-3-hydroxy-7- nitro-2H-1,4-benzodiazepin-2-one; 1,3-Dihydro-5-(2-fluorophenyl)-3-hydroxy-7-nitro- 2H-1,4-

benzodiazepin-2-one; 3-hydroxydesmethylflunitrazepam; DP 370);

Nitrazolam (some trade or other names: 1-methyl-8-nitro-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Norflurazepam (some trade or other names: 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; nor-Flurazepam; N-Desalkylflurazepam; Desalkylflurazepam; Ro 5-3367);

1-Pentyl-3-(2-chlorophenylacetyl)indole (some trade or other names: JWH-203);

1-Pentyl-3-(4-cholor-1-naphthoyl)indole (some trade or other names: JWH-398);

1-Pentyl-3-[(4-methoxy)-benzoyl]indole (some trade or other names: SR-19; BTM-4; RCS-4);

1-Pentyl-3-(1-naphthoyl)indole-7118 (some trade or other names: JWH-018; AM678);

(1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: UR-144);

1-pentyl-N-(tricyclo[3.3.1.$1^{3,7}$]dec-1-yl-1H-indole-3 carboxamide (some trade or other names: APICA; JWH-018 adamantyl carboxamide; 2NE1; SDB-001);

1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester; PB-22; QUPIC);

Phenazepam (some trade or other names: 7-bromo-5-(2-chlorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-bromo-5-(2-chlorophenyl)-1,2-dihydro-3H-1,4-benzodiazepin- 2-one; BD 98; Fenazepam; Elzepam; Phezipam; Phenorelaxan; Phenzitat);

Pyrazolam (some trade or other names: 8-bromo-1-methyl-6-(2-pyridinyl)-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine; 8-bromo-1-methyl-6-(pyridin-2-yl)-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; Pirazolam);

3,4,5-trimethoxyamphetamine;

Bufotenine (some trade or other names: 3-(beta-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethyl-aminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine);

Diethyltryptamine (some trade or other names: DET; N,N-Diethyltryptamine);

Dimethyltryptamine (some trade or other names: DMT; N,N-DMT; N,N-Dimethyltryptamine);

Fluorophenylpiperazine (some trade or other names: FPP, pFPP, 2-fluorophenylpiperazine, 3-fluorophenylpiperazine, 4-fluorophenylpiperazine);

Gamma butyrolactone (some trade or other names: GBL, Gamma Buty Lactone, 4-butyrolactone, dihydro-2(3H)-furanone, tetrahydro-2-furanone, Gamma G, GH Gold);

Gamma hydroxy butyric acid (some trade or other names: GHB);

Ibogaine (some trade or other names: 7-ethyl-6, 6 beta, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5H-pyrido (1',2':1,2) azepino (5,4-b) indole; *Tabernanthe iboga*);

Lysergic acid diethylamide;

Marijuana;

Mescaline;

Methoxyphenylpiperazine (some trade or other names: MeOPP, pMPP, 4-MPP, 2-MeOPP, 3-MeOPP, 4-MeOPP);

Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl);

Peyote (meaning all parts of the plant presently classified botanically as *Lophophora williamsii Lemaire*, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of

such plant, its seeds or extracts);

N-benzylpiperazine (some trade or other names: BZP, 1-benzylpiperazine);

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocin;

Salvinorin A (some trade or other names: Divinorin A; Methyl (2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(furan-3-yl)-6a,10b-dimethyl-4,10-dioxododecahydro-2H-benzofisochromene-7-carboxylate);

Ethylamine analog of phencyclidine (some trade or other names: N-ethyl-1-phenylcyclohexylamine; (1-phenylcyclohexyl) ethylamine; N-(1-phenylcyclohexyl) ethylamine; cyclohexamine; PCE);

Pyrrolidine analog of phencyclidine (some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine; PCPy; PHP);

1-(1-(2-thienyl)-cyclohexyl)-pyrrolidine (some trade or other names: TCPy);

Thiophene analog of phencyclidine (some trade or other names: 1-(1-(2-thienyl)-cyclohexyl)-piperidine; 2-thienyl analog of phencyclidine; TPCP; TCP); or

Trifluoromethylphenylpiperazine (some trade or other names: 1-(3-trifluoromethylphenyl)piperazine; 3-trifluoromethylphenylpiperazine; TFMPP).

 For the purposes of this subsection, “isomer” includes, without limitation, the optical, position or geometric isomer.

5. All parts of the plant presently classified botanically as Datura, whether growing or not, the seeds thereof, any extract from any part of such plant or plants, and every compound,

manufacture, salt derivative, mixture or preparation of such plant or plants, its seeds or extracts, unless substances consistent with those found in such plants are present in formulations that the Food and Drug Administration of the United States Department of Health and Human Services has approved for distribution.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of phencyclidine, mecloqualone or methaqualone having a depressant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation.

7. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers:

Alpha-PBP (some trade or other names: 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one, alpha- pyrrolidinobutiophenone);

Alpha-PVP (some trade or other names: 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone, alpha- pyrrolidinopentiophenone, alpha-pyrrolidinovalerophenone, O-2387);

Alpha-pyrrolidinoheptaphenone (some trade or other names: PV8);

Alpha-pyrrolidinohexanophenone (some trade or other names: alpha-PHP);

Aminorex;

Butylone (some trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1- one, β-keto-N-methylbenzodioxolylpropylamine, bk-MBDB);

Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone; alpha- aminopropiophenone; 2-aminopropiophenone; norephedrone);

4-chloro-alpha-pyrrolidinovalerophenone (some trade or other names: 4-chloro-a-PVP);

Dimethylone (some trade or other names: 3,4-methylenedioxy-N,Ndimethylcathinone; N,N-dimethyl MDCATH; N,N-dimethyl-3,4- methylenedioxycathinone; N,N-dimethylβ-keto-3,4-methylenedioxyamphetamine; 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)propan-1-one; bk-MDDMA);

Dipentylone (some trade or other names: 1-(1,3-benzodioxol-5-yl)-2 (dimethylamino)pentan-1-one and N,N -dimethylpentylone)N-ethylhexedrone;

Ethylone (some trade or other names: N-ethyl-3,4-methylenedioxycathinone; 1-(1,3- benzodioxol-5-yl)-2-(ethylamino)propan-1-one; MDEC; bk-MDEA);

N-ethylpentylone (1-(1,3-benzodioxol-5-yl)-2-ethylamino)-pentan-1-one) (some trade or other names: ephylone);

Ethylphenidate (some trade or other names: ethyl 2-phenyl-2-(piperidin-2-yl)acetate);

Fenethylline;

Fluoroamphetamine (some trade or other names: 2-fluoroamphetamine, 3-fluoroamphetamine, 4-fluoroamphetamine, 2-FA, 3-FA, 4-FA, PFA);

Fluoromethcathinone (some trade or other names: 4-Fluoro-N-methylcathinone, 1-(4-fluorophenyl)-2-(methylamino)propan-1-one, 4-Fluoromethcathinone (Flephedrone), 4- FMC, 3-Fluoro-N-methylcathinone, 1-(3-fluorophenyl)-2-2(methylamino)propan-1- one, 3-Fluoromethcathinone, 3-FMC, 2-Fluoro-N-methylcathinone, 1-(2-fluorophenyl)- 2-(methylamino)propan-1-one, 2-FMC);

Mephedrone (some trade or other names: Methylmethcathinone, 4-Methylmethcathinone,

4-MMC, 4-Methylephedrone);

Methamphetamine;

Methcathinone (some trade or other names: N Methylcathinone,cat);

Methedrone (some trade or other names: Methoxymethcathinone, 4-Methoxymethcathinone, bk-PMMA, methoxyphedrine);

4-methyl-alpha-ethylaminopentiophenone (some trade or other names: 4-MEAP);

4'-methyl-alpha-pyrrolidinohexiophenone (some trade or other names: MPHP);

4-methyl-alpha-pyrrolidinopropiophenone (some trade or other names: 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one, 4-MePPP);

(±)cis-4-methylaminorex ((+)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

Methylenedioxypyrovalerone (some trade or other names: 3,4-Methylenedioxypyrovalerone, MDPV);

Methylethcathinone (some trade or other names: 2-(ethylamino)-1-(4-methylphenyl)propan-1-one, 4-MEC, 4-methyl-N-ethylcathinone);

Methylone (some trade or other names: Methylenedioxy-N-methylcathinone, Methylenedioxymethcathinone, 3,4-Methylenedioxy-N-methylcathinone, bk-MDMA);

N,N-dimethylamphetamine (commonly referred to as N,N-alpha-trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine);

N-ethylamphetamine;

Naphyrone (some trade or other names: 1-(naphthalen-2-yl)-2(pyrrolidin-1-yl)pentan-1-one, naphthylpyrovalerone, naphpyrovalerone, NRG-1, O-2482);

Pentedrone (some trade or other names: 2-(methylamino)-1-phenylpentan-1-one,

α- methylaminovalerophenone); or

Pentylone (trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one; beta-keto-methylbenzodioxolylpentanamine; bk-MBDP; bk-methyl-K).

8. Unless specifically listed in another schedule, coca leaves, cocaine base or free base, or a salt, compound, derivative, isomer or preparation thereof which is chemically equivalent or identical to such substances, and any quantity of material, compound, mixture or preparation which contains coca leaves, cocaine base or cocaine free base or its isomers or any of the salts of cocaine, except decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

9. Unless specifically listed in another schedule, Tetrahydrocannabinols (natural or synthetic equivalents of substances contained in the plant, or in the resinous extractives of Cannabis, sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity such as the following:

Delta 9 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 8 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers;

Tetrahydrocannabinols contained in the genus Cannabis or in the resinous extractives of the genus Cannabis;

Synthetic equivalents of tetrahydrocannabinol substances or synthetic substances, derivatives and their isomers with a similar chemical structure; and

Since nomenclature of these substances is not internationally standardized, compounds of

these structures, regardless of numerical designation of atomic positions covered).

10. Unless specifically listed in another schedule and except as otherwise provided in subsection 11, any material, compound, mixture or preparation which contains any quantity of CBD (natural or synthetic equivalents of the substances contained in the plant or in the resinous extractives of Cannabis sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity).

11. A drug product which:

(a) Has been approved by the United States Food and Drug Administration;

(b) Contains CBD derived from any plant in the genus Cannabis or the resinous extractives thereof; and

(c) Contains not more than 0.1 percent residual THC by weight,

➥ is not a controlled substance.

JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

Proposed Scheduling: Adding mitragynine, 7-hydroxymitragynine (7-OH), and mitragynine pseudoindoxyl to Schedule I

Section 1: Summary

The Nevada State Board of Pharmacy, pursuant to NRS 453.146, proposes the placement of mitragynine, 7-hydroxymitragynine (7-OH) and mitragynine pseudoindoxyl to Schedule I.

Section 2: Background

NRS 453.146 Powers and duties of Board.
The Board shall administer the provisions of NRS 453.011 to 453.552, inclusive, and may add substances to or delete or reschedule all substances enumerated in schedules I, II, III, IV and V by regulation.

In making a determination regarding a substance, the Board shall consider the following:

1. The actual or relative potential for abuse;
2. The scientific evidence of its pharmacological effect, if known;
3. The state of current scientific knowledge regarding the substance;
4. The history and current pattern of abuse;
5. The scope, duration and significance of abuse;
6. The risk to the public health;
7. The potential of the substance to produce psychic or physiological dependence liability; and
8. Whether the substance is an immediate precursor of a controlled substance.

Section 3: Evaluation of the Scheduling Criteria

1. The actual or relative potential for abuse;

Mitragynine is the primary psychoactive alkaloid found in the Mitragyna speciosa plant, commonly known as kratom. Mitragynine accounts for up to 66 percent of the alkaloid content in kratom.[1] Manufacturers of natural kratom products profess that minor alkaloids in natural kratom are undetectable.[2] Kratom has a long history of traditional use in Southeast Asia with the use of its leaf or extracts typically ingested orally for the treatment of pain and to aid in the performance of agricultural labor.[3] These effects have been attributed to mitragynine, which acts as a partial agonist at the human μ-opioid receptor.[4] The effects of

kratom in humans are dose-dependent, with small doses producing a 'cocaine-like' stimulation while larger amounts cause 'morphine-like' sedative-narcotic effects.[5]

Although mitragynine is the most abundant alkaloid in kratom and credited for its effects, the plant contains over 40 naturally occurring known alkaloids. One study examined the likely effects of 25 of those compounds. The study concluded that all the compounds share the most structural similarities with controlled opioid analgesics, such as morphine derivatives. Further analysis determined that 22 (including mitragynine) of the 25 compounds in kratom bind to μ-opioid receptors. The authors further noted:

> The data from the PHASE model shows us that kratom compounds are predicted to affect the body just like opioids. Based on scientific information in the literature and further supported by our computational modeling and the reports of its adverse effects in humans, we feel confident in calling compounds found in kratom, opioids.[6]

The FDA confirms that no marketer has sought to develop a drug that includes kratom in the US.[7] Further, the World Health Organization verifies that kratom and its alkaloids have never been licensed for therapeutic use.[8] Mitragynine has not been approved for medical use as a drug, nor is it generally recognized as safe by the FDA.[9]

Kratom is illegal in 33 countries, including Malaysia where it is found naturally.[10] It is also banned in several states, including Alabama, Arkansas, Indiana, Vermont, Rhode Island, Louisiana, and Wisconsin.[11,12] A new law in Connecticut, effective October 1, 2025, requires the state's Department of Consumer Protection (DCP) to designate kratom and 7-hydroxymitragynie as Schedule I controlled substances.[13] On December 10, 2025, Connecticut's DCP issued a notice of decision to move forward with the scheduling action.[14] Kratom has also been identified as a Drug of Concern by the US Drug Enforcement Administration (DEA).[15]

According to a recent news report, "many people who descended into kratom addiction say gas station products sucked them in. The 'Quitting Kratom' subreddit has 52,000 members and several posts a day from people documenting their journeys trying to quit kratom and 7- OH."[16] Medications approved by the FDA to treat opioid-use disorder have been used to treat individuals experiencing substance-use disorder associated with kratom.[17] For example, a case report of a male in his 40s with a history of kratom use was successfully treated with buprenorphine/naloxone, which helped alleviate his withdrawal symptoms and allowed him to abstain from kratom. Other case examples have been cited throughout medical literature to support the use of buprenorphine/naloxone to treat kratom-use disorder.[18,19]

Another study conducted interviews with 395 kratom users and classified users into four distinct categories. Two classes included people using kratom for the self-treatment of chronic pain or substance use disorder and comprised approximately 52 percent of respondents. The other two classes, about 48 percent of respondents, reported using kratom to "get high." The study also notes that individuals who reported using kratom to "get high" and who had the highest probability of kratom-use disorder were more likely to characterize kratom as "habit-forming, addictive, problematic, and inconsistent in its effects."[20]

2. The scientific evidence of its pharmacological effect, if known;

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) notes that kratom and its related compounds are selective and full agonists of the μ-opioid receptor. The effects of kratom in humans are dose-dependent, with small doses producing a 'cocaine-like' stimulation while larger amounts cause 'morphine-like' sedative-narcotic effects.[21]

A review published in 2024 notes that "mitragynine intake may be beneficial according to previous scientific data that presents its characteristics in antinociception, antiinflammation, antidepressant, stimulant

activity, sedative activity, anxiolytic activity, cognitive effects, and management of opioid withdrawal, which might be used as natural 6 remedies for various illnesses." However, the authors noted that uncontrolled use of mitragynine may promote tolerance development and produce withdrawal symptoms upon abstinence."[22]

One study conducted of kratom users in Malaysia found high rates of severe kratom dependence among regular users. More than half of regular users (those using for more than 6 months) reported severe kratom dependence, while 45% showed moderate kratom dependence. Physical withdrawal symptoms commonly experienced include muscle spasms and pain, sleeping difficulty, watery eyes/nose, hot flashes, fever, decreased appetite, and diarrhea. Psychological withdrawal symptoms commonly reported were restlessness, tension, anger, sadness, and nervousness. The study authors also noted that regular users who consumed 3 or more glasses of kratom per day had "higher odds of developing severe Kratom dependence, withdrawal symptoms, and inability to control Kratom craving.[23]

Medications approved by the FDA to treat opioid-use disorder have been used to treat individuals experiencing kratom-use disorder. Case examples have been cited throughout medical literature to support the use of buprenorphine/naloxone to treat kratom-use disorder.[24,25] There are also examples of treating kratom withdrawal symptoms with medications such as clonidine and hydroxyzine that are often used off-label to manage opioid withdrawal.[26,27,28]

3. The state of current scientific knowledge regarding the substance;

Of the limited pharmacokinetic research available, one study of twelve enrolled subjects monitored plasma levels of mitragynine and one of its metabolites, 7-hydroxymitragynine (7- OH), at various doses. The study found that 7-OH in plasma increased in a dose proportional manner after subjects consumed mitragynine contained in botanical kratom. The study also concluded that 7-OH steady state is reached after seven days of continuous dosing.[29]

An increasing amount of 7-OH in plasma that is proportional with an individual's dose of mitragynine is important for two reasons. First, mitragynine found in consumer products today is often several times more potent than traditional leaf products. Second, 7-OH is approximately 10 times more potent than mitragynine.[30] At just 10 times the potency of mitragynine, the effects and actual abuse of 7- OH prompted Food and Drug Administration (FDA) Commissioner Dr. Martin Makary to warn that it could be the next wave of the opioid crisis.[31]

Mitragynine has not undergone randomized, placebo-controlled studies necessary to demonstrate efficacy for any condition while minimizing the significant risks associated with it.[32] "FDA has warned consumers not to use kratom because of the risk of serious adverse events, including liver toxicity, seizures, and substance use disorder (SUD). In rare cases, deaths have been associated with kratom use, as confirmed by a medical examiner or toxicology reports.

4. The history and current pattern of abuse;

Kratom has been used for centuries in Southeast Asia by laborers for its stimulant and analgesic effects.[33] As previously discussed, kratom and its primary alkaloid, mitragynine, have been used to self-treat conditions such as chronic pain, fatigue, and psychiatric disorders (including substance use disorder and attention deficit hyperactivity disorder). Still others begin using kratom for relaxation, euphoria, or to enhance performance.[34]

Despite a long history of use originating from Southeast Asia, the widespread commercialization of kratom and its primary alkaloid, mitragynine, is a recent development. Both products sold as vegetation and those

labeled as ground vegetation have been found to contain several times the amount of mitragynine than actual kratom leaf material.[35] Indeed, manufacturers of products marketed as "all natural and unadulterated" acknowledge that extracts are several times greater than the plant from which they start.[36] Postmortem toxicology findings from patients who used kratom had concentrations "higher than those reported in Thai individuals consuming traditional kratom tea without adverse effects."[37]

As kratom commercialization has grown, so too have the number of adverse events reported to poison control centers. From January 1 to July 31, 2025, poison control centers in the United States (US) received 1,690 reports of exposure cases involving kratom, a number that already surpasses the total for all of 2024.[38] Notably, adverse events associated with items that can be categorized as supplements are underreported. At least one source estimates the reporting rate for adverse events related to supplements to be approximately 2 percent.[39] Reports of kratom exposure have been associated with opioid toxicities including seizures, agitation, and death.[40]

5. The scope, duration and significance of abuse;

Although there is apparent consensus that the number of Americans who use kratom is in the millions, the precise number of those who use it is more nebulous. The Substance Abuse and Mental Health Services Administration estimated that in 2021, 1.7 million Americans aged 12 and older used kratom.[41] More recently, Harvard Medical School estimated that between 2 and 15 million Americans may be using kratom.[42]

Kratom is desirable to some because it is not always included on drug screens. Treatment providers observed, "Kratom is still one of those things that's out there that's being abused, that's not being caught [through drug screening]; I spoke to our nurse practitioner, and in small doses [kratom] doesn't show up on the [drug] screen. It's because people are taking way high doses that are detectable [on drug screens] that are not good for you, you know, addiction wise; A lot of places don't test for it [on drug screens]. So, until we started testing for it, I didn't hear that much about it, but now our lab tests routinely include kratom."[43]

6. The risk to the public health;

"FDA has warned consumers not to use kratom because of the risk of serious adverse events, including liver toxicity, seizures, and substance use disorder (SUD). In rare cases, deaths have been associated with kratom use, as confirmed by a medical examiner or toxicology reports."[44]

Evidence supports the position that the ingredients in kratom available to consumers are void of robust quality control. In 2019, FDA conducted laboratory testing on 30 different kratom products from a variety of sources. The analysis found "significant levels of lead and nickel at concentrations that exceed safe exposure for oral daily drug intake."[45] A third-party analysis of kratom products also found samples that exceeded daily exposure limits for lead. The authors noted that "non-extract products (powders, capsules, tablets) generally contain greater concentrations of elemental impurities than extract products or the soda preparation."[46]

According to the World Health Organization, chronic kratom use has been associated with at least 92 cases of liver toxicity. They note that common presenting signs and symptoms include abdominal discomfort, jaundice, pruritus, and dark-colored urine. These typically start about 3 weeks after initiation of kratom use and resolve within one month of stopping kratom use.[47]

Additionally, there are no age verification requirements to prevent the sale of kratom products to children. This raises serious concerns about the impact of these compounds on the developing brain. The 2021 National Survey on Drug Use estimates that at least 45,000 adolescents in the US (ages 12-17) used kratom

in the past year. This presents public health risks to adolescents given studies showing "adolescent kratom exposure particularly mitragynine and LKD [lyophilised kratom decoction] may cause selective cognitive and behavioral deficits. The brain metabolite profiles further suggest that the altered metabolic pathway (i.e., arachidonic acid, pantothenate and CoA, and tryptophan) may underlie the kratom-induced cognitive and behavioural deficits. Together, these findings demonstrate that adolescents' brain is sensitive to the impact of early kratom exposure during this critical development period."[48]

7. The potential of the substance to produce psychic or physiological dependence liability; and

Cases of dependence to kratom have been documented for the last several decades.[49] Mitragynine has agonist activity at μ-opioid receptors and may lead to dependence and addiction.[50] Further, the European Union Drug Agency, FDA, DEA, Mayo Clinic, and others agree that individuals can develop a dependence to kratom.[51] According to the FDA, "[c]ases of kratom-related SUD have also been observed. In these cases, individuals met certain criteria for SUD, including using kratom for longer than intended, using more kratom than intended, having cravings for kratom, continuing to use kratom despite adverse consequences (either physically or in their personal life), increasing the amount of kratom used to produce the same effect (tolerance), and experiencing withdrawal symptoms when kratom use was stopped (physical dependence)."[52]

In-person interviews with convenience samples of long-term daily oral kratom users in Southeast Asia find up to three-quarters reporting withdrawal symptoms after cessation of use. Typical withdrawal symptoms include irritability, anxiety, depression, sleep disturbance, lacrimation, rhinorrhea, muscle and bone pain, muscle spasm, diarrhea, and decreased appetite. The likelihood and severity of withdrawal are positively associated with duration, frequency, and intensity of kratom use.[53]

Another news report demonstrates the danger of having these products readily accessible. An individual using a popular kratom-based drink available at local gas stations reported spending about $2,000 per month (consuming about 10 to 12 bottles per day). According to the report, he "…soon found that after the immediate euphoria from the shot, he would be hit with a cycle of unpleasant symptoms, including a runny nose and achy body." The individual closed down their business and had to seek in-patient treatment.[54]

8. Whether the substance is an immediate precursor of a controlled substance.

Mitragynine is a known precursor to mitragynine-related compounds. According to the European Union Drug Agency, "[t]he chemical total syntheses reported for several kratom alkaloids are too complex to be used for economic production of any [of] these compounds. However, mitragynine can serve as a chemical precursor to the more potent 7-hydroxymitragynine."[55]

Mitragynine is highly likely to follow the same pattern seen with other drug classes like bath salts. Bath salts were created by modifying cathinones, a primary active ingredient found in a plant called khat.[56] As soon as one of those modifications was identified and scheduled, a new cathinone-like compound was developed to evade the law.

Looking to past illicit drug patterns, unexpected ways to synthesize mitragynine-related compounds will be established. At least one pathway would use mitragynine to make 7-OH and then MGM-15, which is a semi-synthetic derivative of 7-hydroxymitragynine, already identified in commercially available tablets.[57] Should unfettered access to mitragynine remain, we can anticipate the creation of additional potent novel compounds that are marketed to the general public, including children.

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U.S. FOOD & DRUG ADMINISTRATION

7-Hydroxymitragynine (7-OH):

An Assessment of the Scientific Data and Toxicological Concerns Around an Emerging Opioid Threat

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7-Hydroxymitragynine (7-OH):

An Assessment of the Scientific Data and Toxicological Concerns Around an Emerging Opioid Threat

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EXECUTIVE SUMMARY

Recent reports indicate increased availability and marketing of 7-hydroxymitragynine (7-OH) in the U.S., raising public health concerns due to its pharmacology. This report provides an overview on the chemical, pharmacological, and epidemiological data on 7-OH. It focuses on the characterization of 7-OH-containing products in the marketplace, the evidence of increasing human exposures, and the extensive body of preclinical studies in the scientific literature that indicate the predominant mu opioid agonist pharmacology of 7-OH. These data sources indicate that 7-OH is a potent opioid that poses an emerging public health threat, especially when considering the increasing availability of enhanced or concentrated 7-OH products in the marketplace.

7-OH is a naturally occurring substance in the kratom plant (*Mitragyna speciosa*), but only a minor constituent that comprises less than 2% of the total alkaloid content in natural kratom leaves. However, 7-OH demonstrates substantially greater mu-opioid receptor potency than kratom's primary alkaloid constituent mitragynine, as well as other classical opioids such as morphine. In vitro studies reveal 7-OH exhibits high binding affinity for mu-opioid receptors (Ki = 7.2-70 nM), with functional activity as a mu agonist. Animal behavioral studies demonstrate its rewarding effects from self-administration and conditioned place preference methods, consistent with its opioid properties. Critically, 7-OH produces respiratory depression, physical dependence, and withdrawal symptoms characteristic of classical opioids, such as morphine, fentanyl, oxycodone, and hydrocodone.

Recently, there has been a concerning proliferation of concentrated 7-OH products that are sold over the counter and online. The enhanced amount of 7-OH in these products is likely synthetically derived through oxidate chemical conversion of mitragynine isolates or kratom extracts. Given the trace amounts of 7-OH that are naturally present in kratom, direct extraction of 7-OH from plant material would simply be unfeasible economically.

Surveillance data from multiple sources, including America's Poison Centers National Poison Data System (NPDS), Drug Enforcement Administration toxicology testing programs, and social media monitoring, suggest increasing human exposure to these concentrated 7-OH products. Clinical presentations include euphoria, sedation, respiratory depression, and opioid-like withdrawal syndromes, with users acknowledging its significant addiction potential.

The pharmacological profile, abuse liability, and emerging patterns of non-medical use establish 7-OH as a dangerous substance. Current regulatory gaps have enabled widespread availability of these products despite their opioid-like properties and necessitate immediate policy intervention to address this emerging threat to American public health.

INTRODUCTION

The Context for 7-OH Concerns

7-Hydroxymitragynine (7-OH) is a component of the plant kratom (*Mitragyna speciosa*), a tropical evergreen tree in the Rubiaceae family that grows in the wetlands of Southeast Asia (Brown et al., 2017). Kratom leaves contain over 50 alkaloids, with mitragynine and 7-OH being the primary psychoactive constituents (Warner et al., 2016). Its leaves, consumed as a tea or in dry leaf form, have been used for centuries in both medicinal and recreational settings, largely due the properties of its alkaloids mitragynine and 7-OH. Typically, 7-OH occurs in botanical kratom in amounts no more than ~.01-.04 percent by dry weight (Heywood et al., 2024). Medicinally, kratom has been used to treat headaches, diarrhea, insomnia, anxiety, opioid use withdrawal, and more, while in recreational use cases, it has been associated with feelings of euphoria (Hill et al., 2025). Currently, there are no FDA-approved drugs containing kratom or kratom-derived drug substances such as 7-OH for any therapeutic indications.

Kratom products have grown in popularity since the mid-2000's; however, kratom, mitragynine, and 7-OH have faced regulatory scrutiny in the United States due to concerns about their safety and potential for abuse. None of these substances are lawful when added to conventional foods, as dietary supplements, or as ingredients in any FDA-approved drug, and yet, these substances are still sold in various markets. At the state level, some jurisdictions have implemented restrictions on their sale and use. Until now, 7-OH has not been the sole target of a regulatory response but has always been addressed alongside the kratom plant and mitragynine.

FDA issued its first import alert for kratom in 2012. At the time, kratom was being marketed in various forms for human consumption despite a lack of approved drug uses or established safety as a dietary ingredient. In the years since, additional import alerts have been issued by the Agency. The Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS) had given consideration to kratom, as well as its constituents, mitragynine and 7-OH, to determine whether these substances should be recommended for control under the Controlled Substances Act (CSA). Those actions were ultimately suspended in 2018, with the Assistant Secretary for Health at that time stating that the science was incomplete, and the available data were not adequate to support a recommendation to control these substances under the CSA.

Contemporary Outlook

Given the concerning trends with 7-OH and other kratom-related products, FDA has now determined that a more comprehensive assessment of available scientific and medical data on 7-OH is warranted. Many of the products available today, which are often associated with or advertised as kratom, no longer resemble botanical kratom. Instead, they contain "enhanced" or concentrated amounts of 7-OH and are formulated as powders, capsules, and liquid extracts designed to generate a stronger effect on users. Other products are explicitly advertised as 7-OH-containing products. One analysis of websites selling 7-OH products found that most (82.2 %) were formulated as chewable/sublingual tablets, shots, or gummies and marketed specifically as 7-OH only products (92%). The mean cost per recommended dose/serving was $3.97 (Hill et al., 2025).

As described below, research has shown that 7-OH is a potent mu-opioid receptor agonist, demonstrating pharmacological characteristics that define classical opioids like morphine and fentanyl. Based on its opioid pharmacology, there is significant potential for abuse of 7-OH. In fact, in various preclinical studies it has demonstrated greater potency than classical opioids. For example, 7-OH produces respiratory depression with more than 3-fold greater potency than morphine. Since the substance's therapeutic and psychoactive effects are mediated through the same mu-opioid receptor pathways as classical opioids, it can be considered to have opioid properties warranting similar regulatory consideration (Hill et al., 2025; Obeng et al., 2021).

In this report, FDA presents its new assessment of the available scientific data and literature on 7-OH, as well as more recent law enforcement data and the rapidly evolving trends in kratom-related products. FDA still has concerns about the safety of kratom products more broadly and the unlawful marketing of them under several regulated product categories in the Federal Food, Drug, and Cosmetic Act. However, there is a recognized need for more immediate action to address 7-OH because it is a substance with potent mu opioid agonist properties and significant abuse liability.

ANALYSIS OF DATA ON 7-HYDROXYMITRAGYNINE (7-OH)

7-OH Sources and Products vs. Kratom

The alkaloid 7-hydroxymitragynine (7-OH) is a naturally occurring substance in the kratom plant (*Mitragyna speciosa*), but only a minor constituent, described as early as 1994, when it was reported to comprise about 1.6% of the total alkaloid content of kratom leaves (Ponglux et al., 1994). This early reported value is in agreement with more recent assessments that have consistently demonstrated 7-OH as comprising less than 2% of the total alkaloid content in natural kratom as noted below.

7-OH has the chemical structure shown in Figure 1. Its IUPAC name is methyl (E)-2-[(2S,3S,7aS,12bS)-3-ethyl-7a-hydroxy-8-methoxy-2,3,4,6,7,12b-hexahydro-1H-indolo[2,3-a]quinolizin-2-yl]-3-methoxyprop-2-enoate, and it has the molecular formular $C_{23}H_{30}N_2O_5$, with a molecular weight of 414.40 amu.

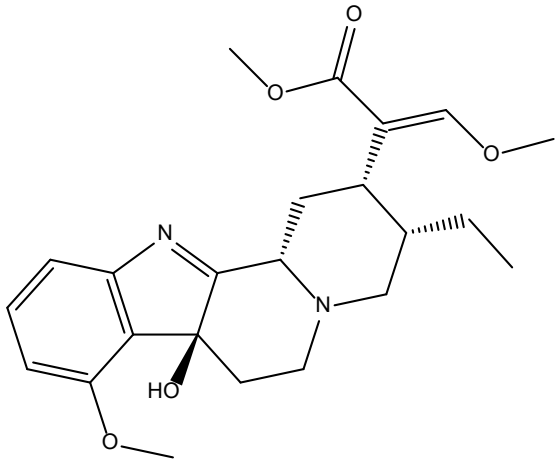


Figure 1. 7-Hydroxymitragynine Chemical Structure

Although details are not well-known, 7-OH is present in some products in amounts far exceeding its natural levels in the kratom plant. The 7-OH in these products is likely derived from the kratom plant. These 7-OH-enhanced products likely involve additional chemical synthetic steps by the producers of these products, converting the more abundant plant alkaloid mitragynine into 7-OH via chemical oxidation.

Data are available regarding 7-OH as a percentage of the total alkaloid content in kratom, and also as a percentage of dried botanical kratom leaf material and other kratom-derived products in the U.S. marketplace. One recent review reports 7-OH as comprising 2% of the total alkaloid content in kratom (Hossain et al., 2023) and this result can be extended to samples of kratom grown in the U.S. (Leon et al., 2009). In another analysis of 13 commercial products purported to contain kratom, the 7-OH content by weight ranged from 0.01-0.04% (Kikura-Hanajiri et al., 2009) a finding in agreement with others that have reported 7-OH to account for less than 0.05% by weight, substantially lower than reported mitragynine amounts (Kruegel et al., 2019). A more

recent study used ecological momentary assessment to evaluate the motivations and patterns of use of adult U.S. kratom consumers (Smith, Panlilio, Feldman, et al., 2024; Smith, Panlilio, Sharma, et al., 2024). As part of the study, subjects provided samples for quantitative testing of their own kratom products that they obtained and were self-administering. Across the 341 samples, the 7-OH content (expressed as a percentage by weight/weight or weight/volume, as indicated) ranged from below the limit of quantitation (< 0.005%) to a maximum of 0.21% with a mean of 0.01% (Sharma et al., 2025). These data suggest 7-OH is present in botanical kratom (i.e., leaf) at relatively low or trace amounts and may be a postharvest oxidative derivative of mitragynine (Karunakaran et al., 2024).

Common forms of kratom sold online include powders, capsules, resin extracts, crushed leaves, and tablets, although loose powder and prepared capsules have been reported to be the most frequently used formulations (Garcia-Romeu et al., 2020; Smith, Panlilio, et al., 2024). While kratom use characteristics are complicated by the diversity of products in the marketplace, survey studies have reported on consumption patterns. Garcia-Romeu collected data from regular kratom users and found that most users reported using 1-3g (49%) or 4-6g (33.4%) of botanical kratom per consumption (Garcia-Romeu et al., 2020). In other survey studies, the self-reported average consumption of kratom powder was 4-5 g per serving with serving sizes ranging between 2.6- 7.5 g (Rogers et al., 2024; Smith et al., 2022). When quantifying the amount of mitragynine consumed through the use of kratom, individuals self-reported consuming an average of 31.3 mg of mitragynine/serving and a range of 78.3 – 134.6 mg of mitragynine per day (Sharma et al., 2025).

Mitragynine, as the most abundant alkaloid in kratom, accounts for about 66% of the *total alkaloid content* of kratom and less than 2% of dried leaf content *by weight*, although there are reports of regional and seasonal variability in the tree's alkaloid composition (Arndt et al., 2011; Leon et al., 2009; Sengnon et al., 2023). For example, Chear and colleagues collected fresh kratom leaves from different locations in Peninsular Malaysia and determined their alkaloid profiles. The mitragynine concentration ranged from 9.38 to 18.85 mg/g or 0.38% to 1.89% of dried leaf weight while the 7-OH concentration ranged from 0.05 to 0.15 mg/g or 0.005% to 0.015% (Chear et al., 2021).

Despite the low amounts of 7-OH in botanical kratom, there are reports of its more-enhanced presence in commercial kratom-related products (Grundmann et al., 2024), although some products have been identified in reports from nearly a decade ago. For example, Lydecker and colleagues tested eight commercially available kratom products for their alkaloid content(s). In seven of the eight products tested, they found levels of 7-OH to be 109-509% higher than expected, based on naturally occurring levels of 7-OH reported in the kratom plant (Lydecker et al., 2016). More recently, the Tampa Bay Times purchased twenty kratom-derived products from local stores. One of those products consisted of pressed pills and contained 15 mg/pill of 7-OH, an amount far greater than observed in any botanical kratom preparation to date (Ogozalek, 2023). In addition to the verified amounts of 7-OH in the products obtained by Lydecker et al. and the Tampa Bay Times, other products *labeled* and/or *purported* to have high levels of 7-OH appear to be readily available for purchase online.

In summary, the low amounts of 7-OH in natural botanical kratom products is well-established as a percentage of alkaloid content, as a percentage of dried kratom leaf material, and in products representing other dosage forms made from natural kratom and consistent with its natural

composition. However, there are also a concerning and increasing number of products being sold that have unexpectedly and unnaturally high levels of 7-OH. This poses a threat to public health that is more clearly understood based on the pharmacological properties and effects of 7-OH, discussed in the preclinical data section below, and also in the limited information available on known patterns of human use and resulting harms discussed below. These sections will present and discuss the evidence in the available data that establishes the mu opioid agonist pharmacology associated with 7-OH in particular.

Patterns of 7-OH Use, Human Exposures, and Law Enforcement Data

There are several sources of information to characterize the current patterns of 7-OH use and the resulting harms to individuals who knowingly or unknowingly are exposed to 7-OH at significant doses from 7-OH-enhanced products, as described in the subsections below.

National Drug Early Warning System (NDEWS)

The National Drug Early Warning System (NDEWS) provides real-time surveillance from sentinel sites across U.S. to detect early signals of potential drug epidemics using novel (e.g., street reporting, web monitoring) and traditional data sources (e.g., OD deaths, treatment admissions).

NDEWS analyzed Reddit posts mentioning 7-OH during January to September 2024 and found that posts increased over this time. These posts are broad and can vary in content but have included warnings from Reddit users about respiratory depression, potency, dependence and long-lasting withdrawal (NDEWS, 2024).

Social Media

A variety of social media outlets were assessed for mentions and/or discussions of 7-OH. Websites included:

- erowid.org - a member-supported organization providing access to information about psychoactive plants, chemicals, and related issues;
- bluelight.org - an international message board that educates the public about responsible drug use by promoting free discussion, advocating harm reduction, and attempting to eliminate misinformation;
- reddit.com - online forum that functions as a vast collection of user-driven communities, known as sub-Reddits, each centered around specific topics.

It is important to note that all considerations of these social media sources are, at best, anecdotal in considering the risks and abuse potential associated with 7-OH products. However, it is clear that there is fairly widespread understanding of the availability of products specifically targeting high levels of the substance 7-OH, distinct from kratom products generally. In analyzing these social media posts, some relevant themes have been identified and include mention of the following: euphoria and an opioid-like “buzz”/high as motivation for consuming 7-OH; availability of “candy-like” formulations which users acknowledge as having a risk of overconsumption to their own detriment; perceptions of therapeutic value of 7-OH in self-treating pain and anxiety; concerns over loss of access to these products if they were to be banned; acknowledgement that use of these products could lead to overdose and serious

outcomes including death; and acknowledgement that use could lead to addiction and has caused users to experience withdrawal symptomology much like that produced by other commonly abused opioids.

Drug Enforcement Administration Toxicology Testing Program (DEA TOX)

The Drug Enforcement Administration Toxicology Testing program (DEA TOX) conducts analyses of voluntarily submitted leftover or previously collected biological samples from drug overdose victims to identify novel psychoactive substances (NPS) and other drugs of abuse in subjects with fatal and nonfatal overdose. The DEA TOX database was queried for reports of mitragynine, 7-OH, or mitragynine pseudoindoxyl from 2019-2025. A total of 103 cases, some fatal and some non-fatal, were identified in this selected sample; this database does not include all overdose cases, and the number of samples voluntarily submitted for analysis may vary year to year based on unknown factors.

It is notable that the utility of the DEA TOX data is limited because it generally cannot be discerned whether deaths are related to mitragynine, 7-OH, or mitragynine pseudoindoxyl, or some combination thereof. In addition, although 7-OH and mitragynine pseudoindoxyl are not typically found in appreciable amounts in fresh kratom leaves (Hill et al., 2025), both are metabolites of mitragynine, complicating forensic assessments of causality (Kamble et al., 2020). These are significant limitations in making inferences from these data; however, the number of fatal overdose cases in which one or more of these substances were detected for 2023 to 2025 are approximately three-fold higher than for the years 2019 through 2022, coinciding with the more recent entry of more-concerning kratom-related products in the marketplace, such as 7-OH.

Human Exposures in Pharmacokinetic Studies

Pharmacokinetic (PK) data for 7-OH are sparse, as to our knowledge, no clinical studies have been performed using isolated or purified 7-OH. Nonetheless, there are 7-OH PK data derived from a small number of studies using botanical kratom. Most available clinical PK data for 7-OH are variable, which may be for several reasons such as genetic differences in kratom plants, different formulations (e.g., teas, capsules, etc.), and methods of analysis. Much of the data is also from non-controlled studies making it difficult to interpret the results. Huestis and colleagues conducted a randomized, between-subject, double-blind, placebo-controlled dose escalation study of 500-4000 mg encapsulated dried kratom leaf powder corresponding to mitragynine doses of 6.65-53.2 mg. Twelve subjects enrolled in the study (n=12). Blood plasma levels of mitragynine and 7-OH were assessed after a single dose, and then again after 15 days of continuous dosing. According to the study authors, peak plasma levels of 7-OH (i.e., C_{max}values) and exposure (i.e., area under the curve, (AUC)) were lower than mitragynine but increased in a dose proportional manner and ranged from 3.6 to 22.7 ng/mL while the time to peak plasma levels (i.e.,T_{max} values) ranged from 1.2 – 1.8 h. The half-life of 7-OH increased with increasing dose and ranged from a mean of 1.7 to 4.7 hours. During the multiple dose phase of the study, 7-OH steady state was reached in about 7 days (Huestis et al., 2024).

In another study examining the PK properties of 7-OH, sixteen healthy subjects (n=16) received kratom tea containing 23.6 mg of mitragynine. Subjects were administered tea in two sessions: once with tea alone, and in a second session following pretreatment with itraconazole, a

CYP3A4 inhibitor. The 7-OH C_{max} was 12.81±3.39 ng/mL which occurred 1.7 h after administration (T_{max}). In the second session after pretreatment with itraconazole (200 mg), the C_{max} decreased 56% with a concomitant 43% decrease in AUC. These data describe the PK of 7-OH and demonstrate that the metabolism of mitragynine to 7-OH is heavily dependent on CYP3A4 (Mongar et al., 2024).

Tanna et. al., assessed the PK of a single orally administered dose of kratom (2 g), in the form of a tea, to healthy adult subjects (n = 5 completers). According to the authors, there were only trace amounts of 7-OH (< LOQ) in the starting product, therefore, the assumption was made that 7-OH was generated from the metabolism of mitragynine *in vivo.* The authors identified a PK difference between enantiomers of kratom alkaloids in either the 3S or 3R configuration. 7-OH has a 3S configuration which, according to the authors, leads to a shorter T_{max}, lower exposure (AUC), longer terminal half-life, and a higher volume of distribution during the terminal phase compared to the 3R alkaloids. Measured 7-OH in plasma samples demonstrated that 7-OH had a C_{max} = 16.1 nM, T_{max} = 1h, half-life = 5.67h, and an AUC0-120h = 103nM x h.(Tanna et al., 2022).

Epidemiological Data Sources

Limitations with the Epidemiological Data Sources

Because 7-OH appears to be a novel, emerging public health threat, the ability of public health surveillance systems to monitor 7-OH specific risks may be limited. For example, large national surveys such as the National Survey on Drug Use and Health include questions about use of kratom, but not 7-OH. Additionally, there may be a lack of awareness among consumers of kratom-related products that they are obtaining 7-OH enhanced products, and thus use of 7-OH would likely be underreported in data collected using self-report. Many forensic laboratories test for mitragynine as a marker of kratom use. In these cases, 7-OH overdose cases and fatalities may incorrectly be classified as kratom and/or mitragynine-related (Smith, Boyer, et al., 2024). Furthermore, toxicology reports documenting presence of 7-OH are difficult to interpret, because 7-OH is a known metabolite of mitragynine in humans. All of these issues complicate the real-world assessment of risks associated with use of 7-OH containing products as distinct from risks associated with kratom and other mitragynine-containing products.

FDA's Adverse Event Reporting System

Although FDA's Adverse Event Reporting System (FAERS) has documented cases reporting adverse events (13 cases, including 2 deaths) suspected to involve 7-OH, ambiguity about the contributory role of 7-OH from uncharacterized products or concomitant medications and underlying disease limits interpretation. Therefore, we do not include further analysis of these FAERS cases here.

America's Poison Centers, National Poison Data System

National Poison Data System (NPDS) receives near real-time data from the nation's poison centers (PC), providing information and assistance to callers on exposures to prescription drugs, over-the-counter medications, unapproved products, and other substances. PC healthcare professionals systematically follow up on exposure cases to document medical and clinical effects. Quality control measures are used to ensure data accuracy and completeness. Notably, 7-OH specific NPDS codes were only recently added (Feb-May 2025), and therefore the NPDS reporting period is limited to 2/1/2025-4/30/2025. As shown below, there were a total of 53 exposure cases involving 7-OH during this time period, the majority of which involved abuse-related reasons for use (i.e., "intentional abuse"). Most single-substance 7-OH exposure cases resulted in minor or moderate clinical outcomes, with several documented has having major clinical outcomes.

Table 1. National Poison Data System Closed Human Exposure Cases*, 2/1/2025-4/30/2025

	Number of exposure cases**	Number of abuse cases**	Single substance exposure cases	Single substance abuse cases
Total cases involving 7-OH	53	24	37	16
Reason				
Adverse drug reaction	4		2	
Intentional- abuse	24		16	
Intentional- misuse	4		3	
Intentional - Suspected suicide	2		0	
Other – Withdrawal	8		6	
Unintentional – general	4		4	
Unintentional- misuse	1		1	
Unintentional therapeutic error	4		3	
Unknown reason	2		2	
Related clinical outcomes				
Minor			6	3
Moderate			13	6
Major			3	1
Not followed, minimal clinical effects possible			5	3
Unable to follow, judged as potentially toxic exposure			1	0
Age				
<18 years	6	1	5	0
≥ 18 years	46	23	32	16
Unknown age	1	0	0	0

*Excludes cases classified as 'confirmed non-exposure'
**Cases may involve other substances, besides 7-OH
Related clinical outcomes include cases with clinical effects deemed "related" to exposure based on timing, severity, and assessment of clinical effects by Poison Center Specialists. Definitions available from America's Poison Centers: NPDS Full Report 2023. Page 235.

Note: This analysis used the case listing data in NPDS to identify and characterize cases documented as involving 7-OH. As of July 2025, an in-depth review NPDS case narrative data was ongoing; this further review may yield different numbers from those presented here.

Summary of Epidemiological Data and 7-OH Concerns

Available surveillance data indicate that abuse of 7-OH is occurring and is associated with serious harms; however, as noted previously, it is difficult to quantify the public health burden because surveillance systems do not provide estimates for the prevalence of 7-OH use and are only beginning to track the specific involvement of 7-OH enhanced products in exposure cases and overdoses. The current epidemiologic data on 7-OH exposures often lack sufficient detail to distinguish with confidence involvement of botanical kratom products from 7-OH enhanced products.

Preclinical Data Characterizing 7-OH Pharmacology

Although there are limited data from human studies to characterize effects of 7-OH in humans, as noted above, there is a large body of in vitro and animal studies that provide extensive evidence of 7-OH as a potent mu opioid agonist, as described in below subsections.

In Vitro Data

Receptor Binding Studies

7-OH has been shown to have affinity and activity at mu opioid receptors. In a study using human embryonic kidney (HEK) cells with cloned, human opioid receptors, 7-OH demonstrated high affinity for the mu opioid receptor (Ki = 47 nM) relative to kappa (Ki = 188 nM) and delta opioid receptors (Ki = 219 nM) (Kruegel et al., 2016). In a second study using HEK 293 cells expressing human mu and other opioid receptors, 7-OH demonstrated high affinity for mu opioid receptors (Ki = 16 ± 1 nM) and its affinity was greater than mitragynine (Ki = 238 ± 28 nM) and lower than morphine (Ki = 1.50 ± 0.04 nM) (Todd et al., 2020). Using an in vitro radioligand binding assay with CHO cells expressing murine-derived opioid receptors, 7-OH demonstrated relatively high affinity for mu-opioid receptors (Ki = 37 ± 4 nM), relative to mitragynine (Ki = 230 ± 47 nM), although its affinity was lower than morphine (Ki = 4.6 ± 1.8 nM) (Varadi et al., 2016). Other studies conducted using whole brain homogenates of guinea pig brain tissue have also demonstrated that 7-OH has high affinity at mu opioid receptors (Ki = 8.0 nM) relative to kappa (Ki = 6.7 nM) and delta opioid receptors (Ki = 6.8 nM) (Matsumoto et al., 2004). Obeng and colleagues evaluated the binding affinity of 7-OH using human recombinant HEK 293 cells expressing mu opioid receptors. Their results are in agreement with the data presented above where the authors found that 7-OH binds with high affinity (Ki = 7.2 nM) to mu opioid receptors relative to delta (Ki = 236 nM) and kappa (Ki = 74.1 nM) receptor subtypes (Obeng et al., 2020). A number of additional binding studies are in keeping with the data described above, demonstrating the affinity of 7-OH for mu opioid receptors across a variety of binding assays (Chakraborty et al., 2021; Matsumoto et al., 2008; Obeng et al., 2021; Takayama et al., 2002).

The results of the receptor binding studies with 7-OH are in keeping with *in silico* receptor binding models that suggest 7-OH has high affinity for the mu opioid receptor. The *in silico* modeling results were subsequently confirmed with a radioligand binding assay where 7-OH demonstrated high affinity for cloned, human mu opioid receptors (K_i = 70 nM). (Ellis et al.,

2020). Collectively, the available receptor binding data demonstrate the affinity and binding of 7-OH to mu opioid receptors.

Functional Studies

Many of the studies referenced above performed additional assessments of 7-OH to determine its functional activity after binding (i.e., agonist or antagonist effects). These studies have consistently demonstrated that 7-OH produces mu-opioid agonist effects. For example, Kruegel and colleagues examined the functional activity of 7-OH and mitragynine in HEK cells expressing opioid receptors using a bioluminescence resonance energy transfer (BRET) assay. Both mitragynine and 7-OH functioned as partial agonists, producing Emax values of 34% and 47% respectively and EC_{50} values of 339 ± 178 nM and 34.5 ± 4.5 nM (Kruegel et al., 2016). Activation of the mu opioid receptor pathway was also investigated using forskolin-stimulated cyclic adenosine monophosphate (cAMP) accumulation in Chinese Hamster Ovary (CHO) cells expressing mu opioid receptors. In this assay, 7-OH produced a maximal activation (Emax) of 85.9%, a value similar to that produced by the positive control comparators DAMGO (86.2%) and morphine (86.9%). These data suggest 7-OH acts a full mu opioid agonist (Todd et al., 2020). Similarly, Matsumoto and colleagues concluded that 7-OH was "found to have an opioid agonist property on μ- and/or κ-opioid receptors" based on its ability to inhibit contraction of isolated guinea pig ileum. In this assay, 7-OH displayed approximately 13-fold greater potency than morphine and 46-fold greater potency than mitragynine. The inhibition was reversed by naloxone, suggesting the effects are mediated via mu opioid receptors (Matsumoto et al., 2004). Other functional assays produced results that are aligned with Matsumoto and colleagues. For example, using a cAMP mobilization assay as a measure of functional effects, 7-OH acted as a full agonist with an EC_{50} of 7.6 nM, and was more potent than mitragynine (EC_{50} 307.5 nM) (Obeng et al., 2020). Likewise, when evaluating the agonist activity of 7-OH in an electrically stimulated guinea pig ileum, 7-OH acted as a full agonist and was more potent than morphine (Takayama et al., 2002). Finally, using a [^{35}S] GTPγS functional assay, 7-OH produced an Emax of 77% with an EC_{50} of 53.4 nM, further demonstrating its agonist effects (Varadi et al., 2016).

<u>Animal Data on Behavioral and Physiological Effects</u>

Conditioned Place Preference

Conditioned place preference (CPP) is a commonly utilized animal model to study the rewarding effects of drugs. In this paradigm, an animal is conditioned to associate a particular environment with a drug treatment, and an alternative environment with a non-drug condition. After repeated sessions, the animal is then observed under non-drug conditions to determine which environment the animal prefers. CPP is established if the animal spends more time in the drug-paired compartment vs. the vehicle-paired compartment (Mombelli, 2022; Prus et al., 2009). Many drugs of abuse produce CPP, though notably, it is not a direct measure of reinforcing effects.

Using the CPP paradigm, several studies have demonstrated the ability of 7-OH to produce rewarding effects and that it does so more potently than morphine. Gutridge and colleagues employed C57BL/6 mice and demonstrated the development of CPP after 3 mg/kg 7-OH. CPP was observed after both doses although 7-OH required more sessions (4 sessions) whereas morphine (6 mg/kg) was able to establish CPP in two sessions (Gutridge et al., 2020). Similarly,

other studies have demonstrated the ability of 7-OH (2 mg/kg) to produce CPP, and that it does so with greater potency than morphine (Matsumoto et al., 2008).

Drug Discrimination

Drug discrimination is an experimental method in which animals identify whether a test drug produces interoceptive effects similar to those produced by a drug to which the animals are trained to differentiate from placebo, and which has known pharmacological properties. If the known drug is one with abuse potential, drug discrimination methods can be used to predict if a test drug will have abuse potential in humans (Balster & Bigelow, 2003; Solinas et al., 2006).

For abuse assessment purposes, an animal is trained to press one bar when it receives a known drug of abuse (the training drug) and another bar when it receives placebo. A challenge session with the test drug determines which of the two bars the animal presses more often as an indicator of whether the test drug is more like the known drug of abuse or more like placebo. A test drug is said to have "full generalization" to the training drug when the test drug produces bar pressing >80% on the bar associated with the training drug (Ator & Griffiths, 2003; Swedberg, 2016; Walker, 2018; Young, 2009). A test drug that generalizes to a known drug of abuse will likely be abused by humans (Balster and Bigelow, 2003).

Male Sprague Dawley rats were trained to discriminate morphine (5.0 mg/kg i.p.) from saline using a 30 min pretreatment time and FR10 schedule of reinforcement. After successful training, substitution tests with 7-OH (0.3, 1.0 and 3.0 mg/kg) were performed. The highest dose of 7-OH (3.0 mg/kg) produced complete substitution for the morphine stimulus cue. Moreover, pretreatment with naloxone significantly reversed the 7-OH substitution and resulted in saline-like responding. Notably, in this study, 7-OH was more potent than morphine (Harun et al., 2015).

In a second study, the discriminative stimulus effects of 7-OH were examined in separate groups of rats trained to discriminate either morphine (3.2 mg/kg i.p., 15 min pretreatment) or mitragynine (32 mg/kg i.p., 30 min pretreatment) from saline. After successful acquisition of discrimination training 7-OH was administered in substitution tests. 7-OH was administered i.p., with a 15 min pretreatment time in a dose range of 0.1-17.8 mg/kg. In the morphine-trained rats, 7-OH produced complete substitution at doses above 0.56 mg/kg, with the 1.0 mg/kg dose producing 100% drug-lever-appropriate responding and a resultant ED_{50} of 0.28 mg/kg. Notably, the dose-response curve was shifted to the left, demonstrating an increased potency of 7-OH relative to morphine. In addition, pretreatment with 0.032 mg/kg naltrexone shifted the dose-response curve to the right suggesting substitution was mediated via mu-opioid receptors (Obeng et al., 2021). Taken together, the drug discrimination data demonstrate the ability of 7-OH to substitute and mimic the stimulus effects of morphine, and that 7-OH is more potent in doing so. These data are a strong indication that 7-OH produces subjective effects in humans that are similar to opioids, along with an associated abuse potential.

Self-Administration

Self-administration is a method that assesses whether a drug produces reinforcing effects that increase the likelihood of behavioral responses in order to obtain additional drug (i.e., whether an animal will press a lever for a drug injection). Drugs that are self-administered by animals are

likely to produce rewarding effects in humans, which is indicative of abuse potential. Generally, a good correlation exists between those drugs that are self-administered by animals and those that are abused by humans (Balster & Bigelow, 2003; Brady et al., 1987; Johanson & Schuster, 1981; Panlilio & Goldberg, 2007). It is notable that self-administration is a behavior that is produced by drugs that have been placed into every schedule of the CSA. Additionally, rates of self-administration for a particular drug will go up or down if the available drug dose or the work requirement (bar pressing for drug) is altered. Positive results from a self-administration study provide an abuse potential signal, suggesting that a drug has rewarding properties, but not necessarily that it produces more rewarding effects than another drug in humans.

7-OH produces reinforcing effects and is self-administered by rodents. In the study, rodents were trained to self-administer morphine (100 µg/infusion) and faded to 50 µg/infusion once stable responding was achieved. Thereafter, extinction sessions were performed to confirm acquisition of the self-administration training prior to substitution tests. Substitution tests were performed with 7-OH doses of 2.5, 5, 10 and 20 µg/infusion. In the substitution tests, 7-OH produced an inverted U-shaped curve and the number of infusions for 5 and 10 µg/infusion of 7-OH were significantly greater than vehicle, demonstrating the reinforcing effects of 7-OH (Hemby et al., 2019).

The self-administration of 7-OH was blocked by both a mu opioid antagonist (naloxonazine) and a delta opioid antagonist (naltrindole), suggesting its reinforcing effects are mediated via opioid receptors. In addition, peak morphine self-administration occurred at 50 µg/infusion while peak 7-OH infusions occurred at 5 µg/infusion, demonstrating a substantially increased potency of 7-OH relative to morphine.

There are some pharmacokinetic (PK) data available from animal studies involving the administration of isolated, i.e., single entity, 7-OH. Following a single oral dose (1 mg/kg 7-OH) to beagle dogs, absorption was rapid, with a peak plasma concentration (i.e., Cmax) of 56 ± 1.6 ng/mL 15 minutes post-dose. The elimination half-life was slower, producing a mean of 3.6 ± 0.5 h. No AEs were observed, and no abnormal laboratory findings were reported (Maxwell et al., 2021). In adult male and female mice, the PK parameters of 7-OH were investigated after a single oral dose of 50 mg/kg 7-OH. The tissue distribution of 7-OH was observed in descending order: liver > kidney > spleen > lung > brain. Plasme C_{max} values were 0.6 and 09 µg/mL in males and females with a T max value of 0.5 hr. Area under the curve (AUC) values over 48 hours (AUC_{0-48} hr* µg/mL) were 1.4 and 2.9 in male and female mice (Berthold et al., 2022).

Antinociceptive Effects

The antinociceptive effects of 7-OH were investigated in mice using the tail flick and hot plate tests. These tests are commonly used to examine pain and analgesic effects in rodents (D'Amour & Smith, 1941). In these tests, rodents are subject to a heat stimulus and timed for the duration it takes to move their tail (i.e., tail flick) or produce a response such as jumping, licking, or shaking of limbs (i.e., hot plate).

In the tail flick test, subcutaneous administration of 7-OH (2.5 – 10 mg/kg) produced both time and dose-related antinociceptive effects. Notably, the dose-effect curve for 7-OH was shifted to the left, indicating a greater potency than the positive control comparator, morphine. Similar results were observed in the hot plate test, and when morphine and 7-OH were administered

orally. Naloxone (2 mg/kg s.c.) inhibited the effects of 7-OH and morphine in both tests (Matsumoto et al., 2004; Matsumoto et al., 2008). Concurrent results were observed by Obeng and colleagues using the hot plate test. In their study, 7-OH (0.0032 – 3.2 mg/kg, i.v.) produced maximum antinociceptive effects and was more potent morphine but less potent than fentanyl when administered intravenously. Likewise, naltrexone (0.1 mg/kg) reversed the antinociceptive effects of 7-OH suggesting the antinociception was mediated via mu opioid receptors (Obeng et al., 2020).

Respiratory Depression

A major risk of opioid exposure and cause of opioid-induced death is respiratory depression (Baldo & Rose, 2022; Bateman et al., 2023). To examine the respiratory effects of 7-OH in rodents, whole body plethysmography was used in freely moving, awake rats. Both morphine (10 and 32 mg/kg, i.v.) and 7-OH (1, 3.2, and 10 mg/kg, i.v.) induced significant respiratory depression as assessed by minute volume, tidal volume, and breathing frequency. The mu-opioid agonist naloxone (1.0 mg/kg i.v.) reversed these effects, a finding consistent with the mu opioid effects of 7-OH (Zuarth Gonzalez et al., 2025). These data highlight a potential risk factor of 7-OH exposure and suggest 7-OH may expose individuals to similar risks as classic opioids, including respiratory depression.

Physical Dependence and Withdrawal

It is well-established that chronic administration of opioids leads to the development of tolerance and physical dependence that may culminate into a withdrawal syndrome. In parallel with some of the hot plate tests described above, the ability of 7-OH to produce physical dependence and withdrawal was examined. Mice were treated with subcutaneous 7-OH (10 mg/kg b.i.d.) or morphine (10 mg/kg b.i.d.) for five days. Tolerance was assessed as a reduction of analgesia in the hot plate test. After five days of treatment, both morphine and 7-OH showed a decreased analgesic response on the hot plate test, demonstrating the development of tolerance. In addition, cross-tolerance was also observed between morphine and 7-OH suggesting a similar mechanism of action between the drugs. Finally, after five days of escalating doses of 7-OH and morphine (8-45 mg/kg b.i.d.) the development of withdrawal was assessed with a 3 mg/kg s.c., dose of naloxone injected two hours after 7-OH administration. Both morphine and 7-OH treatment produced signs of withdrawal such as jumping, rearing, urination, ptosis, forepaw tremor, and diarrhea (Matsumoto et al., 2005).

Summary of Preclinical Data

From the studies described above, 7-OH has high affinity for mu opioid receptors and functional activity as an agonist at these receptors. Consistent with this pharmacological activity, 7-OH is self-administered by animals, substitutes for morphine in drug discrimination studies, produces antinociception, and physical dependence leading to withdrawal when administered to rodents. Moreover, 7-OH has consistently demonstrated an increased potency relative to morphine in preclinical rodent studies. These observations suggest 7-OH has pharmacological properties representative of a full mu opioid agonist and an associated high potential for abuse.

CONCLUSIONS

The data described in this report indicate that 7-OH has a significant potential for abuse and associated harms. Conclusively, 7-OH has high affinity and agonist activity at mu opioid receptors. Consistent with this pharmacological mechanism of action, 7-OH demonstrates rewarding effects in that it is self-administered by animals and also produces conditioned place preference, two well-established animal behavioral models measuring rewarding effects as a predictor of abuse potential in humans. In animal drug discrimination studies, 7-OH substitutes for morphine with full generalization. 7-OH is also demonstrated to produce antinociception consistent with opioid pharmacology, and to produce physical dependence when administered to rodents, as evidenced by a classic set of withdrawal signs associated with opioid withdrawal upon discontinuation of opioid administration. Moreover, 7-OH in all above models has consistently demonstrated an increased potency relative to morphine.

Due to the fact that 7-OH is both a metabolite of mitragynine and naturally present in low amounts in botanical kratom, using toxicology results to identify 7-OH as a primary or sole contributor in human exposures is challenging. There is also a need for improved clinical awareness and population surveillance to better characterize patterns of 7-OH use, the products that people are obtaining, and individual treatment needs following 7-OH exposure. Additionally, questions on 7-OH are not generally included in national surveys, and other data sources that rely on self-reported use of 7-OH likely underestimate the number of 7-OH exposure cases, as individuals may be unaware of the distinction from kratom products. Nonetheless, since specific codes were added earlier this year to document 7-OH exposure cases, U.S. poison centers have identified multiple single-substance cases of 7-OH exposure resulting in serious adverse clinical outcomes. Also, although anecdotal, social media and online forums indicate growing awareness and use of 7-OH, and many testimonials of the negative opioid-mediated effects users have experienced, including 7-OH dependence, associated withdrawal syndrome, and addiction.

In the current marketplace in the U.S., 7-OH is increasingly being marketed over-the-counter and online, in concentrated forms or sufficient doses to cause harms to those individuals engaging, knowingly or unknowingly, in use of 7-OH. Based on demonstrated pharmacology, repeated or prolonged use of 7-OH would lead to tolerance, physical dependence, and potentially to opioid addiction— typical of mu opioid agonist drugs of abuse. This public health threat is troubling and requires immediate and impactful policies to educate consumers and take regulatory action that limits access to 7-OH containing products.

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Kratom

WHAT IS KRATOM?

Kratom is a tropical tree native to Southeast Asia. Consumption of its leaves produces both stimulant effects (in low doses) and sedative effects (in high doses), and can lead to psychotic symptoms, and psychological and physiological dependence. Kratom leaves contain two major psychoactive ingredients (mitragynine and 7-hydroxymytragynine). These leaves are crushed and then smoked, brewed with tea, or placed into gel capsules. Kratom has a long history of use in Southeast Asia, where it is commonly known as thang, kakuam, thom, ketum, and biak. In the U.S., the abuse of kratom has increased markedly in recent years.



Kratom tree

How is it abused?

Mostly abused by oral ingestion in the form of a tablet, capsule, or extract. Kratom leaves may also be dried or powdered and ingested as a tea, or the kratom leaf may be chewed.



Leaf of kratom tree

What are the effects?

At low doses, kratom produces stimulant effects with users reporting increased alertness, physical energy, and talkativeness. At high doses, users experience sedative effects. Kratom consumption can lead to addiction.

Several cases of psychosis resulting from use of kratom have been reported, where individuals addicted to kratom exhibited psychotic symptoms, including hallucinations, delusion, and confusion.



Kratom capsules

What does it do to the body?

Kratom's effects on the body include nausea, itching, sweating, dry mouth, constipation, increased urination, tachycardia, vomiting, drowsiness, and loss of appetite. Users of kratom have also experienced anorexia, weight loss, insomnia, hepatotoxicity, seizure, and hallucinations.

What is its legal status?

Kratom is not controlled under the Controlled Substances Act; however, there may be some state regulations or prohibitions against the possession and use of kratom. The FDA has not approved Kratom for any medical use. In addition, DEA has listed kratom as a Drug and Chemical of Concern.

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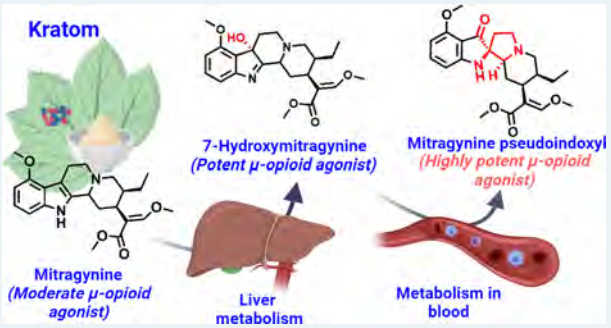
Metabolism of a Kratom Alkaloid Metabolite in Human Plasma Increases Its Opioid Potency and Efficacy

Shyam H. Kamble, Francisco León, Tamara I. King, Erin C. Berthold, Carolina Lopera-Londoño, Kanumuri Siva Rama Raju, Aidan J. Hampson, Abhisheak Sharma, Bonnie A. Avery, Lance R. McMahon, and Christopher R. McCurdy*

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ABSTRACT: Kratom is widely consumed in the United States for self-treatment of pain and opioid withdrawal symptoms. Mitragynine is the most abundant alkaloid in kratom and is a μ-opioid receptor agonist. 7-Hydroxymitragynine (7-HMG) is a mitragynine metabolite that is a more potent and efficacious opioid than its parent mitragynine. 7-HMG contributes to mitragynine's antinociceptive effects in mice, but evidence suggests it may also have a higher abuse potential. This *in vitro* study demonstrates that 7-HMG is stable in rodent and monkey plasma but is unstable in human plasma. Surprisingly, in human plasma 7-HMG is converted to mitragynine pseudoindoxyl, an opioid that is even more potent than either mitragynine or 7-HMG. This novel metabolite is formed in human plasma to a much greater extent than in the preclinical species tested (mouse, rat, dog, and cynomolgus monkey) and due to its μ-opioid potency may substantially contribute to the pharmacology of kratom in humans to a greater extent than in other tested species.



KEYWORDS: *mitragynine, 7-hydroxymitragynine, Mitragyna speciosa, mitragynine pseudoindoxyl, plasma stability, metabolism*

Mitragynine is the most abundant and pharmacologically well-characterized alkaloid (~ 66% of total alkaloidal content)[1,2] contained in the psychoactive substance kratom (*Mitragyna speciosa* Korth.). Mitragynine interacts with several receptors[3] including weak activity as a μ-opioid receptor agonist.[4] 7-Hydroxymitragynine (7-HMG) is a major mitragynine metabolite that in rodent models significantly contributes to mitragynine's analgesic and behavioral pharmacology.[5] 7-HMG is 22-fold more potent than mitragynine as a μ-opioid receptor agonist,[6] and in the electrically stimulated guinea pig ileum twitch assay, it is 13- fold more potent than morphine (46-fold greater than mitragynine).[7] In mice, mitragynine's antinociceptive properties can mostly be largely accounted for by its conversion to 7-HMG,[8] and while rats do not self-administer mitragynine, they will self-administer 7-HMG.[9] If rodent and human mitragynine metabolism is similar, then these data would suggest that 7-HMG may have a significantly higher abuse potential than that of mitragynine. However, different species often show significant quantitative and/or qualitative differences in drug metabolism, so following mitragynine/kratom consumption human exposure to 7-HMG may differ from that of rodents. One example of the differences between species is how rodents predominantly metabolize morphine to its inactive morphine 3-*O*-glucuronide, while humans also form morphine 6-*O*-glucuronide, a metabolite that is a more potent opioid agonist than its parent morphine.[10]

The current study aims to increase understanding of human systemic exposure to opioidergic mitragynine metabolites by comparing the plasma stability of 7-HMG in human and model animal species and elucidating the structures and activity resulting from 7-HMG metabolism.

RESULT AND DISCUSSION

Plasma Stability of 7-HMG. To determine which nonhuman animal model best predicts human exposure to 7-HMG, we evaluated the stability of 7-HMG in pooled mouse, rat, dog, monkey, and human plasma (Figure 1) under standard *in vitro* conditions (incubation of 1 μM 7-HMG in respective species plasma for 120 min at 37 °C). 7-HMG stability varied markedly across species, with high stability observed in mouse, rat, and monkey plasma (>80% 7-HMG

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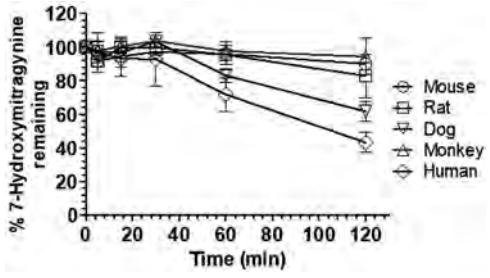


Figure 1. Stability of 7-HMG in mouse, rat, dog, cynomolgus monkey, and human plasma. The data represented as a percentage of 7-HMG remaining versus time in cross-species plasma). All values are plotted as mean ± SD (n = 3).

remaining after 120 min incubation) and intermediate stability in dog plasma (>61% 7-HMG remaining after 120 min). 7-HMG was the least stable in human plasma (~40% 7-HMG remaining after 120 min) with a half-life ($T_{1/2}$) of 98.7 min as shown in Figure 1.

Plasma is known to catalyze numerous hydrolytic drug metabolizing reactions, particularly ester cleavage, such as the β-methoxyacrylate moiety found in 7-HMG. Therefore, we next evaluated the stability of 7-HMG in human plasma in the presence and absence of a protease inhibitor cocktail comprised of 4-(2-aminoethyl)benzenesulfonyl fluoride hydrochloride, aprotinin, bestatin, E-64, EDTA, leupeptin, and pepstatin A. Together this cocktail is sufficient to inhibit most serine proteases, cysteine proteases, metalloproteases, and calpain proteases. The chemical degradation of 7-HMG was also assessed in a 50 mM phosphate buffer (pH 7.4) as a control. In phosphate buffer alone, 7-HMG was stable, and in human plasma, the protease inhibitors somewhat reduced the rate of 7-HMG degradation (68% remaining at 120 min vs 46% in untreated human plasma; Figure 2). These data

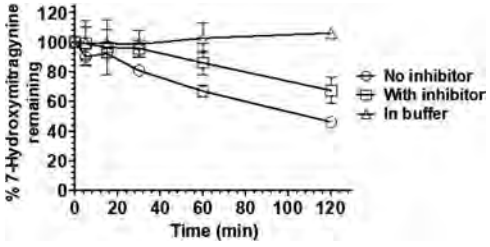


Figure 2. Stability of 7-HMG in human plasma in the presence and absence of protease cocktail inhibitor and 50 mM phosphate buffer pH 7.4 control. The data are represented as a percentage of 7-HMG remaining versus time in either human plasma with or without protease cocktail inhibitor treatment and blank phosphate buffer pH 7.4. All values are plotted as mean ± SD (n = 3).

suggested that 7-HMG was being enzymatically degraded. However, the liquid chromatography high-resolution mass spectrometry (LC-HRMS) analysis failed to identify a plasma metabolite that corresponds to a 7-HMG hydrolysis product with an expected m/z of 401.2071 (Figure S1).

Following incubation of 7-HMG with human plasma, two unknown peaks (unknown-1 and -2) with the same nominal mass (m/z 415.2227) and same daughter ions peaks (m/z 190.0863 and 226.1438) were observed. The abundance of these metabolites increased in a manner proportional to the incubation time of 7-HMG in human plasma (Figure 3). Relative to the conversion in human plasma, the percent

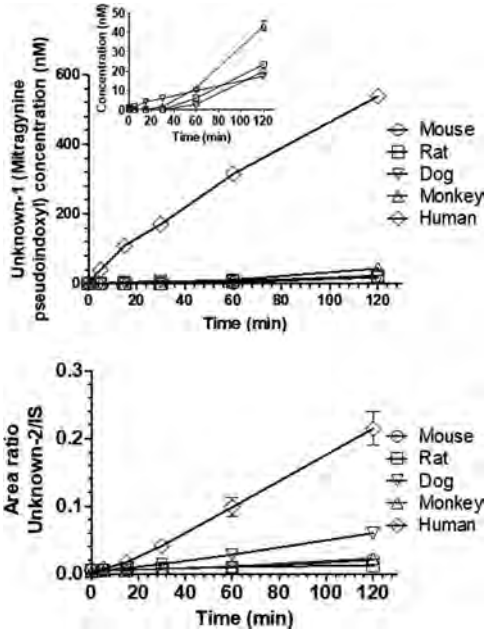


Figure 3. Unknown-1 (mitragynine pseudoindoxyl) and unknown-2 formation upon 7-HMG incubation with the mouse, rat, dog, cynomolgus monkey, and human plasma. Two unknown peaks (Unknown-1 and -2) were detected having mass transitions similar to that of 7-HMG. These are represented as the concentration of unknown-1 (mitragynine pseudoindoxyl, top) and ratio of unknown-2 to internal standard (IS) peak area (bottom) versus time. The inset in the top panel represents the concentration of unknown-1 (mitragynine pseudoindoxyl) in species other than human. All values are plotted as mean ± SD (n = 3).

conversion values of 7-HMG to unknown-1 in mouse, rat, dog, and monkey plasma were 3.7 ± 0.0, 4.4 ± 0.3, 3.2 ± 0.0, and 8 ± 0.0% (mean ± SD), respectively.

Similarly, relative to the conversion in human plasma, the percent conversion values of 7-HMG to unknown-2 in mouse, rat, and monkey plasma were 9.5 ± 0.7, 5.9 ± 0.3, and 10.6 ± 1%, respectively, and 28.0 ± 2.1% in dog plasma. These data demonstrate that human plasma predominantly metabolized 7-HMG to unknown-1. The degradation of 7-HMG in dog plasma to unknown-1 and -2 explains somewhat the contribution toward the total degradation, while other degradation products in dog plasma remain to be identified. Likewise, whether the conversion of 7-HMG in human plasma was exclusively to unknown-1 and -2 remains to be identified. A similar MS2 fragmentation pattern (Figure S2) was observed for unknowns-1 and -2 and 7-HMG suggesting the same molecular structure, i.e., unknown--1 and -2 are structural isomers of 7-HMG.

Isolation, Purification, and Structure Elucidation of Unknown-1 Metabolite. Multiple incubations of 7-HMG with human plasma were necessary to obtain a sufficient amount of unknown-1 for analysis using fractionation, preparative thin-layer chromatography (TLC), and high-performance liquid chromatography (HPLC) techniques. The relative abundance of unknown-2 was almost 10-fold lower than that of unknown-1 in human plasma, so it was not further evaluated due to the challenges in obtaining enough compound for further characterization. The ^{1}H NMR spectrum of unknown-1 (Figure S3) showed an unusual aromatic first-order (large chemical shift separations and clear

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coupling pattern) spin-system AMX, where the aromatic protons at δ_H 6.42 ppm (d, J = 8.1 Hz, 1H) and 6.15 ppm (d, J = 8.0 Hz, 1H) were low-shifted in comparison with those of 7-HMG at δ_H 7.20 ppm (d, J = 7.8 Hz, 1H), and 6.73 ppm (d, J = 7.8 Hz, 1H). Additional ^{1}H NMR signals of unknown-1 revealed the presence of one aromatic methoxy substituent, the typical signals for the β-methoxy acrylate group, and aliphatic protons, similar to those for 7-HMG (Figure S4), suggesting that the structural changes are located in the ring B of the corynanthe skeleton (Figure S4). The main differences between unknown-1 and 7-HMG were the absence of a quaternary carbon on 7-HMG at δ_C 81.0 ppm (Figure S5) and the presence of the highly deshielded carbon on unknown-1 at δ_C 199.5 ppm (Figure S6), suggesting conversion of the quaternary hydroxylated carbon to a carbonyl carbon. The presence of the quaternary carbon at δ_C 75.0 ppm is consistent with a ring B rearrangement, resulting in a spiro linkage between rings B and C of the corynanthe core (Figure S4). Analysis of the ^{1}H−^{1}H correlation spectroscopy (COSY), heteronuclear single quantum coherence spectroscopy (HSQC), heteronuclear multiple bond coherence (HMBC), and selective nuclear Overhauser effect (NOE) data (Figures S7−S10) confirmed the difference between ring B of unknown-1 and 7-HMG. Taken together, these data suggest a semipinacol−pinacolone rearrangement, similar to the biosynthetic pathway for oxindoles on corynanthe skeletons.[11] By comparing the NMR data for unknown-1 with those of reported corynanthe alkaloids, we concluded that unknown-1 was likely to be mitragynine pseudoindoxyl. We then synthesized a mitragynine pseudoindoxyl standard using the Varadi et al. procedure[12] and demonstrated that the standard and unknown-1 exhibited identical NMR spectra, UPLC (retention times), and HRMS data (Figures S11−S13). Therefore, we conclude that unknown-1 is mitragynine pseudoindoxyl (Figure 4). Furthermore, we used the synthetic

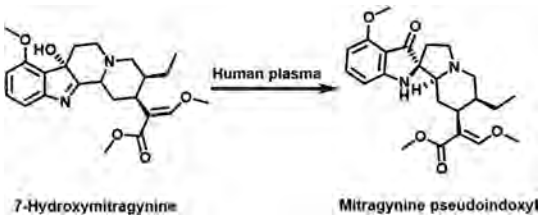


Figure 4. Novel metabolic conversion of 7-HMG to mitragynine pseudoindoxyl in human plasma. The incubation of 7-HMG in human plasma at 37 °C in 5% CO_2 incubator at 100 rpm for 2 h resulted in the metabolic conversion of 7-HMG to mitragynine pseudoindoxyl.

standard of mitragynine pseudoindoxyl to quantify the percentage of mitragynine pseudoindoxyl formed via the plasma incubation of 7-HMG. The percentages of mitragynine pseudoindoxyl formed at the end of 120 min of incubation of 7-HMG in mouse, rat, dog, monkey, and human plasma were 2.0 ± 0.0, 2.4 ± 0.2, 1.7 ± 0.0, 4.3 ± 0.2, and 53.8 ± 1.6%, respectively. Also, we evaluated the stability of mitragynine pseudoindoxyl in the plasma of each tested species using experimental conditions similar to those used for 7-HMG. Mitragynine pseudoindoxyl was found to be stable in the plasma of each species, confirming that the conversion of 7-HMG to mitragynine pseudoindoxyl is irreversible (Figure S14).

Plasma enzymes are known to catalyze hydrolytic and chiral inversion reactions, but to the best of our knowledge semipinacol rearrangement reactions such as those observed here have not been previously described to occur in mammalian plasma. Furthermore, mitragynine pseudoindoxyl biosynthesis has not even been reported in *Mitragyna speciosa*,[1] although Zarembo et al. have reported that some fungi can catalyze the semipinacol rearrangement of mitragynine into mitragynine pseudoindoxyl.[13]

The discovery that 7-HMG is converted in mitragynine pseudoindoxyl in human but not rodent plasma not only is unexpected but also may significantly alter our conclusions about the translatability of mitragynine findings using rodent models to the human condition.[8,9,14] While 7-HMG is more potent and efficacious than mitragynine in its ability to activate μ-opioid receptors, mitragynine pseudoindoxyl is yet more potent and at least as efficacious as 7-HMG. In GTPγS functional assays of μ-opioid activation, mitragynine pseudoindoxyl has been reported to be 31-fold more potent than 7-HMG and 119-fold greater than mitragynine (EC_{50} 1.7 ± 0.1 nM, E_{max} 84 ± 5%).[12] In the electrically stimulated contraction of guinea pig ileum model, mitragynine pseudoindoxyl is 20-fold more potent than morphine at inhibiting contractions and 100-fold more potent than mitragynine.[15] Previously, questions have been raised about whether the observed pharmacological activity in humans following kratom administration is due to mitragynine or mediated by the metabolite, 7-HMG. The systemic exposure of 7-HMG when calculated as percentage ratio of area under the curve of 7-HMG to mitragynine following mitragynine oral dosing of female beagle dogs[16] was found to be 12.6 ± 1.6%. This suggests that a reasonable amount of 7-HMG is present in systemic circulation which could be further metabolized to mitragynine pseudoindoxyl in plasma; however, the absolute conversion rate of 7-HMG to mitragynine pseudoindoxyl is unknown. These findings raise the possibility that opioid-like effects may be mediated by a combination of mitragynine, 7-HMG, and mitragynine pseudoindoxyl. The abuse potential of mitragynine pseudoindoxyl has not been well characterized. However, 7-HMG has been reported to have high abuse potential, and given that mitragynine pseudoindoxyl is an even more potent opioid agonist, it is likely to also be highly abusable.[9]

The metabolism of mitragynine to 7-HMG in humans is known to be catalyzed by the enzyme CYP3A4,[2,8] but the mechanism of this newly discovered conversion into mitragynine pseudoindoxyl in plasma is unknown. Additionally, microsomal metabolism of mitragynine did not result in the formation of mitragynine pseudoindoxyl in mouse, rat, dog, monkey, or human liver microsomes. It is possible that this plasma metabolism may be catalyzed by a genetically polymorphic enzyme or enzymes, which would potentially lead to substantial variability in an individual's relative exposure to 7-HMG and mitragynine pseudoindoxyl following administration of a defined kratom dose. Given the difference in potency between these two metabolites, such differential exposure could result in population variability in the pharmacological and adverse effects of kratom consumption. In the present study, conversion of 7-HMG to mitragynine pseudoindoxyl has been identified, but the extent of systemic exposure will depend on the rates of 7-HMG biosynthesis and its further conversion to mitragynine pseudoindoxyl, which remain to be defined. Assuming similar rates of 7-HMG formation across species, our *in vitro* plasma stability data

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suggest that systemic human exposure to 7-HMG in humans may be lower than that in nonhuman species tested.

7-HMG is substantially metabolized by rat and monkey liver microsomes ($T_{1/2}$ = 15 and 26 min, respectively, Figure S15), but metabolism in mouse, dog, and human liver microsomes was much slower ($T_{1/2}$ > 60 min, Figure S15). These systems only establish the phase I metabolism of 7-HMG, but the data suggest that liver metabolism of 7-HMG in rats and monkeys is much greater than that in plasma. Furthermore, comparing the 7-HMG rate of metabolism in humans (plasma and liver microsomes), the plasma metabolism of 7-HMG could form substantial amounts of mitragynine pseudoindoxyl. Studies comparing the intrinsic clearance of 7-HMG in plasma and hepatocytes (phases I and II metabolic systems present) would help us to gauge the relevance of plasma metabolism of 7-HMG in the respective species and could be used to identify species having a metabolic profile similar to humans for further translational characterization.

CONCLUSION

This study has demonstrated the potential for human plasma to form mitragynine pseudoindoxyl. Further research is required to elucidate whether the same mechanisms also reside in other tissue types, potentially resulting in significant local exposure to this highly potent opioid.

EXPERIMENTAL SECTION

Plasma Stability of 7-HMG. The plasma stability of 7-HMG (synthesized in-house from mitragynine) was performed using heparinized pooled non-Swiss albino mouse (Innovative Research, Novi, MI), Sprague−Dawley rat (GeneTex, Irvine, CA), beagle dog (BioIVT, Hicksville, NY), cynomolgus monkey (BioIVT, Hicksville, NY), and human plasma (with sodium citrate as an anticoagulant; Innovative Research, Novi, MI). 7-HMG was spiked in a respective species preincubated plasma sample (n = 3) at a final concentration of 1 μM and kept in a 5% CO_2 incubator shaker (100 rpm) maintained at 37 °C. The concentration of organic solvents was kept below 0.5% (v/v).[17,18] The aliquots (25 μL) were withdrawn at 0, 5, 15, 30, 60, and 120 min. The reaction was quenched by mixing the aliquots with 4 volumes acetonitrile containing 10 ng/mL phenacetin as IS. The quenched samples were vortex-mixed for 5 min, and these samples were then filtered through 0.45 μm pore size 96-well filtration plate. The filtrate was then subjected to ultraperformance liquid chromatography tandem mass spectrometry analysis (UPLC-MS/MS). The sample analysis was performed using a Waters Acquity UPLC system coupled with Waters Xevo TQ-S micro mass spectrometer (Waters, Milford, MA) using MassLynx V4.1 software (Waters, Milford, MA). Chromatographic separations were performed on a UPLC column Acquity, BEH, C18, 1.7 μm, 2.1 × 50 mm; maintained at 50 °C temperature. The mobile phase consisted of solvent A (10 mM ammonium acetate with 1% acetic acid in water) and solvent B (acetonitrile) delivered at a flow rate of 0.35 mL/min with a linear gradient as follows: 25% B until 3 min, 25−40% B over 3.9 min, 40−70% B from 3.9 to 4 min, decreased to 25% B from 4 to 4.6 min, and maintained at 25% B until 5.5 min. The MS was operated in the positive electrospray mode at a capillary temperature of 450 °C, source temperature of 150 °C, capillary voltage of 0.5 kV, desolvation gas flow of 900 L/h, and cone gas flow of 50 L/h. The analysis was conducted in multiple reaction monitoring modes (MRM, m/z 415.2 > 190.1). Enalapril for rodents and procaine or disulfiram for nonrodent plasma were used as positive controls to assess the enzyme activity. The positive control results were comparable to published reports.[19,20]

Human Plasma Stability of 7-HMG with or without Protease Inhibitors. 7-HMG at 1 μM was incubated with or without a protease inhibitor cocktail treatment and in 50 mM phosphate buffer pH 7.4 for 120 min at 37 °C in a CO_2 incubator. Aliquots (25 μL) were withdrawn at 0, 5, 15, 30, 60, and 120 min and mixed with 4 volumes of acetonitrile containing IS. The quenched reaction mixtures were vortex-mixed for 5 min and then filtered through a 0.45 μm 96-well filtration plate. The filtrate was subjected to UPLC-MS/MS analysis as described above. Procaine was used as a positive control to assess esterases enzyme activity. The percentage of parent compound remaining was calculated as the percentage ratio of analyte peak to the IS peak area ratio at time t to that at 0 min.

Isolation, Purification, and Structure Elucidation of Unknown-1 Metabolite. To identify the chemical structure of the unknown-1 metabolite, multiple incubations of 7-HMG (1 mM) with undiluted human plasma (1 mL) for 24 h at 37 °C were performed to obtain enough amount of metabolite unknown-1. These incubation reactions were mixed and quenched with 4 volumes of acetonitrile. The metabolite unknown-1 was then isolated, purified using several chromatographic techniques, and chemical structure elucidation was performed by 1D and 2D NMR analyses. The details of isolation, purification, and structural elucidation of unknown-1 (mitragynine pseudoindoxyl) and its chemical synthesis are described in the Supporting Information.

ASSOCIATED CONTENT

Supporting Information

The Supporting Information is available free of charge at https://pubs.acs.org/doi/10.1021/acsptsci.0c00075.

Experimental procedures and HPLC, NMR, and HRMS characterization data for mitragynine pseudoindoxyl (PDF)

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Notes

The authors declare no competing financial interest.

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■ ABBREVIATIONS

7-HMG, 7-hydroxymitragynine; $T_{1/2}$, half-life; LC-HRMS, liquid chromatography high-resolution mass spectrometry; TLC, thin-layer chromatography; HPLC, high-performance liquid chromatography; CYP3A4, cytochrome P450 3A4; NMR, nuclear magnetic resonance; MRM, multiple reaction monitoring mode.

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From: Yenh Long
To: Darlene Nases
Cc: David Wuest; Darla Zarley
Subject: Fw: Public Comment for April 16 Board Meeting Re: 7-hydroxymitragynine
Date: Tuesday, March 31, 2026 1:00:06 PM
Attachments: preventing_the_next_wave-7-oh_final.pdf

Hi Darlene,

Below and attached is public comment for the workshop on kratom.

Thank you,

Yenh Long, Pharm.D., BCACP
Nevada State Board of Pharmacy
775-850-1440
Email: ylong@pharmacy.nv.gov

NOTICE: This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not establish an attorney-client relationship. This information does not override the specific provisions of Nevada law as applied to a particular set of facts.

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From: Tess Annique <[redacted]@gmail.com>
Sent: Tuesday, March 31, 2026 11:34 AM
To: Pharmacy Board <pharmacy@pharmacy.nv.gov>
Cc: Yenh Long <ylong@pharmacy.nv.gov>; David Wuest <dwuest@pharmacy.nv.gov>
Subject: Public Comment for April 16 Board Meeting Re: 7-hydroxymitragynine

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Public Comment for April 16 Board Meeting regarding the proposed regulation of 7-hydroxymitragynine for which I am deeply in support of:

"To members of the Board,

My name is Tess Souray. I am a Nevada resident, a parent, and an individual with nine years of sobriety. I am here to speak in deep support of scheduling 7-hydroxymitragynine, also known as 7-OH.

This issue is not theoretical to me. I have directly observed how 7-OH affects individuals, including how quickly use can escalate and how closely its effects mirror those of opioid- type substances. I have seen clear and concerning changes in behavior, mood and overall functioning that is consistent with substances we already recognize as Schedule I. What is particularly concerning is the pharmacological profile of 7-OH itself. It acts directly on mu-opiod receptors in the brain and has been shown to produce opioid-like effects and dependence. The FDA states that “7-OH is 13x more potent than morphine.” *(FDA SOURCE ATTACHED)*.

What is very concerning is the disconnect between the known pharmacological profile of 7-OH and the way it is being sold. The U.S. Food and Drug Administration has explicitly warned that "7-hydroxymitragynine is a potent opioid, is not approved for any use and should be avoided by consumers." The FDA has also recommended that it be evaluated for Class I scheduling due to its abuse potential and associated safety risks.

Despite this, products containing 7-OH remain available in smoke shops and gas stations throughout Nevada. This form of access creates a misleading perception of safety that is not consistent with the substance’s actual risk profile. By way of example, I recently stopped at a gas station with my young toddler and observed 7-OH products displayed at the counter alongside everyday retail items. These products were presented in a manner that made them easily accessible and indistinguishable from everyday consumer goods. This type of exposure underscores the broader public health concern — particularly families and communities who may not be aware of the substance’s potency or effects.

As someone who has nine years of sobriety and an active member of my recovery community, I find it deeply concerning that a compound with known opioid activity is being normalized through casual retail availability.

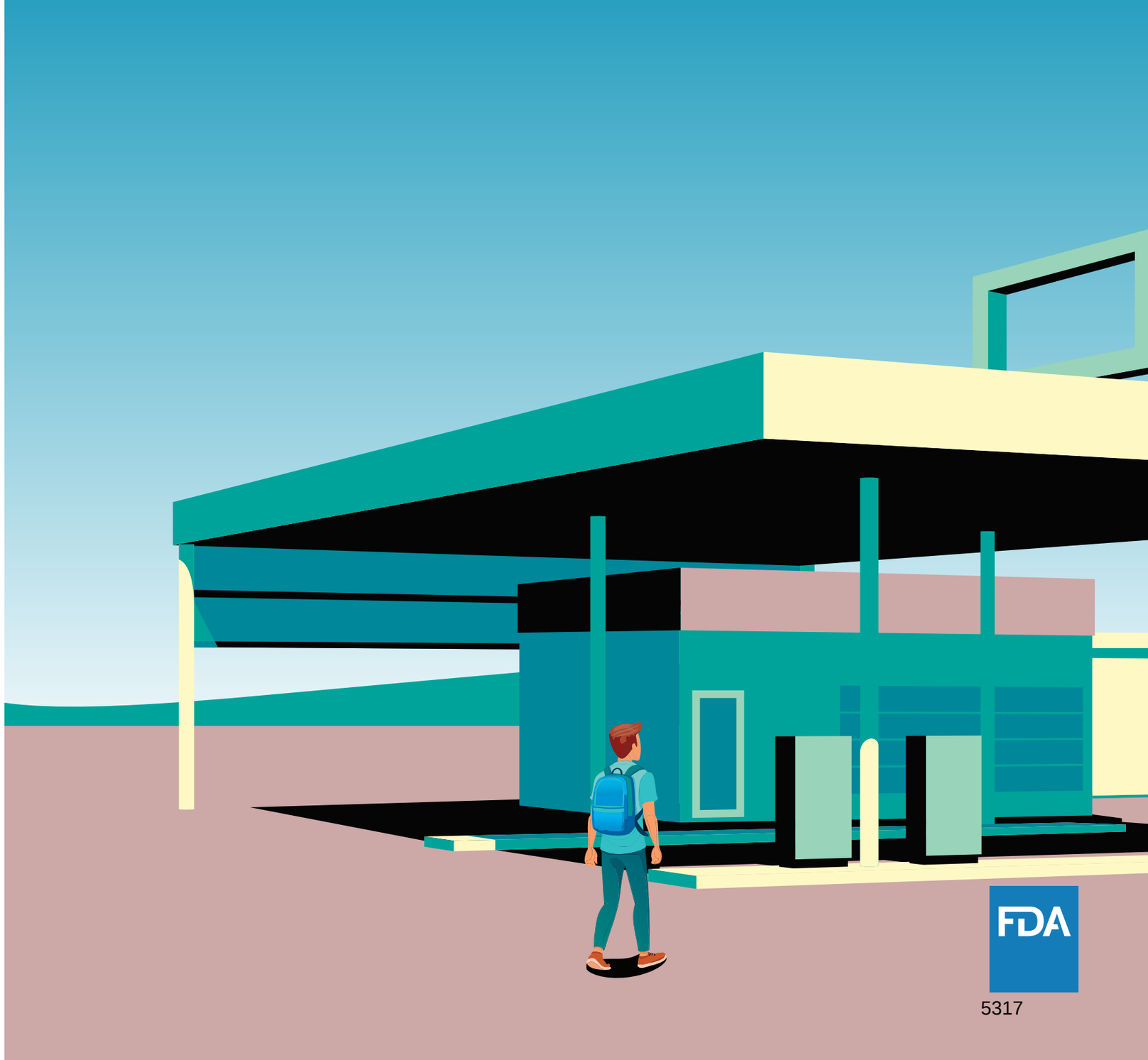
I respectfully urge the Board to move forward with scheduling 7-hydroxymitragynine as a Schedule I substance in Nevada as a necessary and appropriate step to protect public health and safety for all Nevadans.

Respectfully,

Tess Souray
Las Vegas, NV 89148

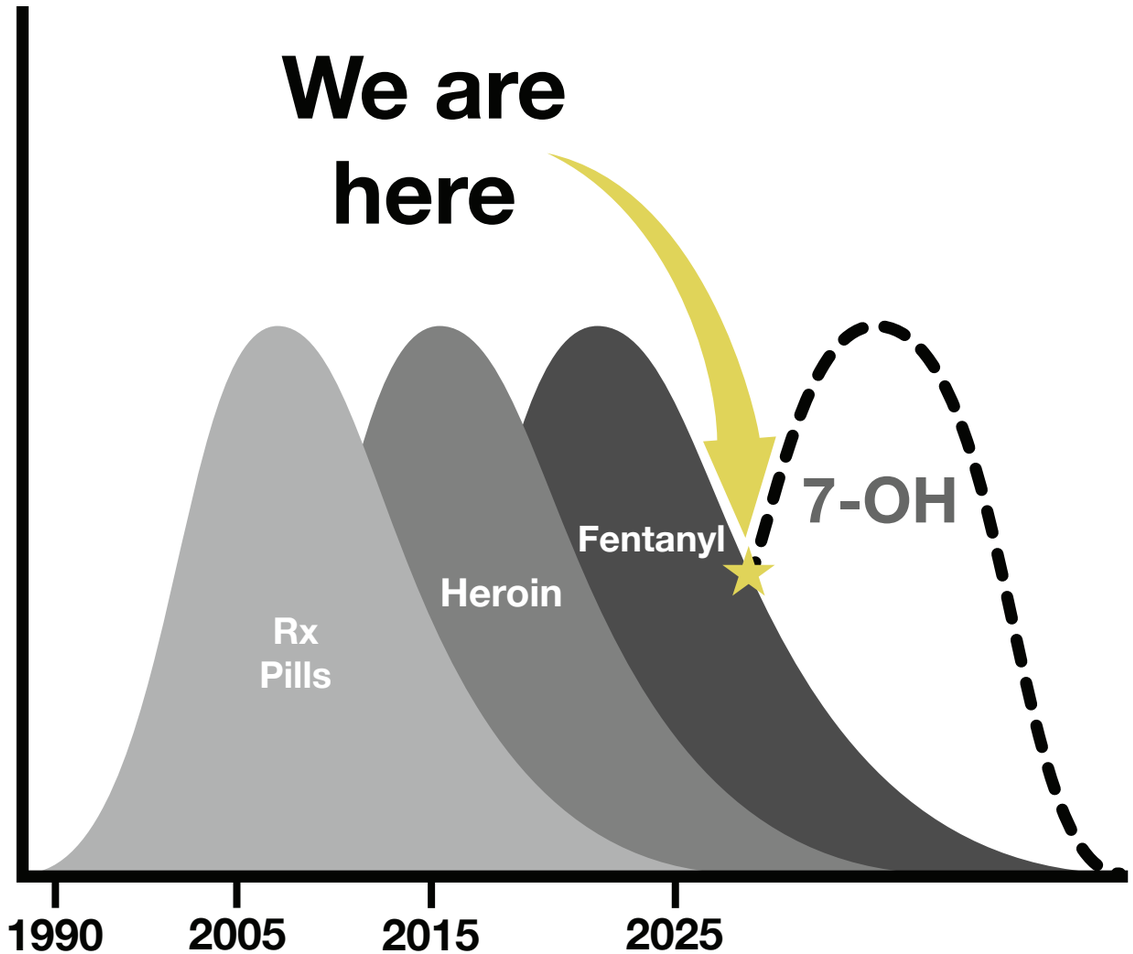
Preventing The Next Wave of the Opioid Epidemic:

What You Need to Know About 7-OH



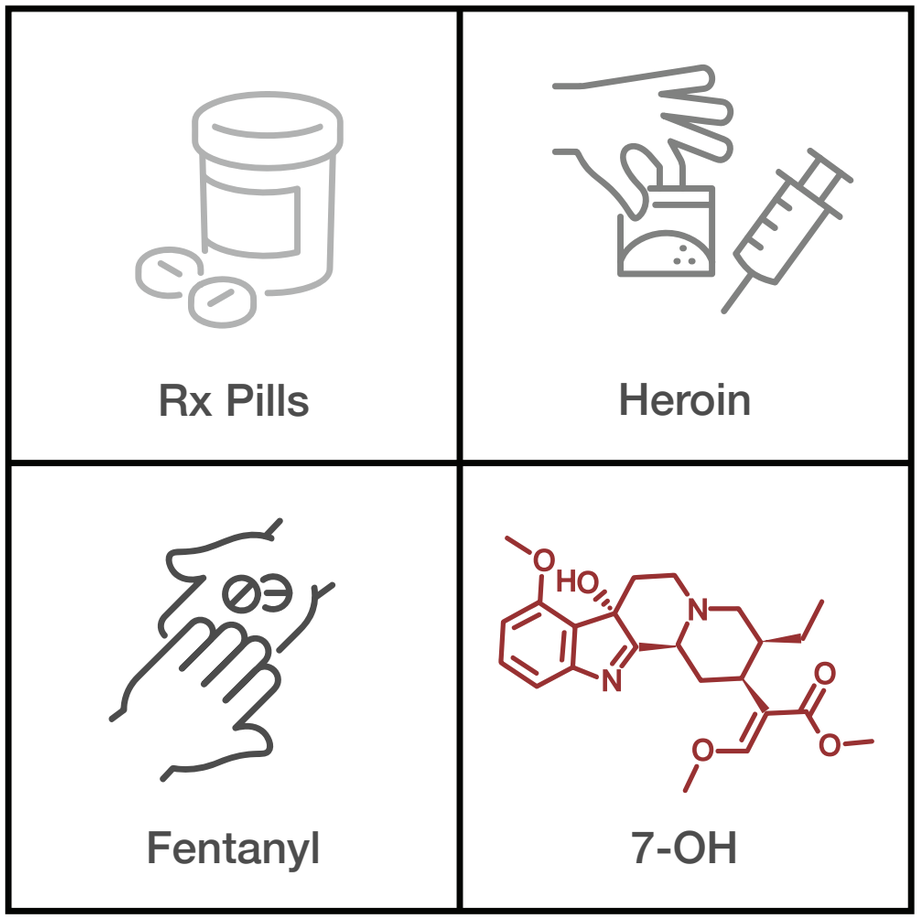
5317

The Opioid Epidemic is Evolving with 7-OH. We Can and Must Act Now to Prevent a New Wave.



Note: The next potential phase of the opioid crisis may be defined by the emergence of novel synthetic opioids like 7-OH, combined with an increasing prevalance of concurrent use of opioids and other controlled substances.

7-OH is Engineered to be Addictive. It is a Potent Opioid by Design.



7-OH (formally known as 7-Hydroxymitragynine) is a powerful psychoactive compound that occurs naturally in very small amounts in the Kratom plant.

7-OH products are concentrated derivatives often falsely marketed as Kratom.

Street names include 7-Hydroxy, 7-OHMG and ‘7’.

This Opioid is not Prescribed or Purchased on the Street - It's Sold like Candy at Retail Stores and Online.



What began as doctor-prescribed painkillers migrated to back-alley dealers when prescriptions dried up. Opioids have disturbingly gone mainstream with 7-OH—no prescription needed, no dealer required. This dangerous opioid is sitting on store shelves, making gas stations and convenience stores risky places where kids can purchase these drugs as easily as buying candy.

Hiding in Plain Sight: 7-OH Products are Designed to Look Like Everyday Treats Like Gummies, Candies and Ice Cream.











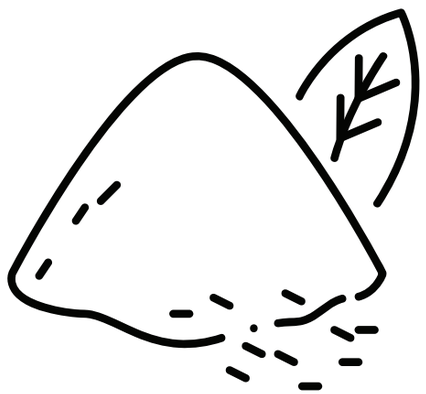




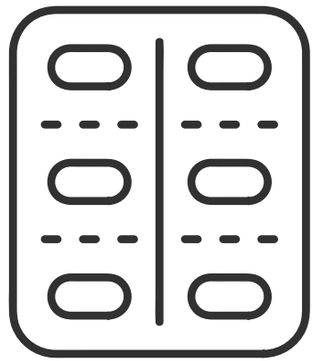


Note: These images are select illustrative examples and do not represent the full scope of 7-OH products on the market. Consumers should read packaging and labels carefully to determine whether a product contains 7-OH.

While Some 7-OH Products are Marketed as Natural Kratom, They are Not the Same. 7-OH Presents Significant Risks.

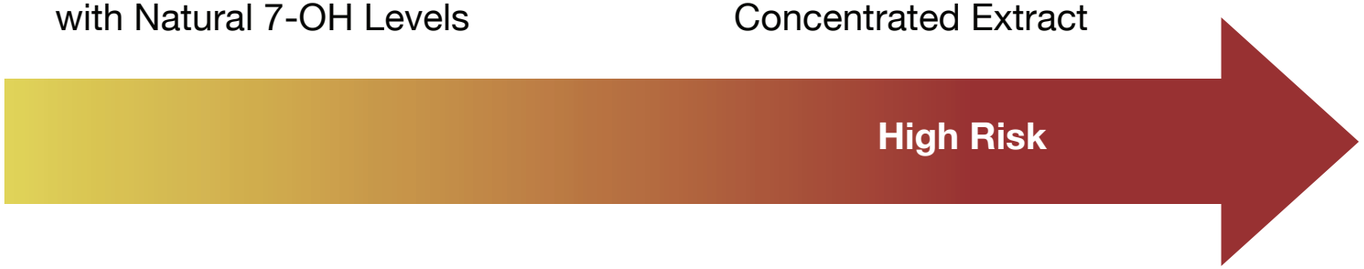


Crushed/Powdered Leaves with Natural 7-OH Levels



Kratom 7-OH Significantly Concentrated Extract

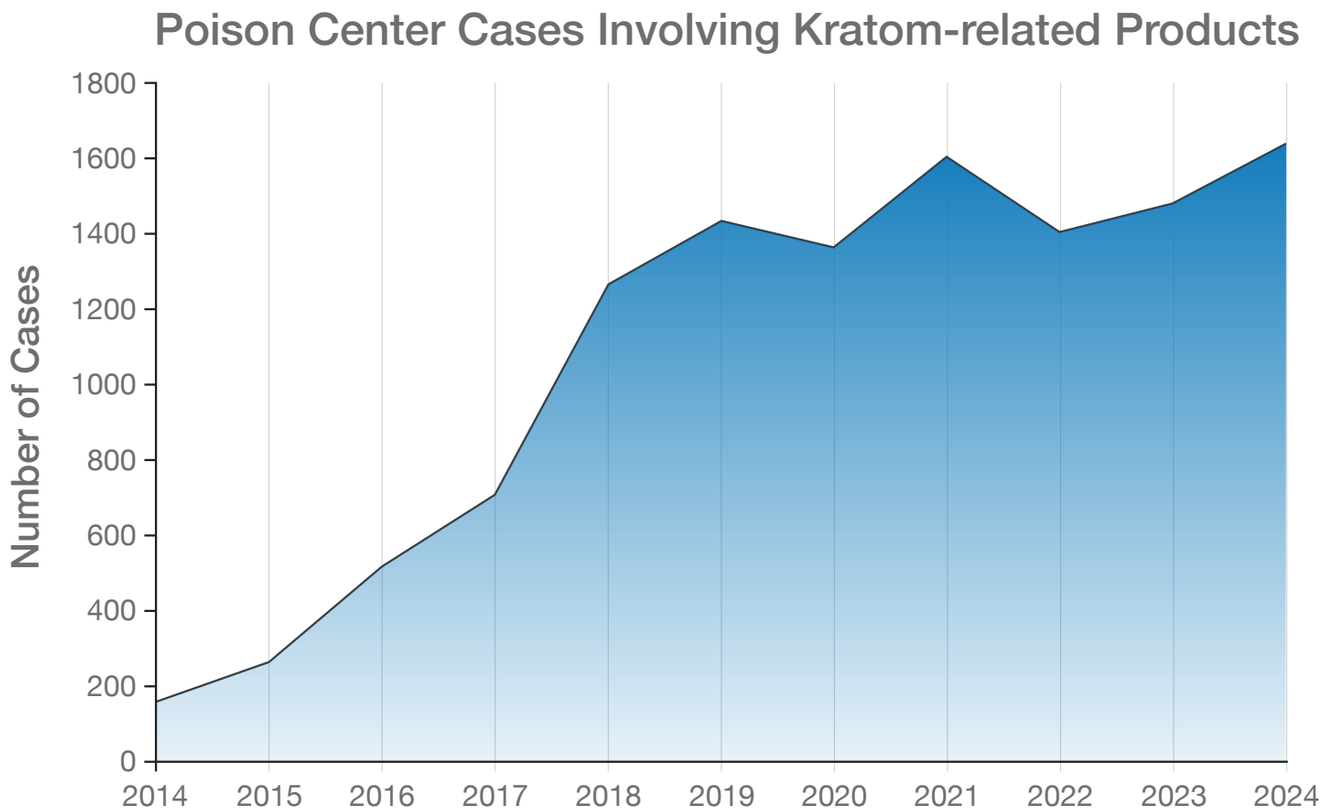
7-OH is 13x more potent than morphine.



"Enhanced" or "spiked" kratom products may appear to be natural leaf, but actually contain as much as 500% more 7-OH than would be expected naturally.

Poison Control is Sounding the Alarm on 7-OH.

American families are reporting side effects such as dependency, withdrawals, overdose and even death.





In 2025*, approximately 40% of 7-OH reports were among individuals abusing the drug.

Note: Kratom-related products refers to a broad category of botanical kratom products and other kratom-derived products, including an unknown number of 7-OH involved cases; ***a classification code for 7-OH products was added to the National Poison Data System only in February, 2025.***

**Data reflect partial year.*

There is No Safe Swap. 7-OH is an Opioid, Not an Alternative for Approved Treatments.

Kratom-related products, including 7-OH, are not safe or approved treatments for opioid or SSRI (selective serotonin reuptake inhibitors) withdrawal symptoms, chronic pain, or to treat depression, anxiety and other mood disorders.



KRATOM



7-OH



FDA APPROVED THERAPIES

Protect You and Your Family



If you believe someone is experiencing an adverse event from a 7-OH product, contact the Poison Help Line (1-800-222-1222) or visit **www.poisonhelp.org** for help.

If someone is unresponsive, dial **911** immediately!

- Avoid buying any products with 7-OH.
- When buying candy or other treats for you or your family, examine the packaging and label so you don't accidentally buy a treat containing 7-OH.
- Talk to your health care professional if you need help with opioid addiction, anxiety, mood disorders, pain, or other ailments.

“Even better than rolling back a public health crisis would be never having one in the first place: Let’s not allow 7-OH to drive the next wave of the U.S. opioid epidemic.”

– Marty Makary, M.D., M.P.H., FDA Commissioner

Scan the QR code or visit fda.gov/7-OH for additional resources and to learn more.



FDA U.S. FOOD & DRUG ADMINISTRATION

5327

15C

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop

April 16th, 2026

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: §1, NRS 639.070

A. A REGULATION relating to authorizing the delivery of a commercially manufactured prescription drug product to a practitioner.

Section 1. NAC 639.

a. A prescription for a commercially manufactured prescription drug product, other than a controlled substance, to be dispensed to an ultimate user may be furnished to a practitioner other than a hospital, pharmacy, or other institution.

b. The pharmacy must process the prescription in a manner that is consistent with dispensing to the ultimate user.

c. The pharmacy must obtain written permission from the patient to send the medication directly to the practitioner.

d. Before furnishing the commercially manufactured prescription drug product to be administered to an ultimate user to a practitioner, the pharmacy must:

1. Ensure the practitioner is licensed as required by both State and Federal Law to possess the medication.

2. Obtain written acknowledgement from the practitioner that the practitioner agrees to comply with subparagraphs i through iv of subsection d.

d. The practitioner who receives the furnished commercially manufactured prescription drug product to be administered to the ultimate user shall:

i. Comply with all State and Federal Laws regarding the handling of the medication.

ii. Store the medication separately from the practitioner's stock of medication.

iii. Administered the medication to only the patient named on the prescription not later than 30 days after the receipt of the medication. If the medication is not administered within 30 days, it must be destroyed or donated in compliance with NRS 453B.

iv. Maintain records of the administration or the destruction of the prescription drug.

e. The pharmacy must maintain records of the prescriptions drug furnished to a practitioner.

Reference.

NAC 639.6631 "Drug product" defined. (NRS 639.070) "Drug product" means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the Food and Drug Administration.
(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

Draft

NRS 639.0125 "Practitioner" defined. "Practitioner" means:

1. A physician, dentist, veterinarian or podiatric physician who holds a license to practice his or her profession in this State;

2. A hospital, pharmacy or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or administer drugs in the course of professional practice or research in this State;

3. An advanced practice registered nurse who has been authorized to prescribe controlled substances, poisons, dangerous drugs and devices;

4. A physician assistant who:

(a) Holds a license issued by the Board of Medical Examiners; and

(b) Is authorized by the Board to possess, administer, prescribe or dispense controlled substances, poisons, dangerous drugs or devices under the supervision of a physician as required by chapter 630 of NRS;

5. A physician assistant who:

(a) Holds a license issued by the State Board of Osteopathic Medicine; and

(b) Is authorized by the Board to possess, administer, prescribe or dispense controlled substances, poisons, dangerous drugs or devices under the supervision of an osteopathic physician as required by chapter 633 of NRS;

6. An optometrist who is certified by the Nevada State Board of Optometry to prescribe and administer pharmaceutical agents pursuant to NRS 636.288, when the optometrist prescribes or administers pharmaceutical agents within the scope of his or her certification;

7. A dental hygienist who:

(a) Holds a valid license to practice dental hygiene in this State;

(b) Is authorized to prescribe and dispense the dangerous drugs and devices listed in NRS 631.3105 in accordance with the provisions of that section and the regulations adopted pursuant thereto; and

(c) Holds a certificate issued pursuant to NRS 639.1374 by the State Board of Pharmacy authorizing him or her to so prescribe;

8. A pharmacist who is registered pursuant to NRS 639.28079 to prescribe and dispense drugs for medication-assisted treatment; or

9. A certified registered nurse anesthetist who orders, prescribes, possesses or administers controlled substances, poisons, dangerous drugs or devices in accordance with NRS 632.2397.

(Added to NRS by 1979, 1696; A 1985, 876; 1989, 1121; 1991, 791; 1993, 2224; 1995, 1711; 1997, 687; 2001, 408, 775, 1631, 1635; 2007, 1844; 2013, 2077; 2019, 3656; 2023, 1446, 2368, 3429)

Draft

16

16A

JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

Posted: March 17, 2026

NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the Adoption and Amendment of
Regulations of the Nevada State Board of Pharmacy

The Nevada State Board of Pharmacy will hold a Public Hearing at 9:00 a.m. on Thursday, April 16, 2026.

Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Hyatt Place
1790 E Plumb Lane
Reno, NV

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

The purpose of the hearing is to receive comments from all interested persons regarding the adoption and amendment of regulations that pertain to Chapter 639 and/or 453 of the Nevada Administrative Code.

The following information is provided pursuant to the requirements of NRS 233B.060:

A REGULATION relating to the authority of a homeopathic physician who is not licensed as an allopathic or osteopathic physician in Nevada to possess, administer, prescribe and dispense controlled substances and dangerous drugs; and providing other matters properly relating thereto. (LCB FILE NO. R106-25)

1. The need for and the purpose of the proposed regulation or amendment.

This regulation is necessary to clearly define and appropriately limit the authority of homeopathic physicians who are not licensed as allopathic or osteopathic physicians in Nevada to handle controlled substances and dangerous drugs, ensuring public safety and regulatory consistency.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation is attached to this notice.

3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:

(a) Both adverse and beneficial effects.

There should be no economic impact from this regulation amendment on the regulated entities or on the public. The regulation amendment will have a beneficial effect on the regulated entities and on the public by enhancing public safety by ensuring that only appropriately qualified practitioners may handle controlled substances and dangerous drugs within the scope of homeopathic practice.

(b) Both immediate and long-term effects.

Both the immediate and long-term economic effects on regulated entities and on the public will be beneficial by ensuring that only appropriately qualified practitioners may handle controlled substances and dangerous drugs within the scope of homeopathic practice.

4. The estimated cost to the agency for enforcement of the proposed regulation.

The cost to the Board for enforcement of the proposed regulation cannot be determined at this time since it will be dependent upon the number of applicants for registration/licensure.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any

other state or local governmental agency that the proposed regulation amendment overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

The regulation is not required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulation of the same activity in which the state regulation is more stringent.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation does not provide a new or increase of fees.

Persons wishing to comment upon the proposed action of the Board may appear at the scheduled public hearing or may address their comments, data, views, or arguments, in written form, to the Board at teambc@pharmacy.nv.gov or to the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521. Written submissions must be received by the Board on or before April 16, 2026. If no person who is directly affected by the proposed action appears to request time to make an oral presentation, the Board may proceed immediately to act upon any written submissions.

Members of the public who are disabled and require special accommodations or assistance at the meeting are requested to notify the Nevada State Board of Pharmacy in writing at 985 Damonte Ranch Pkwy., #206, Reno, Nevada 89521, or by calling (775) 850-1440. Please notify us at least one (1) week prior to the scheduled meeting date to allow time to secure any necessary equipment or provisions prior to the meeting.

This notice and the text of the proposed regulation are also available in the State of Nevada Register of Administrative Regulations which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653, and on the Internet at http://www.leg.state.nv.us. Copies of this notice and the proposed regulation will also be mailed to members of the public upon request.

Pursuant to NRS 233B.064(1), upon adoption of any regulation, the Board, if requested to do so by an interested person, either before adoption or within 30 days thereafter, will issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

This notice of hearing has been posted at:

www.notice.nv.gov
www.bop.nv.gov
www.leg.state.nv.us.

Nevada State Board of Pharmacy
Reno, Nevada

Nevada State Board of Pharmacy
Las Vegas, Nevada

Nevada State Library
100 N. Stewart St.
Carson City, NV 89701

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R106-25

January 21, 2026

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: § 1, NRS 453.221, 454.371 and 639.070.

A REGULATION relating to pharmacy; prohibiting a pharmacist or dispensing practitioner from dispensing a controlled substance or dangerous drug pursuant to a prescription issued by certain homeopathic physicians except under certain circumstances; prohibiting certain homeopathic physicians from possessing, administering, prescribing or dispensing a controlled substance or dangerous drug except under certain circumstances; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations: (1) relating to the registration and control of the dispensing of controlled substances within this State; (2) limiting or restricting the furnishing or dispensing of any drug which the Board finds to be dangerous to the public health or safety; and (3) governing the practice of pharmacy. (NRS 453.221, 454.371, 639.070)

This regulation adopts by reference the *Homeopathic Pharmacopoeia of the United States* published by the Homeopathic Pharmacopeia Convention of the United States. This regulation prohibits a pharmacist or dispensing practitioner from dispensing a controlled substance or dangerous drug pursuant to a prescription issued by a homeopathic physician who is not licensed in this State as an allopathic physician or osteopathic physician or otherwise authorized by the Board to prescribe a controlled substance or a dangerous drug, as applicable, except in dosages authorized by the *Homeopathic Pharmacopoeia*. This regulation also prohibits: (1) a homeopathic physician who is registered by the Board to possess, dispense or conduct research with controlled substances but who is not licensed in this State as an allopathic physician or osteopathic physician or otherwise authorized by the Board to possess, administer, prescribe and dispense controlled substances from possessing, administering, prescribing or dispensing controlled substances except in conformance with the practice of homeopathic medicine and in the dosages authorized by the *Homeopathic Pharmacopoeia*; and (2) a homeopathic physician who is not licensed in this State as an allopathic physician or osteopathic physician or otherwise authorized by the Board to possess, administer, prescribe and dispense dangerous drugs from possessing, administering, prescribing or dispensing dangerous drugs except in conformance with the practice of homeopathic medicine and in the dosages authorized by the *Homeopathic Pharmacopoeia*.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

1. The Board hereby adopts by reference the Homeopathic Pharmacopoeia of the United States, published by the Homeopathic Pharmacopeia Convention of the United States. A copy of this publication may be obtained at the Internet address https://www.hpus.com/become-a-subscriber/ through an online subscription for the price of $2,000.

2. The Board will periodically review the publication adopted by reference pursuant to subsection 1 and determine within 120 days after the review whether any change made to those standards or publications is appropriate for application in this State. If the Board does not disapprove a change to that publication within 120 days after the review, the change is deemed to be approved by the Board.

3. A pharmacist or dispensing practitioner shall not dispense a controlled substance or a dangerous drug pursuant to a prescription issued by a homeopathic physician who is not licensed in this State as an allopathic physician or osteopathic physician or otherwise authorized by the Board to prescribe a controlled substance or dangerous drug, as applicable, except in dosages authorized by the Homeopathic Pharmacopoeia of the United States.

4. A homeopathic physician who is registered pursuant to subsection 1 of NRS 453.226 but is not licensed in this State as an allopathic physician or osteopathic physician or otherwise authorized by the Board to possess, administer, prescribe and dispense controlled substances may not possess, administer, prescribe or dispense controlled substances except in conformance with the practice of homeopathic medicine and in the dosages authorized by the Homeopathic Pharmacopoeia of the United States.

5. A homeopathic physician who is not licensed in this State as an allopathic physician or osteopathic physician or otherwise authorized by the Board to possess, administer, prescribe and dispense controlled substances may not possess, administer, prescribe or dispense dangerous drugs except in conformance with the practice of homeopathic medicine and in the dosages authorized by the Homeopathic Pharmacopoeia of the United States.

6. As used in this section:

(a) "Allopathic physician" means a person who is licensed to practice medicine pursuant to chapter 630 of NRS.

(b) "Homeopathic medicine" has the meaning ascribed to it in NRS 630A.040.

(c) "Homeopathic physician" has the meaning ascribed to it in NRS 630A.050.

(d) "Osteopathic physician" has the meaning ascribed to it in NRS 633.091.

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – December 4, 2025

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 453.221, NRS 454.371, NRS 639.070, NRS 639.0727

A REGULATION relating to the authority of a homeopathic physician who is not licensed as an allopathic or osteopathic physician in Nevada, or otherwise authorized by the Board to possess, administer, prescribe and dispense controlled substances and dangerous drugs; and providing other matters properly relating thereto.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

1. A homeopathic physician who is not licensed as an allopathic or osteopathic physician in Nevada, or otherwise authorized by the Board to possess, administer, prescribe and dispense dangerous drugs, may only possess, administer, prescribe and dispense dangerous drugs in conformance with homeopathic pharmacology as defined in NRS 630A.040 and in the dosages permitted in the Homeopathic Pharmacopoeia of the United States.

2. A homeopathic physician registered pursuant to NRS 453.226(1) who is not licensed as an allopathic or osteopathic physician in Nevada, or otherwise authorized by the Board to possess, administer, prescribe and dispense controlled substances, may only possess, administer, prescribe and dispense controlled substances in conformance with homeopathic pharmacology as defined in NRS 630A.040 and in the dosages permitted in the Homeopathic Pharmacopoeia of the United States.

3. The Board hereby adopts by reference the Homeopathic Pharmacopoeia of the United States, promulgated by the Homeopathic Pharmacopoeia Convention of the United States.

3. As used in this section:

(a) "Homeopathic physician" has the meaning ascribed to it in NRS 630A.050.

(b) "Allopathic physician" means a person licensed to practice medicine pursuant to NRS 630.160.

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(c) "Osteopathic physician" has the meaning ascribed to it in NRS 633.091.

Section 2. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

A pharmacist or dispensing practitioner shall not fill a prescription or dispense a dangerous drug or a controlled substance pursuant to a prescription issued by a homeopathic physician who is not licensed as an allopathic or osteopathic physician, or otherwise authorized by the Board to prescribe, except in dosages permitted in the Homeopathic Pharmacopoeia of the United States.

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JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

Posted: March 17, 2026

NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the Adoption and Amendment of
Regulations of the Nevada State Board of Pharmacy

The Nevada State Board of Pharmacy will hold a Public Hearing at 9:00 a.m. on Thursday, April 16, 2026.

Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Hyatt Place
1790 E Plumb Lane
Reno, NV

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

The purpose of the hearing is to receive comments from all interested persons regarding the adoption and amendment of regulations that pertain to Chapter 639 and/or 453 of the Nevada Administrative Code.

The following information is provided pursuant to the requirements of NRS 233B.060:

Amendment to Chapter 639 of the Nevada Administrative Code. The proposed amendments reduce the minimum age to register to become a pharmaceutical technician in training along with modify certain requirements to become a pharmaceutical technician in training. (LCB FILE NO. R010-26)

1. The need for and the purpose of the proposed regulation or amendment.

This change will lower the minimum age and educational requirements for pharmaceutical technicians in training, expanding opportunities for a broader range of applicants.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation is attached to this notice.

3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:

(a) Both adverse and beneficial effects.

There should be no economic impact from this regulation amendment on the regulated entities or on the public. The regulation amendment will have a beneficial effect on the regulated entities and on the public by expanding the workforce, improving service availability, and reducing wait times.

(b) Both immediate and long-term effects.

Both the immediate and long-term economic effects on regulated entities and on the public will be beneficial by expanding the workforce, improving service availability, and reducing wait times.

4. The estimated cost to the agency for enforcement of the proposed regulation.

The cost to the Board for enforcement of the proposed regulation cannot be determined at this time since it will be dependent upon the number of applicants for registration/licensure.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation amendment overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

The regulation is not required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulation of the same activity in which the state regulation is more stringent.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation does not provide a new or increase of fees.

Persons wishing to comment upon the proposed action of the Board may appear at the scheduled public hearing or may address their comments, data, views, or arguments, in written form, to the Board at teambc@pharmacy.nv.gov or to the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521. Written submissions must be received by the Board on or before April 16, 2026. If no person who is directly affected by the proposed action appears to request time to make an oral presentation, the Board may proceed immediately to act upon any written submissions.

Members of the public who are disabled and require special accommodations or assistance at the meeting are requested to notify the Nevada State Board of Pharmacy in writing at 985 Damonte Ranch Pkwy., #206, Reno, Nevada 89521, or by calling (775) 850-1440. Please notify us at least one (1) week prior to the scheduled meeting date to allow time to secure any necessary equipment or provisions prior to the meeting.

This notice and the text of the proposed regulation are also available in the State of Nevada Register of Administrative Regulations which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653, and on the Internet at http://www.leg.state.nv.us. Copies of this notice and the proposed regulation will also be mailed to members of the public upon request.

Pursuant to NRS 233B.064(1), upon adoption of any regulation, the Board, if requested to do so by an interested person, either before adoption or within 30 days thereafter, will issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

This notice of hearing has been posted at:

www.notice.nv.gov
www.bop.nv.gov
www.leg.state.nv.us.

Nevada State Board of Pharmacy
Reno, Nevada

Nevada State Board of Pharmacy
Las Vegas, Nevada

Nevada State Library
100 N. Stewart St.
Carson City, NV 89701

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R010-26

February 11, 2026

EXPLANATION – Matter in ***italics*** is new; matter in brackets [~~omitted material~~] is material to be omitted.

AUTHORITY: § 1, NRS 639.070 and 639.1371.

A REGULATION relating to pharmaceutical technicians in training; revising provisions governing the registration of pharmaceutical technicians in training; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations necessary for the protection of the public regarding the practice of pharmacy and the lawful performance of its duties. (NRS 639.070) Existing law requires the State Board of Pharmacy to adopt regulations establishing the qualifications for registration as a pharmaceutical technician, including certain training and experience. (NRS 639.1371) Existing law provides for registration as a pharmaceutical technician in training in order for a person to obtain the training and experience required to be a pharmaceutical technician. (NRS 639.0115, 639.1371) Existing regulations establish the qualifications for registration as a pharmaceutical technician in training, which include a minimum age of 18 years and a minimum educational level of graduation from high school or its equivalent. (NAC 639.242) This regulation: (1) reduces the minimum age requirement for an applicant for registration as a pharmaceutical technician in training to 16 years of age; and (2) revises the minimum education level for such registration to include enrollment in a program of instruction leading to graduation from high school or its equivalent.

Section 1. NAC 639.242 is hereby amended to read as follows:

639.242 1. An applicant for registration as a pharmaceutical technician in training must:

(a) Be [~~18~~] ***16*** years of age or older;

(b) Be a high school graduate or the equivalent [~~;~~] ***or enrolled in a program of instruction leading to such;*** and

(c) Participate in training while on the job and acquire experience that is commensurate with the duties of his or her employment.

2. The Board may deny an application for registration as a pharmaceutical technician in training if the applicant has:

(a) Been convicted of any felony or a misdemeanor involving moral turpitude, dishonesty or the unlawful possession, sale or use of drugs; or

(b) A history of drug misuse.

3. A person may perform the duties of a pharmaceutical technician while the person is receiving the training and experience required by paragraph (c) of subsection 1 if he or she is registered with the Board.

4. If the Board does not deny the application pursuant to subsection 2 and determines that the applicant meets the requirements of this chapter and chapter 639 of NRS for registration as a pharmaceutical technician in training, the Board will issue a certificate of registration as a pharmaceutical technician in training to the applicant.

5. Registration as a pharmaceutical technician in training expires on October 31 of each even-numbered year unless renewed before that date.

6. The managing pharmacist of the pharmacy where a pharmaceutical technician in training is employed to receive the training and experience required by paragraph (c) of subsection 1 shall file with the Board a completed form prescribed by the Board certifying:

(a) The number of hours of training and experience the trainee has successfully completed;

(b) The specific training and experience the trainee has completed; and

(c) That the trainee is competent to perform the duties of a pharmaceutical technician.

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – January 15th, 2026

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 453.162; NRS 453.163; NRS 639.070; NRS 639.23916

A REGULATION relating to the registration of pharmaceutical technician in training and other matters properly relating thereto.

NAC 639.242 Registration of pharmaceutical technician in training; grounds for denial of application for registration; expiration of registration; certification by managing pharmacist. (NRS 639.070, 639.1371)

1. An applicant for registration as a pharmaceutical technician in training must:

(a) Be ~~18~~ *16* years of age or older;

(b) Be a high school graduate or the equivalent or be *enrolled in a high school or equivalent*; and

(c) Participate in training while on the job and acquire experience that is commensurate with the duties of his or her employment.

2. The Board may deny an application for registration as a pharmaceutical technician in training if the applicant has:

(a) Been convicted of any felony or a misdemeanor involving moral turpitude, dishonesty or the unlawful possession, sale or use of drugs; or

(b) A history of drug misuse.

3. A person may perform the duties of a pharmaceutical technician while the person is receiving the training and experience required by paragraph (c) of subsection 1 if he or she is registered with the Board.

4. If the Board does not deny the application pursuant to subsection 2 and determines that the applicant meets the requirements of this chapter and chapter 639 of NRS for registration as a pharmaceutical technician in training, the Board will issue a certificate of registration as a pharmaceutical technician in training to the applicant.

5. Registration as a pharmaceutical technician in training expires on October 31 of each even-numbered year unless renewed before that date.

6. The managing pharmacist of the pharmacy where a pharmaceutical technician in training is employed to receive the training and experience required by paragraph (c) of subsection 1 shall file with the Board a completed form prescribed by the Board certifying:

(a) The number of hours of training and experience the trainee has successfully completed;

(b) The specific training and experience the trainee has completed; and

(c) That the trainee is competent to perform the duties of a pharmaceutical technician.

(Added to NAC by Bd. of Pharmacy, eff. 11-15-93; A 11-9-95; 7-17-96; R072-19, 2-7-2020; R041-21, 9-28-2022)

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Executive Secretary Report

A. Financial Report
B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. Licensing Activities Report
F. Citations & Fines issued pursuant to NRS 632.2895
G. Legislative Update
H. Pharmacist DEA Registration Update

April 2026 - Temporary License since last Board Meeting

Pharmacist Name	Pharmacist License #
Vineeta Jagtiani	24997
Kim-Uyen Vu	25009

April 2026 – NV Business Address Change Only

Application Received	Business Name	License Number	New Location	City, State and Zip
3/2/2026	KabaFusion	PH03434	1951 Ramrod Ave, Suite 110	Henderson, NV 89014
3/17/2026	Centerpoint Medical dba Medical n Mobility LV	MP03118	2475 West Cheyenne Ave, Suite 150	North Las Vegas, NV 89032

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
Amendment to Nevada Administrative Code (NAC). The proposed amendments establish the minimum staffing standards in a pharmacy and modify the number of pharmaceutical technicians and pharmaceutical technicians in training a pharmacist may supervise.	5/29/24	6/3/24	R113-24	6/25/24 – To Yenh/Dave for review 7/15/24 –sent revised version to Dave/Yenh	12/10/24	1/16/25 – This public hearing was withdrawn from the agenda and will be heard at a future BM. 4/17/25 – To be heard at a future BM.		
Amendment to the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for treatment with narcotics and provide other matters properly relating thereto.	10/17/24	10/21/24	R197-24	7/21/25 – Sent to Dave/Yenh for review.	10/28/25	12/4/25	1/21/26	2/27/26

Amendment to the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for intermediate care or facilities for skilled nursing licensed by the State Board of Health pursuant to NRS 449.0303 and provide other matters properly relating thereto.	12/5/24	12/9/24	R203-24	9/19/25 – Sent to Dave/Yenh for review	10/28/25	12/4/25	1/21/26	2/27/26
Amendment to the Nevada Administrative Code ("NAC") 639.742. The proposed amendments relate to removing the requirement that Dispensing Practitioners must personally dispense at a facility and provide other matters properly relating thereto. The change would allow Dispensing Practitioners to mail prescriptions to individual patients in their care as allowed by the Center for Medicare and Medicaid Services.	12/5/24 – Waiting for the federal reg to pass. The Board would like to see at a future meeting.							
A REGULATION relating to controlled substances adding ethylphenidate and 2-methyl AP-237 to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.	12/5/24	12/9/24	R204-24	7/23/25 – Sent to Dave/Yenh for review	10/28/25	12/4/25	1/21/26	2/27/26

Amendment to Nevada Administrative Code NAC 454. The proposed amendment revises the ability of an advanced emergency medical technicians to possess and administer dangerous drugs upon the order of a practitioner in a license hospital when practicing under their scope of practice as determined by the State of Nevada Health Department.	4/17/25	4/28/25	R004-25	7/22/25 – Sent to Dave/Yenh for review	10/28/25	12/4/25 Note: Agenda item was "A REGULATION relating to the possession and administration of dangerous drugs by an advanced emergency medical technician or paramedic."	1/21/26	2/27/26
Amendment to Nevada Administrative Code (NAC) 639. The proposed amendment specifies the requirements for pharmacies and practitioners to be authorized to engage in the sterile or nonsterile compounding of drug products.	7/17/25 – Need updated language from Dave to send to LCB for R Number.							

A REGULATION relating to the authority of a homeopathic physician who is not licensed as an allopathic or osteopathic physician in Nevada to possess, administer, prescribe and dispense controlled substances and dangerous drugs; and providing other matters properly relating thereto.	9/4/25 – Tabled and work with Homeopathic Board. 12/4/25	12/9/25	R106-25	1/21/26 – Sent to Dave/Yenh for review	3/17/26	4/16/26		
Amendment to Nevada Administrative Code (NAC). The proposed amendments establish standards for licensees relating to staffing, supervision, duties of a pharmacy, duties of a pharmacist and requirements related to the timing of dispensing prescription drugs and devices	9/4/25 – Tabled and make modifications to language. 10/16/25 – Approved with amendments	10/22/25	R072-25	4/1/26 – Sent to Dave/Yenh for review				
A REGULATION relating to controlled substances adding dipentylone and seven fentanyl related substances to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.	12/4/25	12/9/25	R107-25	12/17/25 – Sent to Dave/Yenh for review	1/28/26	3/5/26	3/19/26	

Amendment to Chapter 639 of the Nevada Administrative Code. The proposed amendments reduce the minimum age to register to become a pharmaceutical technician in training along with modify certain requirements to become a pharmaceutical technician in training.	1/15/26	1/20/26	R010-26	2/11/26 – Sent to Dave/Yenh for review	3/17/26	04/16/26		
Amendment to Nevada Administrative Code (NAC) 453. The proposed amendments relate to controlled substances adding N-pyrrolidino metonitazene and N-pyrrolidino protonitazene to the controlled substances listed in Schedule I.	3/5/26	3/10/26	R038-26	3/31/26 – Sent to Dave/Yenh & Darla				
Amendment to Nevada Administrative Code (NAC) 639. The proposed amendments establishes record keeping requirements of controlled substances by a pharmacy and other matters properly relating thereto.	4/16/26							

Amendment to Nevada Administrative Code (NAC) 453. The proposed amendments relate to controlled substances adding mitragynine, 7-hydroxymitragynine and mitragynine pseudoindoxyl to the controlled substances listed in Schedule I.	4/16/26							
Amendment to Nevada Administrative Code (NAC) 639.708. Regulation authorizing the delivery of a commercially manufactured prescription drug product to a practitioner.	4/16/26							

Citations & Fines issued pursuant to NRS 639.2895 (Since last Board Meeting)

- **Cease & Desist/Citation –**
  - **Unlicensed Practice: 7**
  - **Other: 3**

- **Citation & Fine –**
  - **Unlicensed Practice: 8**
  - **Misfill: 10**
  - **Other: 3**

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

PHARMACIST - CONTROLLED SUBSTANCE REGISTRATION APPLICATION

Non-Refundable $200 fee

This application cannot be returned by fax or email. An original signature and fee are required to process.

NRS 639.28079 authorizes Nevada licensed pharmacists to apply for a Nevada Controlled Substance (CS) and DEA registration to prescribe and dispense dangerous drugs and certain Schedule III controlled substances (FDA-approved buprenorphine and buprenorphine combination products) for the treatment of Opioid Use Disorder (OUD). A pharmacist who has obtained the required registrations must comply with NRS 639.28079, the regulations promulgated (R059-23AP), and federal law as it pertains to the prescribing and dispensing of dangerous drugs and FDA-approved buprenorphine and buprenorphine combination products for the treatment of OUD, including, but not limited to, completing federally mandated training prior to prescribing. Additional information can be found by reviewing NRS 639, NRS 453, NRS 454, NAC 639, NAC 453, and 21 CFR part 1306.

NRS 453.232 A person who dispenses, prescribes, or administers a controlled substance without being registered by the Nevada State Board of Pharmacy (Board) is guilty of a CATEGORY D FELONY and shall be punished as provided in NRS 193.130.

Medication-assisted treatment – means treatment for an OUD using medication approved by the United States Food and Drug Administration for that purpose.

Please COMPLETE in SEQUENTIAL ORDER the following to obtain a controlled substance registration.

Step 1: Obtain your Nevada Prescription Monitoring Program (PMP) account

A. Visit nevada.pmpaware.net, click “Create an Account”, and follow the instructions on the webpage to complete your registration. For assistance contact the PMP at 775-687-5694 or pmp@pharmacy.nv.gov.
B. If your PMP registration is approved, you will receive an automated email confirmation from "No Reply PMP Aware". It is a system-generated email so it may go into your spam or junk file. Once you receive this email proceed to **Step 2**.

Step 2: Submit your Controlled Substance (CS) Application

A. Complete and mail the application that is **attached** to these instructions to the address indicated above with the required **non-refundable fee** of **$200.00**. Fees can be paid for by credit card, debit card, personal check, cashier’s check, or money order made payable to the **Nevada State Board of Pharmacy**. Credit and debit card payments are charged a **5% processing fee**.
B. If your application is approved, you will receive an email with your CS registration. Proceed to **Step 3**.

Step 3: Obtain your Drug Enforcement Administration (DEA) Registration

NOTE: An active CS registration is required to complete this application.

A. Complete the on-line DEA application at deadiversion.usdoj.gov. If you have a DEA number from another state, and want to transfer that DEA number to Nevada, you will need to complete the DEA Registration Change Requests form.
B. If your application or form is approved by the DEA, you will receive your DEA certificate in the mail.
C. You **MUST** email (pharmacylicensing@pharmacy.nv.gov) or fax (775-850-1444) a copy of your DEA certificate to the Board.

You are NOT AUTHORIZED to prescribe dangerous drugs or FDA-approved buprenorphine and buprenorphine combination products, for the treatment of OUD unless you have an active PMP account, an active CS registration, AND an active DEA registration (in which a copy of the certificate has been provided to the Board).

A CS registration expires OCTOBER 31, OF EVEN NUMBERED YEARS, despite when the registration is issued. You MUST notify the Board in writing of any changes to the location of your practice. NAC 453.280.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

PHARMACIST - CONTROLLED SUBSTANCE REGISTRATION APPLICATION

Non-Refundable $200 fee

Approval of this application and obtaining all the required registrations authorizes a pharmacist to prescribe and dispense dangerous drugs and certain Schedule III controlled substances (**FDA-approved buprenorphine and buprenorphine combination products**) for the treatment of OUD.

Section 1: Personal Information

First: _____ Middle: _____ Last: _____

Date of Birth: _____ SSN or ITIN:_____ Sex: ☐ M ☐ F ☐ X

Home Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

NV Pharmacist Registration #: _____

Section 2: Practice Information (A practice address is required for processing of your application.) Where will you be prescribing controlled substances and dangerous drugs for medication-assisted treatment?

Practice Name (if any): _____ Pharmacy license # (if applicable): _____

Practice Address: _____ Suite #: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____ Email: _____

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

Section 6: Acknowledgement and Attestation

I _____ (your name) attest that I have read, understand, and agree to the following **(initial each statement below to indicate you have read, understand, and agree with the following):**

_____ I understand that I am not authorized to prescribe any dangerous drugs or **FDA-approved buprenorphine and buprenorphine combination products** for medication-assisted treatment unless I have an active PMP account, an active CS registration, AND an active DEA registration (in which a copy of the certificate has been provided to the Board).

_____ I understand that by obtaining a CS registration to prescribe dangerous drugs and **FDA-approved buprenorphine and buprenorphine combination products** for medication-assisted treatment, I now fall under the definition of "practitioner" in NRS 453.126, NRS 639.0125, and NRS 454.00958 and must comply with all federal and state laws pertaining to the prescribing of dangerous drugs and controlled substances for a "practitioner" in NRS 639, NRS 453, NRS 454, NAC 639, NAC 453, NAC 454, and 21 CFR part 1306.

_____ I understand that, if I am granted a CS registration, I am only permitted to prescribe dangerous drugs and **FDA-approved buprenorphine and buprenorphine combination products** for the treatment of a patient with an OUD. The dangerous drugs and **buprenorphine and buprenorphine combination products** I prescribe must be approved by the United States Food and Drug Administration.

_____ I understand that, if I am granted a CS registration, I am only permitted to ***prescribe*** dangerous drugs and **FDA-approved buprenorphine and buprenorphine combination products** for medication-assisted treatment, and I am ***NOT permitted*** to ***possess, dispense or administer*** medication-assisted treatment unless I work for a Nevada licensed pharmacy and the dispensing and administration of these medications occur in a Nevada licensed pharmacy (certain exclusions apply).

_____ I understand that, if I am granted a CS registration, before counseling and providing information to a patient concerning evidence-based treatment for OUD, including, without limitation, medication-assisted treatment; and prescribing a drug for medication-assisted treatment, I must:

1. Assess the patient to determine whether:
    a. The patient has an OUD; and
    b. Medication-assisted treatment would be appropriate for the patient
2. Document the assessment in the record of the patient.

_____ I understand that, if I am granted a CS registration, before I offer medication-assisted treatment to a patient, I shall establish a documented treatment plan tailored to the needs of the patient. The documented treatment plan must include, without limitation:

1. A procedure for evaluating the progress or success of the treatment with stated objectives, including, without limitation, improved physical or psychosocial function; and
2. Consideration of pertinent medical history, previous medical records and physical examination and the need for further testing, consultations, referrals, or the use of other treatment modalities.

I further understand that I may only provide medication-assisted treatment in accordance with the documented treatment plan established.

_____ I understand that, if I am granted a CS registration, and provide medication-assisted treatment to a patient, I shall document and conduct periodic reviews of the care of the patient. The periodic reviews must be conducted at reasonable intervals in consideration of the individual circumstances of the patient and include, without limitation:

1. Consideration of the individual circumstances of the patient;
2. Any progress in reaching the objectives of the treatment; and
3. Consideration of the treatment prescribed, ordered, or administered, as well as any new information about the etiology of the OUD of the patient.

_____ I understand that, if I am granted a CS registration, and provide medication-assisted treatment to a patient, I shall maintain complete and accurate records of the medication-assisted treatment provided to a patient, including, without limitation, any records required pursuant to chapter 639 of NRS and the regulations adopted pursuant thereto. I must make all records maintained available for review upon request of the Board.

_____ I attest I have completed the federally required training to prescribe controlled substances and dangerous drugs for medication-assisted treatment.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Board Use Only: Date Processed: _____ Amount: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521

(775) 850-1440 • (800) 364-2081 • FAX (775) 850-1444

• Web Page: bop.nv.gov

Applicant Name: _____

Payment: Pay application fee by providing your credit or debit card information below, or by submitting a check made payable to **Nevada State Board of Pharmacy**. Credit cards are charged a 5% processing fee.		
Credit Type: ☐ Visa ☐ MasterCard ☐ Discover ☐ American Express	**Credit Card #:** __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	
Expiration Date: __ __ / __ __ (MM/YY	**CVV** (3 digits on back of card): _____	**Amount**: $_____
Name on Card: _____		
Billing Address: _____ _____ _____		

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